### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

<b>FORM</b>	10-K/A
(Amendm	ent No. 1)

(Mark	One)
x	

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2009

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_

Commission File Number 0-19034

### REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of incorporation or organization)

13-3444607 (I.R.S. Employer

Identification No)

777 Old Saw Mill River Road, Tarrytown, New York
(Address of principal executive offices)

10591-6707

(Zip code)

(914) 347-7000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Name of each exchange on which registered

Common Stock - par value \$.001 per share

Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗵 No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No 🗵

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  $\ \square$ 

Accelerated filer o

Non-accelerated filer o

Smaller Reporting Company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No 🗵

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$1,355,426,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2009, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 12, 2010:

<u>Class of Common Stock</u> Class A Stock, \$.001 par value Number of Shares 2.211.698

Common Stock, \$.001 par value

### DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement filed in connection with solicitation of proxies for its 2010 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K

### TABLE OF CONTENTS

EXPLANATORY NOTE

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

SIGNATURES

EX - 10.14

EX - 10.14 EX - 10.15 EX - 31.1 EX - 31.2

### **EXPLANATORY NOTE**

The sole purpose of this amendment is to amend Exhibits 10.14 and 10.15 (the "Exhibits") to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009, as originally filed with the SEC on February 18, 2010, to include certain portions of the Exhibits that had previously been omitted (or "redacted") pursuant to a request for confidential treatment. This amendment provides revised redacted versions of the Exhibits. Accordingly, the Exhibits are hereby amended and restated in their entirety. Pursuant to Rule 12b-15 under the Securities and Exchange Act of 1934, as amended, the registrant is including only Item 15 of Part IV below. The remainder of the information contained in the original Form 10-K for the year ended December 31, 2009 is not amended hereby. This amendment does not reflect events occurring after the filing of the original Form 10-K for the year ended December 31, 2009, or modify or update the disclosures therein in any way other than to reflect the new Exhibits which are filed herewith.

### PART IV

### Item 15. Exhibits and Financial Statement Schedules

### (a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

### 2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the r instructions or are inapplicable and, therefore, have been omitted.

### 3. Exhibits

Exhibit <u>Number</u>	<u>Descripti</u>	<u>on</u>
3.1	(0) -	Restated Certificate of Incorporation.
3.2	(a) -	By-Laws, as amended.
10.1 +	(b) -	1990 Amended and Restated Long-Term Incentive Plan.
10.2 +	(p) -	Amended and Restated 2000 Long-Term Incentive Plan.
10.2.1 +	(c) -	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.2.2 +	(c) -	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.2.3 +	(d) -	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.2.4 +	(d) -	Form of option agreement and related notice of grant for use in connection with the grant of stock options to certain of the Registrant's executive officers in connection with a January 2005 Option Exchange Program.
10.2.5 +	(t) -	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers.
10.2.6 +	(t) -	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers.
10.3 +	(s) -	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
10.4* +	(e) -	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.5 +	(s) -	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.6*	(f) -	IL-1 License Agreement, dated June 26, 2002, by and among the Registrant, Immunex Corporation, and Amgen Inc.
10.7*	(u) -	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.8*	(u) -	Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.

10.9*	(a)	_	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.9.1*	(g) (e)	-	Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December
10.3.1	(e)	-	31, 2004.
10.9.2	(h)	-	Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7,
	( )		2005.
10.9.3*	(i)	_	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December
	~ /		21, 2005.
10.9.4*	(i)	-	Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals,
			Inc.) and the Registrant, effective as of January 31, 2006.
10.10*	(j)	-	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant.
10.11*	(k)	-	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007, by and between AstraZeneca UK Limited and the
			Registrant.
10.12	(l)	-	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant.
10.12.1*	(n)	-	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.
10.12.2	(r)	-	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.12.3	(t)	-	Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.12.4	(v)	-	Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009.
10.12.5	(w)	-	Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10.13*	(m)	-	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the
			Registrant.
10.14*	##	-	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis
			Pharmaceuticals Inc. and the Registrant.
10.15*	##	-	Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc.,
			sanofi-aventis Amerique Du Nord, and the Registrant.
10.16	(o)	-	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC, and
			the Registrant.
10.17	(o)	-	Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc.,
			sanofi-aventis Amerique du Nord, and the Registrant.
10.17.1	#	-	First Amendment to the December 20, 2007 Investor Agreement, dated as of November 10, 2009, by and among sanofi-aventis US LLC,
			Aventis Pharmaceuticals, Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.18*	(p)	-	Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and the Registrant.
23.1	#	-	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	#	-	Power of Attorney (included on the signature page of Annual Report on Form 10-K.
31.1	##	-	Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	##	-	Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	#	-	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

#### Description:

- (a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.
- (b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).
- (c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (d) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (e) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2004, filed March 11, 2005.
- (f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2002, filed August 13, 2002.
- (g) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2003, filed November 12, 2003.
- (h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2005, filed February 28, 2006.
- (j) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.
- (k) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2006, filed March 12, 2007.
- (1) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.
- (o) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.
- (p) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed June 17, 2008.
- (q) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008.
- (r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008.
- (s) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009.

- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009.
- (u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009.
- (v) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009.
- (w) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.
  - \* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.
  - + Indicates a management contract or compensatory plan or arrangement.
  - # Previously filed.
- ## Filed herewith.

### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

Dated: Tarrytown, New York June 2, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

	<u>Signature</u>	<u>Title</u>
/s/	Leonard S. Schleifer,	President, Chief Executive Officer, and
	Leonard S. Schleifer, M.D., Ph.D.	Director (Principal Executive Officer)
/s/	Murray A. Goldberg	Senior Vice President, Finance &
	Murray A. Goldberg	Administration, Chief Financial Officer,
		Treasurer, and Assistant Secretary
		(Principal Financial Officer)
/s/	Douglas S. McCorkle	Vice President, Controller, and
	Douglas S. McCorkle	Assistant Treasurer
		(Principal Accounting Officer)
	*	Executive Vice President, Chief Scientific
	George D. Yancopoulos, M.D., Ph.D	Officer, President, Regeneron Research
		Laboratories, and Director
	*	Chairman of the Board
	P. Roy Vagelos, M.D.	
	*	Director
	Charles A. Baker	
	*	Director
	Michael S. Brown, M.D.	
	*	Director
	Alfred G. Gilman, M.D., Ph.D.	
	*	Director
	Joseph L. Goldstein, M.D.	
	*	Director
	Arthur F. Ryan	
	*	Director
	Eric M. Shooter, Ph.D.	
	*	Director
	George L. Sing	
	urray A. Goldberg y A. Goldberg, as Attorney-in-Fact	
iviurra	y A. Goldberg, as Altorney-In-Fact	

Execution Version Exhibit 10.14

Portions of this Exhibit Have Been Omitted and Separately Filed with the Securities and Exchange Commission with a Request for Confidential Treatment

# AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

By and Between

AVENTIS PHARMACEUTICALS INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 10, 2009

### TABLE OF CONTENTS

Page

	ARTICLE 1	
	DEFINITIONS	
	ARTICLE 2	
	DISCOVERY PROGRAM	
2.1	Discovery Program	12
2.2	Term of the Discovery Program	13
2.3	Discovery Plans	13
2.4	Target List	14
2.5	Commercially Reasonable Efforts; Compliance with Laws	16
2.6	Exchange of Information	16
2.7	Further Assurances and Transaction Approvals	16
2.8	Exclusive Discovery Program	17
2.9	Tail Period	20
2.10	Research Licenses; Licenses Generally	20
2.11	Immunoconjugates	20
2.12	Sanofi Target Licenses	22
2.13	Non-Exclusive License to Sanofi	22
2.14	Invention Assignment	22
2.15	Supply of VelociGene® Mice	22
2.16	Option for VelocImmune® License	22
2.17	Option for Additional Technologies	23
2.18	Third Party Platform Licenses	23
	ARTICLE 3	
	JOINT RESEARCH COMMITTEE	
3.1	The Joint Research Committee	23
3.2	Alliance Management	25
3.3	Resolution of Governance Matters	25
3.4	Obligations of the Parties and their Affiliates	26
	ARTICLE 4	
	PAYMENTS	
4.1	Upfront Payment; Reimbursement Payments for Manufacturing Expansion	26
	i	

4.2	Discovery Program Costs	27
4.3	Reports and Discovery Program Cost Payments	27
4.4	***********Opt-in Payment	28
4.5	Royalty Payments for Royalty Products	29
4.6	Royalty Term and Reporting	30
4.7	Payment Method and Currency	30
4.8	Late Payments	30
4.9	Taxes	30
4.10	Special Adjustment	31
	ARTICLE 5	
	OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES	
5.1	Opt-In Rights to License Product Candidates	31
5.2	Process for Opt-In Rights	31
5.3	Initial Development Plan	32
5.4	Opt-In Exercise	32
5.5	Dll4 and REGN 88	32
5.6	Refused Candidates	32
	ARTICLE 6	
	NEWLY CREATED INVENTIONS	
6.1	Ownership of Newly Created Intellectual Property	33
6.2	Prosecution and Maintenance of Patent Rights	35
6.3	Third Party Claims	37
	ARTICLE 7	
	BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS	
7.1	Books and Records	37
7.2	Audits and Adjustments	37
7.3	IAS/IFRS/GAAP	38
	ARTICLE 8	
	REPRESENTATIONS, WARRANTIES AND COVENANTS	
8.1	Joint Representations and Warranties	38
8.2	Knowledge of Pending or Threatened Litigation	38
8.3	Additional Regeneron Representations, Warranties and Covenants	39
8.4	Disclaimer of Warranties	40
	ii	

### ARTICLE 9

### CONFIDENTIALITY

9.1	Confidential Information	40
9.2	Injunctive Relief	41
9.3	Publications	42
9.4	Disclosures Concerning this Agreement	42
	ARTICLE 10	
	INDEMNITY	
10.1	Indemnity and Insurance	43
10.2	Indemnity Procedure	44
	ARTICLE 11	
	FORCE MAJEURE	
	ARTICLE 12	
	TERM AND TERMINATION	
12.1	Term	46
12.2	Termination For Material Breach	46
12.3	Termination for Insolvency	46
12.4	Termination for Breach of Standstill	47
12.5	Termination for Breach of License and Collaboration Agreement	47
12.6	Effect of Termination by Sanofi for Breach	47
12.7 12.8	Effect of Termination by Regeneron for Breach Survival of Obligations	48 48
12.0	Return of Confidential Information	49
12.10	Special Damages	49
12.11	Termination by Sanofi At Will	50
12.11	Termination by Sanon 2t win	50
	ARTICLE 13	
	ARBITRATION	
13.1	Binding Arbitration	50
	ARTICLE 14	
	MISCELLANEOUS	
14.1	Governing Law; Submission to Jurisdiction	51
14.2	Waiver	52
	iii	

14.3	Notices	52
14.4	Entire Agreement	52
14.5	Amendments	52
14.6	Interpretation	52
14.7	Severability	53
14.8	Assignment	53
14.9	Successors and Assigns	53
14.10	Affiliates	53
14.11	Counterparts	54
14.12	Third Party Beneficiaries	54
14.13	Relationship of the Parties	54
14.14	Limitation of Damages	54
14.15	Non-Solicitation Non-Solicitation	54
14.16	No Strict Construction	54

## AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

THIS AMENDED AND RESTATED DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT ("Agreement"), dated as of November 10, 2009 (the "Effective Date"), is by and between AVENTIS PHARMACEUTICALS INC. ("Sanofi"), a corporation organized under the laws of Delaware, having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, an indirect wholly owned subsidiary of Sanofi-Aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75103 Paris, France ("Sanofi Parent"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, USA ("Regeneron") (with each of Sanofi and Regeneron referred to herein individually as a "Party," and collectively as the "Parties").

WHEREAS, Sanofi and Regeneron are parties to a Discovery and Preclinical Development Agreement dated as of November 28, 2007 (the "Original Agreement"); and

WHEREAS, the Parties have undertaken a broad therapeutic antibody discovery and development program under the Original Agreement with the objective of identifying and validating potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates against those targets using Regeneron's proprietary VelocImmune® and related suite of technologies;

WHEREAS, the Parties plan to expand these antibody discovery and development efforts under the terms set forth in this Agreement; and

WHEREAS, Sanofi is interested in continuing to collaborate with Regeneron to discover and validate potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates and to receive an option to license certain rights to the resulting fully human monoclonal antibodies under the terms set forth in this Agreement and in the License and Collaboration Agreement (as further defined in Article 1 below);

WHEREAS, the Parties now desire to amend the Original Agreement in accordance with <u>Section 14.5</u> of the Original Agreement and restate the amended Original Agreement as set forth in this Agreement;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

#### ARTICLE 1

#### **DEFINITIONS**

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

"Acquired Antibody" shall mean a specific Antibody against a Program Target in preclinical or clinical development acquired by a Party or its Affiliate from a Third Party (other than Sanofi Pasteur or Merial Limited in the case of Sanofi), whether such acquisition is by direct acquisition, by license or through the acquisition of a Third Party that owns or controls the applicable Antibody.

"Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by, or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract, or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.

"Alliance Manager" shall have the meaning set forth in Section 3.2.
"Annual Draft Meeting" shall have the meaning set forth in Section 2.4(a).
" <u>Antibody</u> " shall mean **********************************.
"Antibody Discovery Plan" shall have the meaning set forth in Section 2.3.
" <u>Arm</u> " shall mean *********************************.
"Available Slots" shall mean the difference between ***** and the total number of Program Targets that were on the Rolling Target List the day immediately ceding the Special JRC Meeting or Annual Draft Meeting, as the case may be, as described in Section 2.4(a).

"Agreement" shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

preceding the Special JRC Meeting or Annual Draft Meeting, as the case may be, as described in <u>Section 2.4(a)</u>.

"Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between sanofi-aventis US (as successor in interest to Sanofi) and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Stock Purchase Agreement, as the same may be further amended from time to time.

\*\*\*\*\*\*\*\*\*\*\*\*

"Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.

"Collaboration Objectives" shall have the meaning set forth in Section 2.1(b).

"Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a Target-by-Target and Antibody-by-Antibody (including MTCs) basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors; including, but not limited to the possibility that significant increases in the CPI over the Term will lead to an increase in the cost of external services and a reduction in the number of FTEs funded under the Discovery Program; which, in turn, may adversely affect the likelihood of Regeneron achieving the Collaboration Objectives.

"Competing Refused Candidate" shall mean any Refused Candidate having the same Target as a Licensed Product (as long as such Licensed Product is licensed to Sanofi under the License and Collaboration Agreement at the time the applicable Product Candidate becomes a Refused Candidate and for the duration of time for which such Licensed Product is licensed to Sanofi under the License and Collaboration Agreement).

"Confidential Information" shall have the meaning set forth in Section 9.1.

"Contract Year" shall mean the period beginning on the Original Agreement Effective Date and ending on December 31, 2008, and each succeeding twelve (12) month period thereafter during the term of the Discovery Program (except that the last Contract Year shall end on the effective date of any termination or expiration of this Agreement).

"CPI" shall mean the Consumer Price Index – All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

"Damages" shall have the meaning set forth in Section 10.1(a).

"Default Interest Rate" shall have the meaning set forth in Section 4.7.

"Disclosing Party" shall have the meaning set forth in Section 9.1.

"Discovery Expiration Date" shall mean December 31, 2017.

"<u>Discovery Program</u>" shall mean all research and development activities performed under the Original Agreement and to be performed under this Agreement from Target identification, discovery and validation through the completion of IND Preparation for Product Candidates using Regeneron's technologies, Mice and improvements thereto or otherwise, including, \*\*\*\*\*\*\*\*\*\*\*, and which shall include, but not be limited to, (a) discovery research activities directed at Target identification, validation, and selection, (b) Antibody (including MTCs) discovery, (c) Lead Candidate identification, characterization, pharmacological assessment (if applicable) and selection, (d) the production of Antibodies (including MTCs) for preclinical experiments and Phase I Clinical Trials (and such other clinical trials as may be agreed by the Parties), and (e) IND Preparation.

"<u>Discovery Program Costs</u>" shall mean all Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron after the Original Agreement Effective Date directly in connection with the performance of the Discovery Program (and, as such costs relate to a particular Licensed Product, ending on the last day of the month preceding the month in which the Opt-In Notice for such Licensed Product is received by Regeneron).

"Excluded Candidates" shall mean Antibodies (including MTCs) against Excluded Targets.

"Excluded Targets" shall mean (i) Targets set forth in Schedule 2, (ii) Targets removed from the Rolling Target List pursuant to Section 2.4(b), (iii) Targets excluded or removed from the Rolling Target List by Sanofi pursuant to Section 2.4(c), (iv) Targets of Sanofi Divested Antibodies, (v) Targets of Sanofi Regulatory Divested Antibodies, and (vi) Program Targets that are not included on the Target List during the Tail Period pursuant to Section 2.9.

"Executive Officers" shall mean the Chief Executive Officer of Regeneron and the most senior Research and Development Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

"FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

"Force Majeure" shall have the meaning set forth in Article 11.

"FTE Cost" shall mean, for all activities performed under the Discovery Program, the product of (a) the number of FTEs performing activities under the Discovery Program and (b) the FTE Rate.

"FTE Rate" shall mean \*\*\*\*\*\*\*\*\* in the Contract Year ending December 31, 2019 and \*\*\*\*\*\*\*\* in the Contract Year ending December 31, 2010, such amount to be adjusted as of January 1, 2011 and annually thereafter by the CPI Adjustment.

"GAAP" shall mean generally accepted accounting principles as applicable in the United States.

"Governmental Authority." shall mean any court, agency, authority, department, regulatory body, or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city, or other political subdivision of any such government or any supranational organization of which any such country is a member.

"IAS/IFRS" shall mean International Financial Reporting Standards adopted by the International Accounting Standards Board.

"IFM" shall have the meaning set forth in Section 2.11(d)(ii).

"Immunize" or "Immunization" shall mean the introduction of an antigen to a Mouse for the purpose of generating Antibodies against a Target.

"Immunized Target List" shall mean and shall reflect those Targets identified in Schedule 3, together with Targets for which Immunization has begun under the Discovery Program after the Effective Date.

"IND" shall mean, with respect to each Product Candidate, an Investigational New Drug Application filed with the FDA with respect to such Product Candidate pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving such Product Candidate, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.

"IND Preparation" shall mean all drug development activities in support of a Lead Candidate or Product Candidate up to the filing of the IND for the Phase I Clinical Trial, including, but not limited to, assay development, sample analysis, preclinical toxicology, preclinical pharmacokinetics and toxicokinetics, pharmacological assessment (if applicable), cell line development and protein chemistry sciences, formulation development, clinical trial protocol development, IND drafting and data compilation, and manufacturing preclinical and clinical supplies.

"Indemnified Party" shall have the meaning set forth in Section 10.2(a).

- "Indemnifying Party" shall have the meaning set forth in Section 10.2(a).
- "Initial Development Plan" shall have the meaning set forth in Section 5.3.
- "Investor Agreement" shall mean the Investor Agreement, dated as of December 20, 2007, by and between (a) Sanofi, Sanofi Parent, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron, as amended as of the Effective Date, and as the same may be further amended from time to time.
  - "Joint Research Committee" or "JRC" shall mean the Joint Research Committee described in Section 3.1(a).
  - "Joint Inventions" shall have the meaning set forth in Section 6.1(b).
  - "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.
- "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.
  - "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions, and/or ordinances of any Governmental Authority in the Territory.
- "<u>Lead Candidate</u>" shall mean, for any Program Target, each Antibody, including MTCs, that satisfies the applicable criteria set forth in Schedule 4 and is selected by Regeneron to begin IND Preparation under this Agreement.
- "<u>License and Collaboration Agreement</u>" shall mean the Amended and Restated License and Collaboration Agreement between the Parties, dated as of the date of this Agreement, the terms of which are incorporated by reference into, and are part of, this Agreement, as the same may be amended from time to time.
  - "Licensed Product" shall mean any Product Candidate for which Sanofi has exercised its Opt-In Rights pursuant to Section 5.4 below.
  - "Licensed Refused Sanofi Candidate" shall have the meaning set forth in Section 2.12.
- "Manufacturing Cost" shall mean the fully burdened cost (without mark-up) of manufacturing Product Candidates and Lead Candidates for preclinical activities and Phase I Clinical Trials (and, if agreed by the Parties other clinical trials), and the cost for providing dedicated manufacturing capacity for Lead Candidates and Product Candidates, in each case, as calculated in accordance with Schedule 5.
  - "Maximum Annual Discovery Program Costs" shall have the meaning set forth in Section 4.2.

"Mice"	or	"Mouse"	shall	mean	*******
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"Modified Clause" shall have the meaning set forth in Section 14.7.

"Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Royalty Products in the Territory by or on behalf of a Party, or its Affiliates or sublicensees to Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:

- (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Royalty Products;
- (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
- (c) chargebacks and other amounts paid on sale or dispensing of Royalty Products;
- (d) Third Party cash rebates and chargebacks related to sales of Royalty Products, to the extent allowed;
- (e) retroactive price reductions that are actually allowed or granted;
- (f) compulsory refunds, credits and rebates directly related to the sale of Royalty Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or governmental regulations;
- (g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering Royalty Products that are separately identified on the invoice or other documentation;
- (h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Royalty Products, which are separately identified on the invoice or other documentation;
- (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Royalty Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof;
- (j) invoiced amounts that are written off as uncollectible in accordance with a Party's or its Affiliates' or sublicensees' respective accounting principles as applied consistently Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 4.7 of this Agreement.

Sales between the Parties, or between the Parties and their Affiliates or sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Royalty Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if a Party or its Affiliates or sublicensee sells such Royalty Products in the form of a combination product containing any Royalty Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the first commercial sale of such Combination Product, the Parties shall agree on the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates shall not be deemed Combination Products.

"Original Agreement Effective Date" shall mean November 28, 2007.

"Opt-In Notice" shall have the meaning set forth in Section 5.4.

"Opt-In Period" shall have the meaning set forth in Section 5.4.

"Opt-In Report" shall have the meaning set forth in Section 5.2.

"Opt-In Rights" shall have the meaning set forth in Section 5.1.

"Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by Regeneron (or its Affiliate) directly in connection with the performance of the Discovery Program.

"Party" or "Parties" shall have the meaning set forth in the introductory paragraph.

"Patent Application" shall mean any application for a Patent.

"Patent Rights" shall mean unexpired Patents and Patent Applications.

"Patents" shall mean patents together with all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, extensions, registrations, patent term adjustments or extensions, supplemental protection certificates and renewals of any of the foregoing, and all counterparts thereof in any country in the Territory.

"Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

- "Phase I Clinical Trial" shall mean the first clinical trial of a Product Candidate following IND Preparation.
- "Product Candidate" shall mean any Lead Candidate that substantially completes IND Preparation and is ready to be offered for license to Sanofi under the Opt-In Rights.
- "Product Patent Rights" shall mean any Patent or Patent Application having a specification which supports a claim that may be infringed by making, using, selling, importing or exporting a Lead Candidate or Product Candidate in the Discovery Program, including, without limitation, any derivatives, fragments, compositions of matter or uses, thereof.
  - "Program Targets" shall mean all Targets on the Target List.
  - "Publishing Party" shall have the meaning set forth in Section 9.3.
  - "Receiving Party" shall have the meaning set forth in Section 9.1.
  - "Refused Candidate" shall have the meaning set forth in Section 5.6 (i).
  - "Regeneron" shall have the meaning set forth in the introductory paragraph.
  - "Regeneron Indemnitees" shall have the meaning set forth in Section 10.1(a).
  - "Regeneron Intellectual Property," shall mean the Regeneron Patent Rights and the Regeneron Know-How.
- "Regeneron Know-How" shall mean any and all Know-How as of the Original Agreement Effective Date or thereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.
- "Regeneron Patent Rights" shall mean those Patent Rights as of the Original Agreement Effective Date or thereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.
  - "Regeneron Sole Inventions" shall have the meaning set forth in Section 6.1(a).

"Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the activities conducted under the Discovery Program.

"Rolling Target List" shall mean the rolling list of Targets designated for Immunization under the Discovery Program over a two-Contract Year period, as initially prepared and thereafter revised in accordance with Section 2.4.

"<u>Royalty Product</u>" shall mean \*.

"Royalty Term" shall have the meaning set forth in Section 4.5.

"Sanofi" shall have the meaning set forth in the introductory paragraph.

"Sanofi Divested Antibody" shall have the meaning set forth in Section 2.8(b)(iii).

"Sanofi Indemnitees" shall have the meaning set forth in Section 10.1(b).

"Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.

"Sanofi Know-How" shall mean any and all Know-How as of the Original Agreement Effective Date or thereafter during the term of the Discovery Program (including the Tail Period) owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.

"Sanofi Patent Rights" shall mean those Patent Rights as of the Original Agreement Effective Date or thereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.

"Sanofi Regulatory Divested Antibody" shall have the meaning set forth in Section 2.8(b)(v).

"Sanofi Sole Inventions" shall have the meaning set forth in Section 6.1(a).

"Sanofi Sole Projects" shall have the meaning set forth in Section 2.8(b)(iii).

"Sanofi Targets" shall have the meaning set forth in Section 2.4.

"Solely Developed Immunoconjugate" shall have the meaning set forth in Section 2.11(b).

"Special JRC Meeting" shall have the meaning set forth in Section 2.4(a).

"Stock Purchase Agreement" shall mean the Stock Purchase dated as of the Original Agreement Effective Date by and between (a) Sanofi, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron.

"Tail Period" shall have the meaning set forth in Section 2.9.

"Target" shall mean any gene, receptor, ligand, or other molecule (a) potentially associated with a disease activity, and (b) which potentially has a biological activity that is modified by direct interaction with an Antibody, including any MTC, or (c) to which an Antibody, including any MTC, binds,

"Target Discovery Plan" shall have the meaning set forth in Section 2.3.

"Target List" shall mean the list of Targets on the Rolling Target List and the Immunized Target List, but excluding Excluded Targets.

"Term" shall have the meaning set forth in Section 12.1.

"Territory" shall mean all the countries and territories of the world.

"Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

"Third Party Opportunities" shall have the meaning set forth in Section 2.8(a)(ii).

"Valid Claim" shall mean a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Government Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, reexamination, disclaimer or otherwise.

#### **ARTICLE 2**

#### **DISCOVERY PROGRAM**

2.1 Discovery Program. (a) From the Effective Date, the objective of the Parties during the Discovery Program is for Regeneron to discover, identify and/or validate Targets from which Regeneron shall select Targets for the Rolling Target List, generate MTCs (and, if agreed to by the JRC, other Antibodies) against Program Targets (including Program Targets that are Sanofi Targets) from which to select Lead Candidates, and develop such Lead Candidates through IND Preparation to offer to Sanofi for joint development and commercialization under the terms set forth herein and in the License and Collaboration Agreement. During the first ten (10) Contract Years, Regeneron will use Commercially Reasonable Efforts to discover, identify and validate Targets as part of the Discovery Program. The Parties will select Targets for the generate MTCs (and if agreed by the JRC, other Antibodies) against Program Targets and manufacture preclinical and clinical supplies of the Lead Candidates and Product Candidates for the Discovery Program and Phase 1 Clinical Trials. The JRC will evaluate and prioritize Program Targets. Subject to the JRC's prioritization of Program Targets, Sanofi's Target selection and exclusion rights under Section 2.4, and the other terms of this Agreement, Regeneron will have sole responsibility for the design and conduct of all activities under the Discovery Program, including, without limitation, decisions relating to initiation and termination of programs and activities, manufacturing activities, and staffing and resource allocation between different programs and activities in the Discovery Program. The JRC will also prioritize the Antibodies, including MTCs, to be further pursued as Lead Candidates, and Regeneron will commence IND Preparation activities only for those Antibodies, including MTCs, that meet the applicable criteria set forth in Schedule 4. Sanofi shall be responsible for completing relevant portions of Schedule 4 for all Sanofi Targets at the time that such Target is selected for the Rolling Target List to the extent such information is not available at Regeneron. Sanofi, through the JRC, will provide consultation and advice to support Regeneron's efforts. Neither Regeneron nor Regeneron's representative on the JRC shall have the right to discriminate against Sanofi Targets without the agreement of Sanofi's representatives on the JRC.

- (c) As part of the Discovery Program, Regeneron may \*.
- 2.2 <u>Term of the Discovery Program</u>. The Discovery Program commenced on the Original Agreement Effective Date and shall end on December 31, 2017 unless (a) this Agreement is earlier terminated in accordance with <u>Article 12</u>, in which event the Discovery Program shall end on the effective date of such termination or (b) extended by Sanofi for the Tail Period pursuant to the terms of <u>Section 2.9</u> in which event the Discovery Program shall end upon the earlier of the expiration of the Tail Period or the earlier termination of this Agreement.
  - 2.3 <u>Discovery Plans</u>. Regeneron will annually prepare a "<u>Target Discovery Plan"</u> and an "<u>Antibody Discovery Plan"</u> for the Discovery Program.
- (a) The Target Discovery Plan shall set forth the overall strategy, plan and goals over the next Contract Year for identifying and validating Targets from which Regeneron shall choose its Targets for the Rolling Target List; it being understood that the Target Discovery Plan will not include information on the identity of Targets that are the subject of Regeneron's discovery research activities under the Discovery Program that have not yet been selected as Program Targets. The Target Discovery Plan will also include an estimated budget for the portion of the Discovery Program covered by the Target Discovery Plan for the ensuing Contract Year. Regeneron will submit each Target Discovery Plan, including the estimated budget, to the JRC for review and comment.
- (b) The Antibody Discovery Plan shall set forth the overall strategy and plans over the next Contract Year for generating Antibodies against Program Targets, conducting research on Program Targets and Antibodies generated against Program Targets, and preclinically developing Antibodies under the Discovery Program through IND Preparation. The Antibody Discovery Plan will also include an estimated budget for the portion of the Discovery Program covered by the Antibody Discovery Plan for the ensuing Contract Year. Regeneron will submit each Antibody Discovery Plan, including the estimated budget, to the JRC for review and comment. For each Lead Candidate, the Antibody Discovery Plan will include activities and a planned timeline for IND Preparation. Regeneron shall consider in good faith comments on the Antibody Discovery Plan from Sanofi's representatives on the JRC.
- (c) Except for the initial Target Discovery Plan and Antibody Discovery Plan (which will be provided to the JRC within ninety (90) days of the Effective Date), Regeneron will present an updated Target Discovery Plan and Antibody Discovery Plan to the JRC at least two (2) months prior to the end of each Contract Year.

#### 2.4 Target List.

- (c) Sanofi shall have the right to exclude from the Rolling Target List a Target selected by Regeneron for the Rolling Target List as provided in <u>Section 2.4(c)(i)</u>, and shall have the right to remove a Program Target from the Target List, as provided in <u>Sections 2.4(c)(ii)</u> and <u>(iii)</u>.

(i) Sanofi shall have the right to exclude from the Rolling Target List a Target selected by Regeneron for the Rolling Target List (a "Regeneron Selected"
<u>Target</u> ") if at the time of selection by Regeneron of such Regeneron Selected Target either (A) Sanofi or its Affiliate has an existing Antibody against the Regeneron
Selected Target that is **************************, (B) Sanofi or its Affiliate has *****************, or (C) Sanofi or its Affiliate has ***********************************
has ********************************** for the Rolling Target List in any
Contract Year, nor ************** over any rolling three (3) Contract Year period. Sanofi must notify Regeneron of its exclusion pursuant to this Section 2.4(c)
(i) within ten (10) Business Days of the Annual Draft Meeting or Special JRC Meeting at which Regeneron selects the applicable Regeneron Selected Target or Sanofi's
receipt of written notice from Regeneron regarding Regeneron's selection of a Regeneron Selected Target pursuant to Section 2.4(b) above or this Section 2.4(c)(i).
Sanofi's exclusion of a Regeneron Selected Target pursuant to this Section 2.4(c)(i) must be followed promptly by written notice to Regeneron that describes the
condition in either (A), (B), or (C) above that has been met supporting the Target exclusion. Regeneron shall have ten (10) Business Days from the exclusion of a Target
under this Section 2.4(c) to select replacement Regeneron Selected Target(s) for the Rolling Target List under Section 2.4(a) or Section 2.4(b), as the case may be, in
which case the terms of this Section 2.4(c) shall remain in effect.

- 2.5 <u>Commercially Reasonable Efforts; Compliance with Laws</u>. During the term of the Discovery Program, Regeneron will use Commercially Reasonable Efforts to discover and develop Product Candidates to offer for license to Sanofi pursuant to the Opt-In Rights. Without limiting the foregoing, Regeneron will use Commercially Reasonable Efforts to identify Lead Candidates and complete IND Preparation for Lead Candidates in a timely manner during the term of the Discovery Program. Each Party hereby covenants and agrees to comply with applicable Laws in performing activities connected with the Discovery Program.
- 2.6 Exchange of Information. Regeneron will share information with the JRC in a timely manner concerning the progress of the Target Discovery Plan and the Antibody Discovery Plan consistent with Sections 2.3 and 3.1(b). Without limiting the foregoing, at least five (5) calendar days prior to each regular quarterly meeting of the JRC, Regeneron will use its Commercially Reasonable Efforts to provide to Sanofi's representatives on the JRC a written report (in electronic form) summarizing the material activities undertaken by Regeneron in connection with the Target Discovery Plan and the Antibody Discovery Plan, including information concerning new Program Targets, Lead Candidates and Product Candidates. Sanofi shall have the right to reasonably request and to receive in a timely manner clarifications and answers to questions with respect to such reports (other than with respect to the identity and progress of Targets in the Target Discovery Plan which are not Program Targets) and any other data and any other information it reasonably requests with respect to the conduct of the Target Discovery Plan and the Antibody Discovery Plan.
- 2.7 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations, or orders required to be obtained or made in connection with the authorization, execution, and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions, or changes suggested in connection therewith. Each Party will furnish all information required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

#### 2.8 Exclusive Discovery Program.

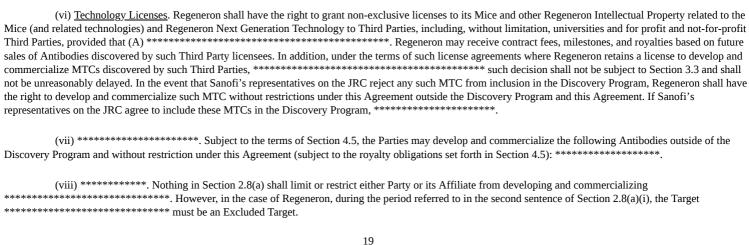
#### (a) Exclusivity.

- (i) <u>General</u>. Subject to the other subparagraphs in this <u>Section 2.8</u>, until the end of the Term, neither Party nor any of their respective Affiliates will either directly, or with any Third Party, work to discover Antibodies against, or develop or commercialize Antibodies against, Program Targets in the Territory, except pursuant to this Agreement or the License and Collaboration Agreement. Furthermore, subject to the other subparagraphs in this <u>Section 2.8</u>, until the earlier to occur of (A) the Discovery Expiration Date, and (B) the effective termination of this Agreement, neither Regeneron nor any of its Affiliates will, either directly or with any Third Party, work to discover, develop or commercialize Antibodies in the Territory, except pursuant to this Agreement or the License and Collaboration Agreement. Solely as used in this <u>Section 2.8(a)</u> and in <u>Section 2.8(b)</u>, the terms "develop," "developing" or "development" shall mean any and all activities related to Antibody discovery and Antibody preclinical and clinical development. In the event this Agreement is terminated early pursuant to <u>Sections 12.2</u>, 12.3, 12.4, 12.5, or 12.11, the obligations stated in this <u>Section 2.8(a)</u> shall also terminate as of the effective date of such early termination.

### (b) Exclusions.

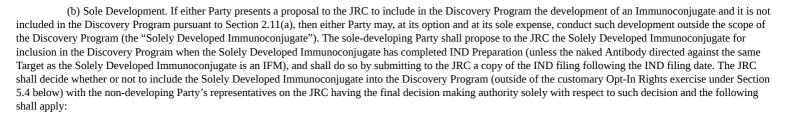
(i) Excluded Candidates. Each Party (and its Affiliates) shall have the right to develop and commercialize Excluded Candidates either on its own or with Third Parties outside the Discovery Program without restriction under this Agreement; provided that Sanofi shall have no rights under this Agreement to any Excluded Candidates developed under the Discovery Program. Regeneron shall have and retain exclusive rights to any such Excluded Candidates developed in the Discovery Program against such Excluded Target without restrictions under this Agreement, subject to the royalty obligations set forth in Section 4.5. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any such MTCs or other Antibodies (or any Acquired Antibodies of Regeneron) against Excluded Targets and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with the development of Antibodies against Excluded Targets.

- (iii) Sanofi Acquired Antibodies. Sanofi and its Affiliates shall have the right to develop and commercialize Acquired Antibodies that are the subject of filed INDs, whether such acquisition is by direct acquisition, by license or through acquisition of a Third Party) (a "Sanofi Acquired Antibody"), even if such Sanofi Acquired Antibodies are against Program Targets. Sanofi shall promptly notify Regeneron of any such acquisition or license (including the identity of the Program Target), and may continue the development of such Sanofi Acquired Antibody without restriction outside the Discovery Program and this Agreement. In the event of such an acquisition or license, unless otherwise agreed to by the Parties, the applicable Program Target shall be considered an Excluded Target and Sanofi shall no longer have any rights to any Excluded Candidates against such Excluded Target developed under this Agreement (such Antibodies being referred to herein as "Sanofi Divested Antibodies"). Regeneron may develop and commercialize (on its own or with one or more Third Parties) any Sanofi Divested Antibodies or other Excluded Candidates against such Excluded Targets, and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities without restrictions under this Agreement, subject to the royalty obligations set forth in Section 4.5. Until the time of IND filing for a Sanofi Divested Antibody, Regeneron shall have the right to consider development of Sanofi Divested Antibodies against the applicable Excluded Target as development under the Discovery Program solely for purposes of seeking reimbursement of Discovery Program Costs pursuant to Section 4.2.



2.10 <u>Research Licenses</u>; <u>Licenses Generally</u>. Each Party hereby grants to the other Party and its Affiliates a non-exclusive, non-transferable, worldwide, royalty-free, research license, without the right to sublicense, under the Regeneron Intellectual Property and the Sanofi Intellectual Property, respectively, solely to perform the Discovery Program. For the avoidance of doubt, neither Party shall use the licenses granted in this <u>Section 2.10</u> for the benefit, directly or indirectly, of any Third Party. Except as expressly provided for herein, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). Except as expressly provided for in this <u>Section 2.10</u> or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights or Know-How, either expressly or by implication, estoppel or otherwise. Upon expiration or earlier termination of the Discovery Program, the licenses granted in <u>Section 2.10</u> herein shall automatically terminate.

### 2.11 Immunoconjugates.



- (1) Inclusion in the Discovery Program. If the JRC decides to include the Solely Developed Immunoconjugate into the Discovery Program, then the Solely Developed Immunoconjugate shall be considered a Product Candidate and become a Licensed Product under the License and Collaboration Agreement. In such case, \*. For clarification, the royalty as described in Section 2.11(d)(i), to be negotiated in good faith by the Parties, shall apply if the sole-developing Party's Patent Rights and Know How are practiced or used with respect to the Solely Developed Immunoconjugate as described herein.
- (2) Continue Sole Development. If at the time when such Solely Developed Immunoconjugate has completed its IND Preparation the License and Collaboration Agreement is not in effect, or if the JRC decides not to include the Solely Developed Immunoconjugate into the Discovery Program, then the sole-developing Party shall have the right to continue development and to commercialize such Solely Developed Immunoconjugate on its own and at its sole expense, or with a Third Party, outside the Discovery Program without restrictions under this Agreement.
- (c) Failed MTCs. The Parties may independently develop Immunoconjugates using Failed MTCs. For the purposes of this Section 2.11, "Failed MTC" shall mean (i) any MTC against a Program Target that does not progress to IND Preparation in its naked Antibody form or (ii) any Lead Candidate, in its naked Antibody form, for which an IND is not filed, in each case (A) due to lack of evidence of biological activity and (B) only if both Parties agree that the Program Target or Lead Candidate, as applicable, will not be the subject of any further activities under the Discovery Program, such agreement not to be unreasonably withheld or delayed.

With respect to any Failed MTC each Party hereby grants to the other a non-transferable, non-exclusive, worldwide, royalty-bearing (in accordance with Section 4.4 herein) license, with the right to sublicense, and with respect to Regeneron Target IP and Sanofi Target IP (as the case may be) solely to make, have made, use, sell, offer to sell and import IFMs. For the avoidance of doubt, such a license shall not include rights to any underlying Immunoconjugate technology owned by the licensing Party.

#### (d) Royalties.

- (ii) Failed MTCs. In the event that a Party or its Affiliate develops Immunoconjugates using Failed MTCs ("IFMs") outside the Discovery Program and this Agreement, then such Party shall be required to pay to the other Party, within sixty (60) days following the end of each calendar quarter, royalty payments for such IFMs in accordance with Section 4.5.
- 2.13 Non-Exclusive License to Sanofi. Regeneron hereby grants Sanofi and its Affiliates a perpetual, worldwide, non-exclusive, non-transferable, royalty-free license, without the right to sublicense, under Regeneron Intellectual Property discovered directly in connection with the performance of the Discovery Program claiming Targets on the Target List and/or methods of use related to the inhibition or use of such Targets for use by Sanofi and its Affiliates in connection with the manufacture, use, sale, offer to sell, and import of small molecule drug and diagnostic products.
- 2.14 <u>Invention Assignment</u>. All of the employees, officers and consultants of each Party that are supporting the performance of its obligations under this Agreement shall have executed agreements or have existing obligations under law requiring, in the case of employees and officers, assignment to such Party of all inventions made during the course of and as the result of their association with such Party and, in the case of employees, officers and consultants, obligating the individual to maintain as confidential such Party's Confidential Information which such Party may receive, to the extent required to support such Party's obligations under this Agreement.
- 2.15 <u>Supply of VelociGene® Mice</u>. On August 4, 2008, Regeneron and sanofi-aventis U.S. Inc. entered into a Mouse Purchase Agreement pursuant to which Regeneron is using its proprietary technology for the production of genetically modified mouse embryonic stem cell lines and mice derived from the corresponding mouse stem cell lines.

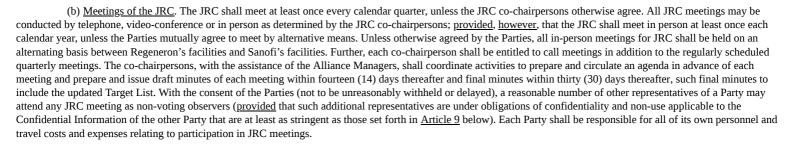
2.17 Option for Additional Technologies. To the extent that Regeneron decides to license either ************************************
technologies and Know How being licensed by Regeneron, being referred to as the "Additional Technologies) to commercial entities, then at Sanofi's request, during the
one hundred eighty (180) day period following the expiration or earlier termination of the Discovery Program, the Parties shall enter into a definitive agreement under
which Regeneron will license the applicable Additional Technologies to Sanofi. The definitive agreement(s) for the Additional Technologies to be licensed to Sanofi shall
contain commercial and other terms and conditions that are not materially less favorable, when taken as a whole, than those included in any then-existing license
agreements with Third Parties for such Additional Technologies, if any.

- 2.18 <u>Third Party Platform Licenses</u>. The Parties acknowledge that, during the Term, the Parties may mutually agree \*. In such an event, including mutual agreement of the Parties, the following provisions shall apply:
- (a) License by Regeneron. Regeneron shall use Commercially Reasonable Efforts to obtain and maintain any Third Party licenses \*\*\*\*\*\*\*\*\*\*\*\*, including research necessary for \*.
- (b) License by Sanofi. In the event that \*\*\*\*\*\*\*\*\*\* pursuant to subsection (a) above or the Parties decide that \*\*\*\*\*\*\*\*\*\*\*\*\*, Sanofi shall use Commercially Reasonable Efforts to obtain and maintain such Third Party licenses.

# JOINT RESEARCH COMMITTEE

## 3.1 The Joint Research Committee.

(a) <u>Formation, Composition and Membership</u>. The Parties have established the JRC, which shall consist of at least three (3) senior representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party; <u>provided</u> that such replacement is of comparable standing and authority within that Party's organization as the person he or she is replacing (or is otherwise reasonably acceptable to the other Party). The JRC will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi.



- (c) Duties. The JRC shall:
  - (i) discuss the objectives of the Discovery Program;
  - (ii) review and comment on the Target Discovery Plan and the Antibody Discovery Plan;
- (iii) exchange and review scientific information and data relating to the Target List and activities being conducted under, and the then-current progress of, the Target Discovery Plan and the Antibody Discovery Plan, and establish processes for the exchange of information relating to the progress of the activities under the Target Discovery Plan and the Antibody Discovery Plan (subject to the limitations concerning the identification of Targets in the Target Discovery Plan as set forth in Section 2.3(a));
- (iv) discuss experiments believed by a Party's representatives on the JRC to be necessary to properly evaluate Program Targets, Lead Candidates and Product Candidates;
  - (v) provide assistance and recommendations on the direction of the Target Discovery Plan and the Antibody Discovery Plan;
  - (vi) evaluate and prioritize Program Targets;
  - (vii) discuss the use of \*\*\*\*\* with regard to Program Targets;
  - (viii) discuss whether an Antibody, including any MTC, satisfies the criteria of Lead Candidates attached in Schedule 4;
  - (ix) review and prioritize Lead Candidates;

- (x) maintain the Rolling Target List, Immunized Target List, and the list of Excluded Targets as provided in this Agreement;
- (xi) conduct the Special JRC Meeting and Annual Draft Meetings;
- (xii) consider and act upon such other matters as specified in this Agreement or as otherwise agreed to by the Parties, including, without limitation, any request for Sanofi to perform activities under the Discovery Program costs for which to be treated as Discovery Program Costs in accordance with the last paragraph of Section 4.
  - (xiii) make any such decisions as are expressly allocated to the JRC under this Agreement; and

At the request of either Party's representatives to the JRC, conduct ad hoc meetings in addition to the quarterly meetings of the JRC as reasonably necessary to coordinate and expedite all decisions made by the JRC.

- (d) <u>Decision Making</u>. The JRC shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; <u>provided</u> that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on the JRC and leave decisions of the JRC to representatives of the other Party.
- 3.2 <u>Alliance Management</u>. Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, and regulatory issues to act as its Alliance Manager ("<u>Alliance Manager</u>"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for providing single-point communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization, including facilitating review of external corporate communications.

### 3.3 Resolution of Governance Matters.

- (a) <u>Generally</u>. The Parties shall cause their respective representatives on the JRC to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible.
- (b) Executive Officers' Resolution of Disputes. In the event that the JRC is, after a period of thirty (30) days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, or the Parties are unable to agree on the budget for the Initial Development Plan for a Product Candidate in accordance with Section 5.3 below, either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, the co-chairpersons of the JRC, by written notice to each Party delivered within five (5) days after receipt of the notice from a Party pursuant to the immediately preceding sentence, shall formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within thirty (30) days of receiving such written notification or such longer period of time as the Executive Officers may agree in writing. Regeneron's Executive Officer shall have the deciding vote over all matters referred to the Executive Officers by the JRC, other than (i) matters related to the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate which shall be resolved in accordance with Section 13.1 below should the Executive Officers fail to resolve such matter, (ii) decisions concerning whether Sanofi shall perform any activities under the Discovery Program, which shall require a joint decision of both Parties' Executive Officers, (iii) any decision of the Executive Officers pursuant to Section 2.4(d), and (iv) any decision of the Executive Officers pursuant to Section 4.4.

3.4 <u>Obligations of the Parties and their Affiliates</u>. The Parties shall cause their respective designees on the JRC and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

### **ARTICLE 4**

### **PAYMENTS**

4.1 <u>Upfront Payment; Reimbursement Payments for Manufacturing Expansion</u>. Within five (5) Business Days of the Original Agreement Effective Date, Sanofi paid to Regeneron a non-refundable, non-creditable amount of US \$85,000,000 as consideration for access to Regeneron's research capabilities and suite of discovery technologies and the co-exclusive (with Regeneron) rights granted to Sanofi hereunder during the Term. Regeneron plans to expand its facilities in Rensselaer, New York (the "Expansion Plans") to help provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements (as those terms are defined in the License Agreement) of Licensed Products. The Parties have agreed on the general description, plan and budget of the Expansion Plans as set forth in Schedule 7. Sanofi shall reimburse Regeneron for up to US\$30,000,000 of costs incurred by Regeneron to implement the Expansion Plans (the "Maximum Reimbursable Amount"). Within forty-five (45) days following the end of each calendar quarter, until Regeneron has been reimbursed for the Maximum Reimbursable Amount under this Section 4.1, Regeneron shall provide to Sanofi a detailed report of the costs incurred by it in such calendar quarter to implement the Expansion Plans, together with an invoice therefor. Sanofi shall reimburse Regeneron for all costs set forth in such report and invoice within thirty (30) days after its receipt thereof. Regeneron shall not be entitled to include depreciation for equipment and other items included in the Expansion Plan as Development Costs (as defined in the License Agreement) under the License Agreement to the extent Sanofi has reimbursed Regeneron for such equipment and other items pursuant to this Section 4.1, and shall provide evidence of the same. Regeneron may only use the production suites identified in Schedule 7 to manufacture products other than Licensed Products if the production of such other products does not interfere with the production of Formulated Bulk Product for Clinical Su

4.2 <u>Discovery Program Costs</u>. Commencing on the Original Agreement Effective Date and continuing during the term of the Discovery Program, Sanofi shall be responsible for paying one hundred percent (100%) of all Discovery Program Costs, including Discovery Program Costs incurred for a Product Candidate until the anticipated IND filing date for such Product Candidate, regardless of whether Sanofi exercises its Opt-In Rights in accordance with <u>Section 5.1</u>; <u>provided</u> that, except as set forth below and in <u>Section 4.10</u>, the total annual Discovery Program Costs to be paid by Sanofi in each of the first ten (10) years of the Discovery Program (the "<u>Maximum Annual Discovery Program Costs</u>") shall not exceed the following amounts (as calculated for each Contract Year):

Contract Year	Maximum Annual Discovery Program Costs
1 (ending December 31, 2008)	US \$75,000,000
2	US \$100,000,000
3	US \$160,000,000
4	US \$160,000,000
5	US \$160,000,000
6	US \$160,000,000
7	US \$160,000,000
8	US \$160,000,000
9	US \$160,000,000
10 (ending December 31, 2017	US \$160,000,000

In the event that the Discovery Program Costs incurred in any Contract Year are less than the Maximum Annual Discovery Program Costs for such Contract Year, the amount of such shortfall up to ten percent (10%) of the Maximum Annual Discovery Program Costs stated immediately above for each Contract Year may be carried over to the ensuing Contract Year and added to the Maximum Annual Discovery Program Costs for such ensuing Contract Year except for any such shortfall at the end of Contract Year 10, such that Regeneron's right to carry over any shortfall shall not be applicable into or during the Tail Period. At least sixty (60) days prior to the end of each Contract Year, Regeneron shall notify Sanofi if it reasonably believes that the total Discovery Program Costs for such Contract Year will be less than the Maximum Annual Discovery Program Costs for such Contract Year and whether Regeneron intends to apply such shortfall amount to the Discovery Program Costs for the ensuing Contract Year.

To the extent that Sanofi performs any activities under the Discovery Program, it shall do so at its sole cost and expense and such costs and expenses shall not be treated as Discovery Program Costs for purposes of calculating the Maximum Annual Discovery Program Costs unless the JRC expressly requests Sanofi to perform any such activities, in which case the mutually agreed upon costs directly related to such activities shall be included in the calculation of the Maximum Annual Discovery Program Costs. The Parties acknowledge that payments made by Sanofi pursuant to this <u>Section 4.2</u> are being made as research and development expenses, as defined in the U.S. Internal Revenue Code Section 41, and agree that any and all credits or deductions to which either party may be entitled on account of research performed pursuant to such payments shall be allocated to Sanofi to the extent of such payments.

4.3 <u>Reports and Discovery Program Cost Payments</u>. Within forty-five (45) days following the end of each calendar quarter, Regeneron shall deliver electronically to Sanofi a written report setting forth in reasonable detail the Discovery Program Costs incurred by Regeneron in such calendar quarter along with an invoice therefore. Sanofi shall reimburse Regeneron for all undisputed Discovery Program Costs set forth in each report within thirty (30) days after its receipt thereof. Any disputed, unpaid Discovery Program Costs that are determined to be due and payable to Regeneron under this Agreement shall be paid with the Default Interest Rate.

4.4 ********* Opt-in Payment. (a) In the event that Sanofi exercises its Opt-In Rights in accordance with Section 5.1 with regard
********* then Sanofi shall, on an Opt-In Notice by Opt-In Notice basis, make a US \$10,000,000 payment to Regeneron with the applicable Opt-In
Notice or, in the case of a dispute under this <u>Section 4.4(a)</u> , upon the resolution of the dispute hereunder. Regeneron shall indicate in the Opt-In Report
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Regeneron, including any supporting information supporting its belief. In the event of a disagreement between the Parties as to ****************************, the
matter shall be referred to the Executive Officers for a joint decision in accordance with Section 3.3. In the event the Executive Officers are unable to reach agreement with
respect to the matter in accordance with Section 3.3, then the dispute shall be referred to an independent Third Party expert (the "Expert"). The Parties shall alternate having
the right to select an Expert to resolve disputes in accordance with this Section 4.4, with Sanofi selecting the Expert for the first such dispute and neither Party selecting an
Expert that was used previously by either Party without the written consent of the other Party. Each Expert shall be selected by the applicable Party within thirty (30) days
of the end of the thirty (30) day period referred to in Section 3.3. Each Expert must be a person selected in good faith who is knowledgeable in the field of Antibodies,
possessing senior executive experience in the biotechnology or pharmaceutical industry, and has no known prior, current, or planned future association (by contract,
employment, or otherwise) with the selecting Party, any of its Affiliates, or any officer, director, or employee of such Party or any of its Affiliates. The Parties will both
enter into a consulting agreement with each Expert and will share equally in all fees charged by each Expert. Each Expert shall be instructed in the consulting agreement to
make his decision as to ******************************* within two (2) weeks of his selection. The Expert's decision shall be final and binding upon the Parties.
For the avoidance of doubt, any dispute under this <u>Section 4.4(a)</u> shall not delay the development of the applicable Licensed Product.

- 4.5 <u>Royalty Payments for Royalty Products</u>. If either Party, or its Affiliate or licensee successfully develops and commercializes a Royalty Product, then the commercializing Party shall pay to the non-commercializing Party, within sixty (60) days following the end of each calendar quarter, the following royalties on the aggregate Net Sales of such, respective Royalty Products during the Royalty Term:
  - (i) Refused Candidates. Royalty payments for Refused Candidates, including a Competing Refused Candidate, of \*\*\*\*\*\*\*\* provided that no such royalty amount shall be due for Antibodies \*\*\*\*\*\*\*\*\*\*.

  - - (v) IFMs/Failed MTCs. Royalty payments for IFMs of \*\*\*\* as described in Section 2.11(d)(ii) of this Agreement.
    - (vi) Solely Developed Immunoconjugates. Royalty payments for Solely Developed Immunoconjugates of \*\*\*\* as described in Section 2.11(b).

In the event that any Royalty Product requires a sub-license to Sanofi Patent Rights or Regeneron Patent Rights, as applicable, and such sub-license is granted under this Agreement, then any financial remuneration that the licensing Party is required to pay to a Third Party for its license from the Third Party shall be considered a pass-through cost to be borne by the Party developing and/or commercializing the Royalty Product.

- 4.7 <u>Payment Method and Currency</u>. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.
- 4.8 <u>Late Payments</u>. All late payments made under this Agreement (including payments made pursuant to <u>Sections 4.4</u> and <u>4.5</u> above), shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (U.S., Eastern Edition) effective for the date on which the payment was due, \*\*\*\*\* (such sum being referred to as the "<u>Default Interest Rate</u>").
- 4.9 <u>Taxes</u>. Except as set forth in <u>Section 4.1</u>, any withholding or other taxes that a Party is required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to such other Party; <u>provided</u>, <u>however</u>, that the remitting Party shall furnish the other Party with proper evidence, including any self-reporting documentation, of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

#### ARTICLE 5

## OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES

5.1 Opt-In Rights to License Product Candidates. Subject to the penultimate sentence of this Section 5.1 and the other terms of this Agreement, Sanofi shall have the exclusive right during the term of the Discovery Program to elect to jointly (with Regeneron) develop and commercialize each Product Candidate as set forth below, under the terms and conditions set forth in the License and Collaboration Agreement (the "Opt-In Rights"). While the Opt-In Rights are in effect with respect to an Antibody from the Discovery Program, including a MTC in the Discovery Program, Regeneron will not grant to any Third Party rights to any such Antibody. The Opt-In Rights will expire and Sanofi will no longer have any rights or licenses to any Antibodies, including MTCs, under this Agreement upon the expiration or earlier termination of the Discovery Program. After the first ten (10) years of the Discovery Program, the Opt-In Rights shall remain in effect during the Tail Period solely with respect to Lead Candidates and other Antibodies and MTCs against any applicable Program Targets properly identified by Sanofi in its notice to extend the Discovery Program through the Tail Period provided under Section 2.9. For the avoidance of doubt, Sanofi shall have no Opt-In Rights to Excluded Candidates owned or licensed by Regeneron or its Affiliates.

5.3 <u>Initial Development Plan</u>. Within thirty (30) days after Sanofi's receipt of the Opt-In Report, the Parties shall jointly commence, and thereafter as promptly as practicable complete, preparation of a plan and budget for the planned development activities for such Product Candidate through the completion of the Phase I Clinical Trial (the "<u>Initial Development Plan</u>"), the final budget included in which shall be subject to Sanofi's written approval, not to be unreasonably withheld or delayed; provided, however, that (i) the Parties shall not be required to continue or complete such preparation if the Opt-In Period for such Product Candidate has expired without Sanofi having timely exercised its Opt-In Rights with respect thereto or Sanofi shall have otherwise advised Regeneron in writing that it will not exercise its Opt-In Rights with respect to such Product Candidate and (ii) if the Parties are unable to agree on a final budget the matter shall first be referred to the Executive Officers in accordance with <u>Section 3.3(b)</u> above, and if such Executive Officers are unable to resolve such matter, it shall be submitted to binding arbitration to be conducted in accordance with <u>Section 13.1</u> below. If Sanofi properly exercises its Opt-In Rights with respect to a Product Candidate, such Product Candidate shall be developed in accordance with the Initial Development Plan until the Parties agree to the "<u>Global Development Plan</u>" as such term is defined in the License and Collaboration Agreement.

- 5.5 <u>Dll4 and REGN 88</u>. Sanofi exercised its Opt-In Rights to REGN 88 as of the Original Agreement Effective Date and was deemed to have exercised its Opt-In Rights with respect to the MTC against Delta-like ligand 4 (Dll4) as of the Original Agreement Effective Date.
- 5.6 <u>Refused Candidates</u>. If Sanofi does not provide Regeneron with an Opt-In Notice within the Opt-In Period with respect to a particular Product Candidate, or Sanofi notifies Regeneron that it will not exercise Opt-In Rights with respect to the Product Candidate, then the following shall apply:
  - (i) <u>Refused Candidate</u>. The Opt-In Rights shall expire with respect to that Product Candidate (a "<u>Refused Candidate</u>"). All licenses granted in <u>Section 2.10</u> shall automatically expire with respect to each Product Candidate upon such Product Candidate becoming a Refused Candidate. Following such time as a Product Candidate becomes a Refused Candidate, except as set forth below, the applicable Target shall no longer be deemed a Program Target and shall be removed from the Targe List and Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement. Sanofi shall have a one-time right within fo (4) weeks of the date a Product Candidate becomes a Refused Candidate to designate the Target for such Refused Candidate as one of its Sanofi Targets, otherwise it shall be considered an Excluded Target.

(ii) Regeneron Rights. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any Refused Candidate without restriction outside the Discovery Program and this Agreement, unless the Refused Candidate is a Competing Refused Candidate, in which case, Section 2.8(b)(ii) shall apply. In addition, unless Sanofi has exercised its right under Section 5.6(i) to designate the applicable Target for a Refused Candidate as one of its Sanofi Targets, then Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any MTCs or other Antibodies against such Target and may practic and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities. If Sanofi has designated the applicable Target for the Refused Candidate as a Sanofi Target pursuant to Section 5.6(i), then all Antibodies (including MTCs) against such Target that were generated under the Discovery Program other than the Refused Candidate shall remain part of the Discovery Program.

#### ARTICLE 6

## **NEWLY CREATED INVENTIONS**

## 6.1 Ownership of Newly Created Intellectual Property.

(a) Each Party shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created solely by such Party, its employees, agents and consultants under the Discovery Program ("Sole Inventions"). Sole Inventions made solely by Sanofi, its employees, agents and consultants are referred to herein as "Sanofi Sole Inventions." Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.

- (b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Discovery Programs that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi (or for which ownership vests in Sanofi by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron (or for which ownership vests in Regeneron by operation of law), on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions").
- (c) Notwithstanding the foregoing in Section 6.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, as determined, if necessary, by an independent third party, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.
- (d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under this Agreement vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.
- (e) The Parties hereby agree that each Party's use of the Joint Inventions shall be governed by the terms and conditions of this Agreement including the following: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement or the License and Collaboration Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as otherwise set forth herein or in the License and Collaboration Agreement, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 6.1(e), (iii) during the Discovery Program, each Party agrees not to license its interest in any Joint Invention with the right to use such Joint Invention for developing, manufacturing or commercializing antibodies (except for developing, manufacturing or commercializing a Party's Antibodies that may be included in the exclusions described in Section 2.8 (b) of the Agreement), and (iv) nothing in this Article 6 shall relieve a Party or its Affiliates of their obligations under Article 9 with respect to Confidential Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Discovery Program. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties aga

### 6.2 Prosecution and Maintenance of Patent Rights.

- (c) The Parties shall have the following obligations with respect to the filing, prosecution and maintenance of any Joint Patent Rights, as well as any Product Patent Rights: (i) the prosecuting Party (the "Prosecuting Party") shall provide the other Party (the "Non-Prosecuting Party") with notice and a copy of a substantially completed draft of any Patent Application at least thirty (30) days prior to the filing of any such Patent Application by the Prosecuting Party and incorporate all reasonable comments provided by the Non-Prosecuting Party within such thirty (30) day period unless the Prosecuting Party reasonably believes that such comments will adversely affect the scope or validity of the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) the Prosecuting Party shall notify the Non-Prosecuting Party prior to its filing of a Patent Application; (iii) the Prosecuting Party shall consult with the Non-Prosecuting Party promptly following the filing of the Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Prosecuting Party shall provide the Non-Prosecuting Party promptly with copies of all material communications received from or filed in patent offices with respect to such applications and incorporate all reasonable comments provided by the Non-Prosecuting Party, unless the Prosecuting Party reasonably believes that such comments will adversely affect the validity or scope of the Patent Application or resulting Patent for both Parties; and (v) the Prosecuting Party shall provide the Non-Prosecuting Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the Non-Prosecuting Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances, including assuming the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right or Joint Patent Right and becoming the Prosecuting Party. With respect to Joint Inventions, it is understood that the Prosecuting Party and Non-Prosecuting Party shall use all reasonable efforts to reach agreement on all material filings and amendments and no such material filings or amendments shall be made by the Non-Prosecuting Party without the prior written agreement of the Non-Prosecuting Party, such agreement not to be unreasonably withheld or delayed. In addition, in the event that the Prosecuting Party materially breaches the foregoing obligations and such material breach is not cured within thirty (30) days of a written notice from the Non-Prosecuting Party describing such breach in reasonable detail, or in the event that the Prosecuting Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the Non-Prosecuting Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the Non-Prosecuting Party may assume the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right and will thereafter be deemed the Prosecuting Party for purposes hereof. Notwithstanding the foregoing, the Prosecuting Party may withdraw from or abandon any Patent or Patent Application on thirty (30) days' prior notice to the Non-Prosecuting Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the Non-Prosecuting Party a free-of-charge option to assume the prosecution or maintenance thereof. The Parties will file and prosecute Patent Applications described in this Section 6.2(a) in the list of countries set forth in Exhibit B, unless otherwise agreed upon by the Parties.

(d) All costs incurred in the filing, prosecution and maintenance of any Joint Patent Rights and Product Patent Rights and in performing freedom to operate analyses on Program Targets or Lead Candidates shall be shared equally by the Parties.

(e) Each Party shall have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. 103(c)(2)-(c)(3) (the "CREATE Act") with respect to Joint Inventions, without the prior written consent of the other Party. In the event that a Party intends to invoke the CREATE Act, as permitted by the preceding sentence, it shall notify the other Party and the Parties shall reasonably cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act. For the avoidance of doubt, nothing in this Section 6.2(e) shall amend or modify the determination of ownership of intellectual property as set forth in Section 6.1.

6.3 Third Party Claims. In the normal course of business, Regeneron shall carry out patent searches in relation to the Program Targets, Lead Candidates, and Product Candidates, as well as the technologies used to discover, develop and commercialize any of the foregoing, and will disclose, along with any analysis, to Sanofi's counsel any conflict or likely conflict of which Regeneron is aware with respect to the Patent Rights of any Third Party with respect to any such Program Targets, Lead Candidates and Product Candidates prior to selection to enter IND Preparation. If either Party or its Affiliates shall learn of a Third Party claim that the activities under the Discovery Program infringe or otherwise violate the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practical after the receipt of such notice, the Parties shall cause their respective legal counsel to meet to confer on such allegation of infringement. In particular, with regard to issues related to freedom to operate concerning Targets pursued under this Agreement, the Parties shall conduct and maintain ongoing and regular communications between their legal/intellectual property departments.

#### **ARTICLE 7**

## **BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS**

7.1 <u>Books and Records</u>. Each Party shall keep proper books of record and account in which full, true and correct entries (in conformity with GAAP) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall permit auditors, as provided in <u>Section 7.2</u>, to visit and inspect, during regular business hours and under the guidance of its employees, the books of record and account of such Party to the extent relating to this Agreement and discuss its affairs, finances and accounts to the extent relating to this Agreement.

### 7.2 Audits and Adjustments.

- (a) Each Party shall have the right, upon no less than thirty (30) days' advance written notice and at such reasonable times and intervals and to such reasonable extent as the Party shall request, not more than once during any Contract Year, to have the books and records of the other Party to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable, appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.
- (b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of delivery. If a Party over billed or underpaid an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than \*\*\*\*\*\*, it shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the Party initiating the audit in all other cases). Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in <u>Article 9</u>.

- (c) If any examination or audit of the records described above discloses an over billing or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.2(b) above, the Party that overbilled or underpaid shall pay the same (plus interest thereon at the Default Interest Rate from the date of such over billing or underpayment through the date of payment of the amount required to be paid pursuant to this Section 7.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 7.2.
- (d) <u>Disputes</u>. Any disputes with respect to the results of any audit conducted under <u>Section 7.2</u> above shall be resolved by binding arbitration in accordance with <u>Section 13.1</u> below.
- 7.3 <u>IAS/IFRS/GAAP</u>. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with IAS/IFRS, and for the US, if desired, GAAP, as generally and consistently applied.

### REPRESENTATIONS, WARRANTIES AND COVENANTS

- 8.1 <u>Joint Representations and Warranties</u>. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from performing the Discovery Program or granting the rights and/or licenses hereunder; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.
- 8.2 <u>Knowledge of Pending or Threatened Litigation</u>. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator, or Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the term of the Discovery Program, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

- 8.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:
  - (a) Regeneron owns or has a valid license to all Regeneron Patent Rights in existence as of the Effective Date;
- (b) Regeneron has the right and authority to grant the rights (including the Opt-In Rights) granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted, and will not grant during the term of this Agreement, any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;
- (c) there is no pending litigation of which Regeneron has received notice or is otherwise aware that alleges that any of Regeneron's activities relating to the Mice or the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);
- (d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Mice or the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;
- (e) to Regeneron's knowledge, after due inquiry, the use of the Mice and the Regeneron Intellectual Property generally in the Discovery Program (but not with respect to a specific MTC or Target) does not and will not infringe or otherwise violate any valid Patent or provisional rights to applications or other intellectual property of any Third Party claiming genetically modified mice or the use thereof to make antibodies;
- (f) neither the development or reproduction of the Mice nor the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has constituted or involved the misappropriation of trade secrets or other rights of any Person;
- (g) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;
- (h) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings; and

(i) neither Regeneron nor any of its Affiliates shall transfer ownership, assign ownership, grant a security interest in or otherwise encumber any of its rights in, to or under any Regeneron Intellectual Property in a way that will impair Sanofi's rights or Regeneron ability to perform its obligations under this Agreement.

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8.4 <u>Disclaimer of Wartanties</u>. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

#### ARTICLE 9

### **CONFIDENTIALITY**

9.1 <u>Confidential Information</u>. During the term of this Agreement and for a period of five (5) years thereafter, each Party (in such capacity, the "<u>Receiving Party</u>") shall keep confidential, and other than as provided herein or in the License and Collaboration Agreement, shall not use or disclose, directly or indirectly, any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, documents, ideas, information, discoveries, or materials, owned, developed, or possessed by the other Party (in such capacity, the "<u>Disclosing Party</u>"), whether in tangible or intangible form, the confidentiality of which the Disclosing Party takes reasonable measures to protect, including but not limited to Regeneron Know-How and Sanofi Know-How disclosed by the Disclosing Party under this Agreement (the "<u>Confidential Information</u>"). For purposes of this Agreement, all confidential information disclosed by Regeneron under the terms of the confidentiality agreements between Sanofi Parent and Regeneron dated February 1, 2007 and October 23, 2007 is hereby deemed Confidential Information of Regeneron. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party to any Third Party except to its employees, agents, consultants or any other Person under its authorization; <u>provided</u> such employees, agents, consultants or other Persons are subject in writing to confidentiality obligations applicable to the Disclosing Party's Confidential Information no less strict than those set forth herein.

(a) Notwithstanding the foregoing, Confidential Information shall not be deemed to include information and materials (and such information and materials shall not be considered Confidential Information under this Agreement) to the extent that it can be established by written documentation by the Receiving Party that such information or material is: (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the Receiving Party or any Person to whom the Receiving Party provided such information; (ii) is or was already in the possession of the Receiving Party at the time of disclosure by the Disclosing Party; (iii) is disclosed to the Receiving Party on an unrestricted basis from a Third Party not under an obligation of confidentiality to the Disclosing Party or any Affiliate of the Disclosing Party with respect to such information; (iv) information that has been independently created by the Receiving Party (or its Affiliate), as evidenced by written or electronic documentation, without any aid, application or use of the Disclosing Party's Confidential Information; or (v) required by Law to be disclosed, provided that the Receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the Disclosing Party to seek confidential treatment for such information, and provided further that the Receiving Party provides all reasonable cooperation to assist the Disclosing Party to protect such information and limits the disclosure to that information which is required by Law to be disclosed.

- (b) Information and other Know-How that is discovered by Regeneron in connection with the Discovery Program will be considered Regeneron's Confidential Information, except to the extent it relates to a Licensed Product, in which case it shall be Confidential Information of both Parties, subject to the terms of the License and Collaboration Agreement.
- (c) Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of either Person merely because individual elements thereof are in the public domain or in the prior possession of a Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of that Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of a Person.
- (d) Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any party) relating to such tax treatment or tax structure, provided, however, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws. This authorization of disclosure is retroactively effective immediately upon commencement of the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than thirty (30) days from the first day that any Party hereto (or any employee, representative, or other agent of any party hereto) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.
- 9.2 <u>Injunctive Relief</u>. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

9.3 <u>Publications</u>. If either Sanofi or Regeneron (the "<u>Publishing Party</u>") desires to publish or publicly present any results from the Discovery Program in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance final copy of any proposed publication or summary of a proposed oral presentation relating to the information from the Discovery Program prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve the confidentiality of its Confidential Information and to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it as a result of the publication or disclosure, to which the Publishing Party shall give due consideration. If such other Party informs the Publishing Party, within thirty (30) days of receipt (or such other period agreed to by the JRC) of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment should not be published or presented, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved. The Parties shall establish a publication review process to ensure compliance with this <u>Section 9.3</u>.

9.4 <u>Disclosures Concerning this Agreement</u>. The Parties will mutually agree upon the contents of a their respective press releases with respect to the execution of this Agreement and the License and Collaboration Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 9 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. Each Party acknowledges that the other Party as a publicly traded company is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

### **INDEMNITY**

### 10.1 Indemnity and Insurance.

- (a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:
  - (i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Sanofi or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates; or
    - (ii) material breach by Sanofi of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.
- (b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:
  - (i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Sanofi or its Affiliates; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

### 10.2 Indemnity Procedure.

- (a) The Party entitled to indemnification under this Article 10 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened in writing against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.
  - (i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such l

- (ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 10.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.
- (iii) The amount of any Damages for which indemnification is provided under this <u>Article 10</u> will be reduced by the insurance proceeds received, and any other amount recovered, if any, by the Indemnified Party in respect of any Damages.
- (iv) If an Indemnified Party receives an indemnification payment pursuant to this <u>Article 10</u> and subsequently receives insurance proceeds from its insurer with respect to the damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this <u>Article 10</u> and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this <u>Article 10</u>.

### FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances. In the event of a Force Majeure, the performance of the Party giving such notification shall be abated and any time deadlines shall be extended for so long as the performance is prevented by Force Majeure. In no event will any Force Majeure extend beyond one hundred eighty (180) days. In the event of a Force Majeure affecting satisfaction of the criteria set forth in Section 4.10, the applicable time deadline set forth in Section 4.10 shall be extended for so long as such Force Majeure continues, but in no event shall such extension period exceed one hundred eighty (180) days.

### TERM AND TERMINATION

12.1 <u>Term</u>. The "<u>Term</u>" of this Agreement commenced on the Original Agreement Effective Date and shall end upon the end of the Discovery Program, including any Tail Period, unless this Agreement is earlier terminated in accordance with this <u>Article 12</u> in which event the Term shall end on the effective date of such termination.

12.2 <u>Termination For Material Breach</u>. Upon and subject to the terms and conditions of this <u>Section 12.2</u>, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period. Notwithstanding the foregoing, in the case of breach of a payment obligation not subject to a bona fide dispute hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be forty-five (45) days. For purposes of this <u>Section 12.2</u>, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above), material breach by a Party as determined by binding arbitration consistent with the provisions of <u>Section 13.1</u> of this Agreement.

12.3 <u>Termination for Insolvency</u>. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (b) if the other Party proposes a written agreement of composition or extension of its debts, or (c) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (d) if the other Party shall propose or be a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any Patent Rights in any country of a Party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code, and any similar law or regulation in any other country.

- 12.4 <u>Termination for Breach of Standstill</u>. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Stock Purchase Agreement, dated as of September 5, 2003, by and between Sanofi and Regeneron (the "Aventis Stock Purchase Agreement"), to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 20.16(a) remains in effect after the Effective Date) or (ii) an inadvertent breach of Section 3.1(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date) or an inadvertent breach of Section 20.16 or of paragraphs (a) through (e) of Section 3.1 of the Investor Agreement, as applicable. Sanofi's rights under Sections 2.16 and 2.17 shall survive termination of this Agreement
- 12.5 <u>Termination for Breach of License and Collaboration Agreement</u>. Notwithstanding anything to the contrary herein, (a) Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Sanofi, if Regeneron has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3, 19.4, or 19.5 of the License and Collaboration Agreement, and (b) Sanofi shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Regeneron, if Sanofi has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3 or 19.4 of the License and Collaboration Agreement.
- 12.6 <u>Effect of Termination by Sanofi for Breach</u>. In addition to the provisions of <u>Section 12.8</u> below, notwithstanding anything herein to the contrary, in the event that Sanofi terminates this Agreement pursuant to <u>Section 12.2</u> of this Agreement the following shall apply:
- (a) Sanofi shall be granted a non-exclusive, non-transferable, royalty free, worldwide license, without the right to sublicense, for a period that shall expire eleven (11) years from the Original Agreement Effective Date, to the Mice and the underlying Regeneron Intellectual Property for Sanofi and its Affiliates to use to discover and develop MTCs for any and all purposes;

- (b) Regeneron shall perform a timely and expeditious technology transfer as required by Sanofi to pursue its rights under <u>subsection (a)</u> without delay above subject to the execution of a material transfer agreement containing non-financial terms and conditions related to the use of the Mice consistent with Regeneron's commercial license agreements for the Mice;
  - (c) the licenses granted to Regeneron under this Agreement shall automatically terminate;
- (d) Sanofi shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense, under Regeneron Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Sanofi Targets (and for no other uses), and the co-exclusive (with Regeneron and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Regeneron Target IP to develop and commercialize Antibodies against all other Program Targets at the effective time of termination (and for no other uses);
  - (e) Sanofi's rights under Sections 2.16, and 2.17 shall survive; and
  - (f) Sanofi shall have no further funding obligations under Section 4.2 of the Agreement.
- 12.7 Effect of Termination by Regeneron for Breach. In addition to the provisions of Sections 12.8 and 12.10 below, notwithstanding anything herein to the contrary, in the event that Regeneron terminates this Agreement pursuant to Section 12.2 or 12.4 of this Agreement, the following shall apply:
  - (a) the licenses granted to Sanofi under this Agreement shall automatically terminate;
  - (b) the rights granted to Sanofi under this Agreement in Sections 2.16 and 2.17 shall automatically terminate;
- (c) Regeneron shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide, exclusive license, with the right to sublicense, under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Program Targets other than Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Sanofi and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Sanofi Target IP to develop and commercialize Antibodies against all Sanofi Discovery Targets at the effective time of termination (and for no other uses).
- 12.8 <u>Survival of Obligations</u>. Subject to <u>Sections 12.6</u>, <u>12.7</u>, and <u>12.11</u> and except as otherwise provided below, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect:

- (a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of the Discovery Program (even if such costs and expenses arise following termination or expiration, as the case may be); <u>provided</u>, <u>however</u>, that Sanofi shall not be obligated to pay or reimburse Regeneron for any such costs or expenses in the event Sanofi terminates this Agreement pursuant to <u>Section 12.2</u> above;
- (b) the obligations of the Parties with respect to the protection and nondisclosure of the other Party's Confidential Information in accordance with Article 9, as well as other provisions (including, without limitation, Sections 2.11(b), 2.11(c), 2.12 (except as set forth in Section 12.6 above), 2.13 (except as set forth in Section 12.7 above), 2.16, 2.17, 6.1(e), 6.2(b), 6.2(c), 6.2(d)(as it relates to Joint Patent Rights), 7.2, 10.1, 10.2, this Article 12, and Article 13) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable;
- (c) for the avoidance of doubt, the early termination of this Agreement by either Party, and the expiration of this Agreement shall not relieve either Party of any of its royalty or other obligations under Article 4 with respect to any Royalty Product, for which royalties remain payable to the other Party under this Agreement; and such royalty provisions of Article 4 shall survive;
- (d) for the avoidance of doubt, the licenses granted in Sections 2.11(b)(3), 2.11(c), 2.12, and 2.13 shall survive the termination or expiration of this Agreement; and
  - (e) such expiration or termination and this Article 12 shall be without prejudice to any rights or remedies a Party may have for breach of this Agreement.
- 12.9 Return of Confidential Information. Subject to either Parties' licenses that survive termination or expiration, Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to the terms of the License and Collaboration Agreement (with respect to Licensed Products), upon the earlier to occur of (a) the termination of this Agreement or (b) the expiration of the Discovery Program, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the Receiving Party also shall certify in writing that it has satisfied its obligations under this Section 12.9 within ten (10) days of a written request by the Disclosing Party.
- 12.10 <u>Special Damages</u>. If Regeneron terminates this Agreement pursuant to <u>Section 12.2</u> or <u>12.4</u>, then Sanofi shall pay to Regeneron, within sixty (60) days of the termination of this Agreement, in addition to any other amount payable by Sanofi to Regeneron under this Agreement under Laws, or pursuant to any contractual remedies available to Regeneron, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the remaining unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement.

- 12.11 <u>Termination by Sanofi At Will</u>. Sanofi shall be entitled to terminate this Agreement at any time (except following a material breach of this Agreement by Sanofi pursuant to <u>Section 12.2</u>) without cause upon three months' written notice to Regeneron. If Sanofi terminates the Agreement under this <u>Section 12.11</u>, then Sanofi shall pay to Regeneron within five (5) days of its notice of termination, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the Remaining Unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement. In addition, Sanofi shall complete GLP toxicology studies conducted by Sanofi at the time of termination, if applicable, and such other critical activities conducted by Sanofi at the time of termination that cannot be transferred to Regeneron without a material adverse effect on the completion of such activities. In the event of such termination, in addition to the provisions of <u>Section 12.8</u>, the following shall apply:
  - (a) the rights granted to Sanofi under <u>Sections 2.16</u> and <u>2.17</u> shall automatically terminate; and
- (b) Regeneron shall be granted a non-exclusive, non-transferable, royalty bearing (in accordance with <u>Section 4.5</u>) worldwide license with the right to sublicense under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize (i) MTCs against Program Targets, and (ii) any other Antibodies against Program Targets in existence and included in the Discovery Program at the effective time of termination.

### **ARBITRATION**

- 13.1 <u>Binding Arbitration</u>. In the event the Parties cannot reach agreement with respect to (i) the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate, (ii) the royalty on Net Sales of Immunoconjugates under <u>Section 2.11(d)(i)</u> of this Agreement, (iii) whether a breach constitutes a "material breach" as described in <u>Section 12.2</u> of this Agreement, and (iv) audits under <u>Section 7.2(d)</u> above, and such disputes are not resolved by the Executive Officers in accordance with <u>Section 3.3(b)</u> above, then the following shall apply:
- (a) General. The respective disputed issue shall be referred to binding arbitration by one (1) arbitrator who shall be an independent expert in the pharmaceutical or biotechnology industry mutually acceptable to the Parties. The Parties shall use their best efforts to mutually agree upon one (1) arbitrator; provided, however, that if the Parties have not done so within ten (10) days after initiation of arbitration hereunder, or such longer period of time as the Parties have agreed to in writing, then such arbitrator shall be an independent expert as described in the preceding sentence selected by the New York office of the American Arbitration Association. Such arbitration shall be limited to casting the deciding vote with respect to the disputed issues as more fully described in Sections 13.1 (b)-(e) below. In connection therewith, each Party shall submit to the arbitrator in writing its position on and desired resolution of such matter. Such submission shall be made within ten (10) days of the selection or appointment of the arbitrator, and the arbitrator shall rule on such matter within ten (10) days of receipt of the written submissions by both Parties. The arbitrator shall select one of the Party's positions as his or her decision, and shall not have authority to render any substantive decision other than to so select the position of either Regeneron or Sanofi. Except as provided in the preceding sentence, such arbitration shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association. The arbitrator's ruling shall be final and binding upon the Parties. The costs of any arbitration conducted pursuant to this Section 13.1 shall be borne equally by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within sixty (60) days following a request by any Party for such arbitration.

- (b) <u>Initial Development Plan Budget</u>. The specific issue that shall be submitted to the arbitrator shall be limited to determining the overall commercial reasonableness of the budget that is the subject of the dispute. If the arbitrator determines that such budget is commercially reasonable, then the dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the arbitrator determines that such budget is not commercially reasonable, then the arbitrator shall, within fifteen (15) days after such determination, render a final determination as to what modifications must be made to such budget in order for it to be commercially reasonable (the "<u>Budget Modification Decision</u>"). In connection with reaching a Budget Modification Decision, the arbitrator may order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their proposed modifications to the budget in order for it to be commercially reasonable, at least five (5) days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision, the arbitrator shall be limited to choosing a resolution proposed by a Party without modification.
  - (c) Royalty on Net Sales of Immunoconjugates: The issue that shall be submitted to the arbitrator shall be the royalty rate to apply under Section 2.11(d)(i).
- (d) <u>Material Breach Under Section 12.2:</u> The issue that shall be submitted to the arbitrator shall be whether the breach committed by a Party meets the requirements for a material breach under <u>Section 12.2</u> of this Agreement.
  - (e) Audit Disputes. The issue that shall be submitted to the arbitrator shall be disputes as described under Section 7.2(d) of this Agreement.

### **MISCELLANEOUS**

14.1 <u>Governing Law; Submission to Jurisdiction</u>. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in <u>Article 13</u> and <u>7.2(d)</u>, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

- 14.2 <u>Waiver</u>. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.
- 14.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 10 attached hereto and shall be (a) delivered personally, (b) sent via a reputable nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.
- 14.4 Entire Agreement. This Agreement and the License and Collaboration Agreement contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof. It is understood and agreed that in the event of any conflict or inconsistency between this Agreement and the License and Collaboration Agreement, this Agreement shall control regarding the Parties' rights and obligations with respect to any Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program (prior to Sanofi's exercise of its Opt-In Rights with respect to such Product Candidate), and the License and Collaboration Agreement shall control regarding the Parties' rights and obligations with respect to any Licensed Product from and after the time a Product Candidate becomes a Licensed Product.
- 14.5 <u>Amendments</u>. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.
- 14.6 <u>Interpretation</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words "herein" or "hereunder" relate to this Agreement. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP, but only to the extent consistent with its usage and the other definitions in this Agreement.

- 14.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 14.8 <u>Assignment</u>. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, <u>provided</u> that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.
- 14.9 <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of <u>Section 14.12</u> below.
- 14.10 <u>Affiliates</u>. Each Party may carry out its obligations under this Agreement through its Affiliates and absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. Sanofi shall not, directly or indirectly, cause or direct Sanofi Pasteur or Merial Limited to take any action for which Sanofi and its Affiliates are prohibited hereunder from committing. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

- 14.11 <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.
- 14.12 <u>Third Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, <u>Article 10</u> is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.
- 14.13 <u>Relationship of the Parties</u>. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.
- 14.14 <u>Limitation of Damages</u>. EXCEPT AS SET FORTH IN <u>SECTION 12.10</u>, IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS <u>SECTION 14.14</u> IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD PARTY CLAIMS.
- 14.15 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the performance of the Discovery Program to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.
  - 14.16 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.



IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

# AVENTIS PHARMACEUTICALS INC.

By /s/ John M. Spinnato

Name: John M. Spinnato

Title: VP & General Counsel, US Legal

By /s/ Christian Blin

Name: Christian Blin Title: VP, R&D Finance

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray Goldberg

Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

Execution Version

SCHEDULE 1

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SCHEDULE 2

Excluded Targets

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SCHEDULE 3

<u>Initial Immunized Target List</u>

# SCHEDULE 4

Lead Candidate Criteria

# SCHEDULE 5

Manufacturing Cost

# SCHEDULE 6

<u>Initial Rolling Target List</u>

# SCHEDULE 7

# Expansion Plan

Technical Appendices 1 through 4 describe the general capacity expansion plans for Regeneron's Rensselaer Operations in Rensselaer, New York. The "IN" items
escribed in appendices 1 and 2 will be initiated immediately.
********************************

SCHEDULE 8

SCHEDULE 9

# SCHEDULE 10

# **Notices**

If to Sanofi:

Aventis Pharmaceuticals Inc. 200 Crossing Boulevard Bridgewater, New Jersey 08807 United States

Attn: President US Research and Development

Copy: Sanofi Aventis 174 Avenue de France

> 75013 Paris France

Attn: Senior Vice President and General Counsel

If to Regeneron:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attention: President & CEO Copy: General Counsel

#### EXHIBIT A

#### Form of Opt-In Notice

[Sanofi Letterhead]

[DATE]

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel Regeneron Pharmaceuticals, Inc.

Reference is hereby made to the Amended and Restated Discovery and Preclinical Development Agreement (the "Discovery Agreement") by and between Aventis Pharmaceuticals Inc., a [ ], corporation with a principal place of business located at [ ], and Regeneron Pharmaceuticals, Inc., a New York corporation with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Capitalized terms used herein shall have the defined meanings set forth in the Discovery Agreement.

Pursuant to Section 5.4 of the Discovery Agreement, Sanofi hereby provides this Opt-In Notice to Regeneron to license [INSERT PRODUCT CANDIDATE] under the License and Collaboration Agreement. Effective immediately, [INSERT PRODUCT CANDIDATE] shall be considered a Licensed Product.

seemse and condoctation rigitetiment directive immediately, [11.02211 11.02001	
	AVENTIS PHARMACEUTICALS INC.
	Name:
	Title:

EXHIBIT B

Execution Version Exhibit 10.15

Portions of this Exhibit Have Been Omitted and Separately Filed with the Securities and Exchange Commission with a Request for Confidential Treatment

# AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

By and Among

AVENTIS PHARMACEUTICALS INC.,

SANOFI-AVENTIS AMERIQUE DU NORD

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 10, 2009

# TABLE OF CONTENTS

		Page
ARTICLE I	DEFINITIONS	2
1.1	"Additional Major Market Country"	2
1.2	"Affiliate"	2
1.3	"Ancillary Agreements"	2
1.4	"Anticipated First Commercial Sale"	3
1.5	"Approval"	3
1.6	"Aventis LLC"	3
1.7	"Aventis Collaboration Agreement"	3
1.8	"Aventis Stock Purchase Agreement"	3
1.9	"BLA"	3
1.10	"Business Day"	3
1.11	"Clinical Supply Cost"	3
1.12	"Clinical Supply Requirements"	4
1.13	"Co-Commercialize" or "Co-Commercialization"	4
1.14	"Co-Commercialization Country"	4
1.15	"COGS"	4
1.16	"Commercial Overhead Charge"	4
1.17	"Commercial Supply Cost"	4
1.18	"Commercial Supply Requirements"	4
1.19	"Commercialize" or "Commercialization"	4
1.20	"Commercially Reasonable Efforts"	5
1.21	"Committee"	5
1.22	"Competing Opt-Out Product"	5
1.23	"Competing Product"	5
1.24	"Confidentiality Agreements"	5
1.25	"Consolidated Payment Report"	5
1.26	"Contract Sales Force"	5
1.27	"Contract Year"	5
1.28	"Controlling Party"	6
1.29	"Co-Promote" or "Co-Promotion"	6
1.30	"Country/Region Commercialization Budget"	6
1.31	"Country/Region Commercialization Plan"	6
1.32	"Country/Region Commercialization Committee", or "CRCC"	6
1.33	"Detail"	6
1.34	"Develop" or "Development"	6
1.35	"Development Costs"	7
1.36	"Development FTE Cost"	7
1.37	"Development FTE Rate"	8
1.38	"Development Plan"	8
1.39	"Discovery Program"	8
1 40	"EMEA"	8

i

	1.41	"Executive Officers"	8
-	1.42	"FDA"	8
	1.43	"Field"	8
-	1.44	"Finished Product"	8
	1.45	"First Commercial Sale"	8
-	1.46	"Formulated Bulk Product"	8
	1.47	"FTE"	8
- :	1.48	"GAAP"	8
	1.49	"Global Commercialization Budget"	9
- :	1.50	"Global Commercialization Plan"	9
	1.51	"Global Development Budget"	9
-	1.52	"Global Development Plan"	9
	1.53	"Good Practices"	9
- :	1.54	"Governmental Authority"	9
	1.55	"IAS/IFRS"	9
-	1.56	"ICH"	9
	1.57	"IND"	9
- :	1.58	"Indication"	9
	1.59	"Initial Development Plan"	9
- :	1.60	"Initial IND Filing Date"	10
	1.61	"Investor Agreement"	10
- :	1.62	"Joint Patent Rights"	10
	1.63	"Know-How"	10
	1.64	"Law" or "Laws"	10
	1.65	"Lead Regulatory Party"	10
	1.66	"Legal Dispute"	10
	1.67	"License"	10
	1.68	"Licensed Products"	10
	1.69	"Major Market Country"	10
:	1.70	"Manufacture" or "Manufacturing"	10
	1.71	"Marketing Approval"	11
-	1.72	"Manufacturing Plan"	11
	1.73	"Medical Post-Approval Cost"	11
	1.74	"Medical Post-Approval FTE Rate"	11
	1.75	"Net Sales"	11
	1.76	"New Information"	12
	1.77	"Non-Approval Trials"	13
	1.78	"Opt-In Right"	13
	1.79	"Opt-Out Product"	13
	1.80	"Other Shared Expenses"	13
	1.81	"Out-of-Pocket Costs"	13
	1.82	"Party Information"	13
	1.83	"Patent Application"	13
-	1.84	"Patent Rights"	13
	1.85	"Patents"	13

13

1.86 "Person"

1.87	"Phase 3 Trial"	13		
1.88	"Plan"			
1.89	"Positive Phase 3 Trial Results"			
1.90	"Pre-Launch Marketing Expenses"	14		
1.91	"Pricing Approval"	14		
1.92	"Product Candidate"	14		
1.93	"Product Trademark"	14		
1.94	"Promotional Materials"	14		
1.95	"Quarter" or "Quarterly"	14		
1.96	"Regeneron Intellectual Property"	14		
1.97	"Regeneron Know-How"	15		
1.98	"Regeneron Patent Rights"	15		
1.99	"Region"	15		
1.100	"Registration Filing"	15		
1.101	"Regulatory Authority"	15		
1.102	"Reporting Country/Region"	15		
1.103	"Rest of World" or "ROW"	15		
1.104	"Rest of World Country"	15		
1.105	"ROW CPI"	15		
1.106	"Sales Force Cost"	15		
1.107	"Sales Force FTE Rate"	16		
1.108	"Sanofi Intellectual Property"	16		
1.109	"Sanofi Know-How"	16		
1.110	"Sanofi Patent Rights"	16		
1.111	"Sanofi Stock Purchase Agreement"	16		
1.112	"Shared Commercial Expenses"	16		
1.113	"Shared Phase 3 Trial Costs"	18		
1.114	"Sublicensee"	18		
1.115	"Target"	18		
1.116	"Terminated Licensed Product"	18		
1.117	"Termination Notice Period"	18		
1.118	"Territory"	18		
1.119	"Third Party"	18		
1.120	"United States," "US" or "U.S."	18		
1.121	"US CPI"	18		
1.122	"Valid Claim"	18		
1.123	Additional Definitions	19		
	COLLABORATION	21		
2.1	Scope of Collaboration	21		
2.2	Compliance With Law	21		
2.3	Further Assurances and Transaction Approvals	21		
2.4	Compliance with Third Party Agreements	21		
2.5	Plans	22		
2.6	Limitation on Exercise of Rights Outside of Collaboration	22		

ARTICLE II	II MANAGEMENT	27
3.1	Committees/Management	27
3.2	Joint Steering Committee	27
3.3	Joint Development Committee	28
3.4	Joint Commercialization Committee	29
3.5	Country/Region Commercialization Committees	31
3.6	Joint Finance Committee	32
3.7	Joint Manufacturing Committee	32
3.8	Membership	32
3.9	Meetings	32
3.10	Decision-Making	32
3.11	Resolution of Governance Matters	33
ARTICLE IV	V LICENSE GRANTS	34
4.1	Regeneron License Grants	34
4.2	Sanofi License Grants	34
4.3	Newly Created Intellectual Property	34
4.4	Sublicensing	35
4.5	No Implied License	35
4.6	Retained Rights	35
ARTICLE V	DEVELOPMENT ACTIVITIES	36
5.1	Development of Licensed Products	36
5.2	Global Development Plans	36
5.3	Global Development Budgets	37
5.4	Development Reports	37
5.5	Review of Clinical Trial Protocols	37
5.6	Regeneron Early Development Opt-Out	37
ARTICLE V	T COMMERCIALIZATION	38
6.1	Commercialization of Licensed Products in the Field in the Territory	38
6.2	Global Commercialization Plan(s)	38
6.3	Country/Region Commercialization Plans	39
6.4	Commercialization Efforts; Sharing of Commercial Information	40
6.5	Co-Commercialization of Licensed Products	40
6.6	Licensed Product Pricing and Pricing Approvals in the Territory	42
6.7	Sales and Licensed Product Distribution in the Territory; Other	
	Responsibilities	43
6.8	Contract Sales Force	43
6.9	Promotional Materials	43
6.10	Promotional Claims/Compliance	44
6.11	Restriction on Bundling in the Territory	44
6.12	Inventory Management	44
6.13	Medical and Consumer Inquiries	44
6.14	Market Exclusivity Extensions	44
6.15	Post Marketing Clinical Trials	45

ARTICLE V	VII CLINICAL AND REGULATORY AFFAIRS	45
7.1	Ownership of Approvals and Registration Filings	45
7.2	Regulatory Coordination	45
7.3	Regulatory Events	46
7.4	Pharmacovigilance and Product Complaints	47
7.5	Regulatory Inspection or Audit	47
7.6	Recalls and Other Corrective Actions	48
ARTICLE V	VIII MANUFACTURING AND SUPPLY	48
8.1	Manufacture and Supply of Clinical Supply Requirements of Formulated	
	Bulk Product	48
8.2	Finished Product Supply of Clinical Supply Requirements	49
8.3	Manufacture and Supply of Commercial Supply Requirements	49
8.4	Supply Agreement	50
8.5	Process Development and Manufacturing Plans	50
8.6	Manufacturing Shortfall	51
8.7	Manufacturing Compliance	51
ARTICLE I	IX PERIODIC REPORTS; PAYMENTS	51
9.1	Development Costs	51
9.2	Milestone Payments	51
9.3	Royalties	51
9.4	Sharing of Profits from Licensed Products	52
9.5	Periodic Reports	52
9.6	Funds Flow	53
9.7	Invoices and Documentation	53
9.8	Payment Method and Currency	53
9.9	Late Payments	53
9.10	O Taxes	54
9.11	1 Adjustments to FTE Rates	54
9.12	y <u>1</u>	54
ARTICLE 2	X DISPUTE RESOLUTION	54
10.1	<u>.</u>	54
10.2	2 Governance Disputes	55
10.3	3 Legal Disputes	55
10.4	4 Expert Panel	55
10.5	5 No Waiver	57
ARTICLE 2	XI TRADEMARKS AND CORPORATE LOGOS	57
11.1	1	57
11.2	2 Selection of Product Trademarks	57
11.3	1	58
11.4	4 Prosecution and Maintenance of Product Trademark(s)	58
11.5	5 License to the Product Trademark(s)	58
11.6	5 Use of Corporate Names	59

ARTICLE X	III NEWLY CREATED INVENTIONS AND KNOW-HOW	59
12.1	Ownership of Newly Created Intellectual Property	59
12.2	Prosecution and Maintenance of Patent Rights	61
12.3	Interference, Opposition and Reissue	64
ARTICLE X	IIII INTELLECTUAL PROPERTY LITIGATION AND LICENSES	64
13.1	Third Party Infringement Suits	64
13.2	Patent Marking	66
13.3	Third Party Infringement Claims; New Licenses	66
ARTICLE X	IV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND	
ADJU	JSTMENTS	67
14.1	Books and Records	67
14.2	Audits and Adjustments	67
14.3	GAAP/IAS/IFRS	68
ARTICLE X	V REPRESENTATIONS, WARRANTIES AND COVENANTS	68
15.1	Due Organization, Valid Existence and Due Authorization; Financial	
	Capability	68
15.2	Knowledge of Pending or Threatened Litigation	68
15.3	Additional Regeneron Representations, Warranties and Covenants	68
15.4	Disclaimer of Warranties	69
15.5	Mutual Covenants	70
ARTICLE X	VI CONFIDENTIALITY	70
16.1	Confidential Information	70
16.2	Injunctive Relief	71
16.3	Publication of New Information	72
	Disclosures Concerning this Agreement	72
ARTICLE X	VII INDEMNITY	73
17.1	Indemnity and Insurance	73
17.2	Indemnity Procedure	74
	IVIII FORCE MAJEURE	76
ARTICLE X	XIX TERM AND TERMINATION	76
19.1	Term/Expiration of Term	76
19.2	Termination Without Cause	77
19.3	Termination For Material Breach	78
19.4	Termination for Insolvency	79
19.5	Termination for Breach of Standstill or Lock-Up	79
19.6	Termination of Discovery Agreement	80
19.7	Effect of Termination	80
19.8	Survival of Obligations	81

ARTICLE XX	ARTICLE XX MISCELLANEOUS 82					
20.1 Governing Law; Submission to Jurisdiction						
20.2	Waiver	82				
20.3	Notices	82				
20.4	Entire Agreement	82				
20.5	Amendments	82				
20.6	Interpretation	82				
20.7	Severability	83				
20.8	Registration and Filing of the Agreement	83				
20.9	Assignment	83				
20.10	Successors and Assigns	83				
20.11	Affiliates	83				
20.12	Counterparts	84				
20.13	Third-Party Beneficiaries	84				
20.14	Relationship of the Parties	84				
20.15	Limitation of Damages	84				
20.16	Non-Solicitation	84				
20.17	No Strict Construction	84				

# AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), dated as of November 10, 2009 (the "Effective Date"), is by and between AVENTIS PHARMACEUTICALS INC., a corporation organized under the laws of the state of Delaware having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807 ("Sanofi"), an indirect wholly owned subsidiary of sanofi-aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75013 Paris, France ("Sanofi Parent"), SANOFI-AVENTIS AMERIQUE DU NORD, a partnership organized under the laws of France with its principal headquarters at 174 avenue de France, 75013 Paris, France ("Sanofi Amerique"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of the state of New York having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties", and with Sanofi Amerique being a party to this Agreement for purposes of Sections 15.1, 15.2 and 20.11 only).

WHEREAS, the Parties previously entered into a License and Collaboration Agreement (the "Original Agreement"), dated as of November 28, 2007, whereby, pursuant to the terms and conditions set forth therein, the Parties agreed to collaborate on the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory (each capitalized term not previously defined being defined below);

WHEREAS, concurrently with the execution and delivery of the Original Agreement, the Parties entered into a Discovery and Preclinical Development Agreement (the "Original Discovery Agreement") whereby, upon the terms and conditions set forth therein, Regeneron agreed to use its proprietary VelocImmune® technology and related suite of technologies with the objective of discovering Product Candidates (as defined below) which Sanofi may have elected, in accordance with the Discovery Agreement, to advance into Development (as defined below) and thereupon automatically obtain from Regeneron a license of certain rights thereto upon the terms and conditions set forth herein:

WHEREAS, concurrently with the execution and delivery of this Agreement, the Parties have entered into an agreement amending and restating the Original Discovery Agreement (such amended and restated agreement, the "Discovery Agreement");

WHEREAS, Sanofi and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory (each as defined below);

WHEREAS, Regeneron and Sanofi desire to continue to collaborate on the Development, Manufacture and Commercialization of Licensed Products (each as defined below) in the Field in the Territory (each as defined below) upon the terms and conditions set forth herein (the "Collaboration");

WHEREAS, Regeneron and Sanofi now desire to amend the Original Agreement in accordance with Section 20.5 of the Original Agreement as set forth in this Agreement.

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

# ARTICLE I DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

- 1.1 "Additional Major Market Country" shall mean any country in the Territory, other than the Major Market Countries referred to in clause (i) of the definition thereof, in which Net Sales in the immediately preceding Contract Year were \*\*\*\*\*\*\* or more of aggregate Net Sales in the Territory, and such designation shall remain effective from and after the determination of such Net Sales amount; provided, however, that a country shall not be deemed an Additional Major Market Country if, at the time that Net Sales in such country in a given Contract Year first exceed \*\*\*\*\*\*\* of aggregate Net Sales in the Territory, the Parties mutually agree otherwise.
- 1.2 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates. For purposes of this Agreement, neither Sanofi Pasteur nor Merial Limited, nor any of their respective subsidiaries or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.
  - $1.3 \ "\underline{Ancillary\ Agreements}"\ means\ the\ Sanofi\ Stock\ Purchase\ Agreement\ and\ the\ Investor\ Agreement.$
  - 1.4 "Antibody" shall have the meaning ascribed to such term in the Discovery Agreement.

- 1.5 "Anticipated First Commercial Sale" shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.
- 1.6 "Approval" shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Licensed Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.
  - 1.7 "Aventis LLC" shall mean sanofi-aventis US LLC (successor in interest under the Aventis Collaboration Agreement to Aventis Pharmaceuticals Inc.).
- 1.8 "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Aventis LLC and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Sanofi Stock Purchase Agreement, as the same may be further amended from time to time.
- 1.9 "Aventis Stock Purchase Agreement" shall mean the Stock Purchase Agreement dated as of September 5, 2003 by and between Aventis Pharmaceuticals Inc. and Regeneron, as amended by Sections 4.2(b) and 4.4 of the Investor Agreement, and as may be further amended from time to time.
- 1.10 "<u>BLA</u>" shall mean, with respect to each Licensed Product, a biologics license application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.
- 1.11 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States or Paris, France are authorized or required by Law to remain closed.
- 1.12 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the applicable Global Development Plan, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the applicable Global Development Plan, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging, labeling and delivery of such Clinical Supply Requirements, comparator agent, combination agent and/or placebo, as the case may be, for activities contemplated under the applicable Global Development Plan and (d) any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements. To the extent that manufacturing cost for comparator agent, combination agent or placebo includes any markup over Manufacturing Cost to the benefit of one of the Parties or its Affiliates, such markup shall be deducted in the calculation of Clinical Supply Cost.

- 1.13 "Clinical Supply Requirements" shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.
  - 1.14 "Co-Commercialize" or "Co-Commercialization" shall mean the act of Co-Promoting in a Co-Commercialization Country.
- 1.15 "Co-Commercialization Country." shall mean each country in which Regeneron has elected to Co-Promote a Licensed Product, so long as, after commencing such Co-Promotion, Regeneron is Co-Promoting at least one Licensed Product in such country.
- 1.16 "COGS" for a Licensed Product for a Quarter shall mean cost (calculated in accordance with IAS/IFRS) of Manufacturing the Licensed Product sold in the Field in the Territory in the Quarter.
- 1.18 "Commercial Supply Cost" shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of Commercial Supply Requirements, including, without limitation, scale-up after First Commercial Sale, any filling, packaging and labeling costs, and any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.
- 1.19 "Commercial Supply Requirements" shall mean, with respect to each Licensed Product, quantities of Finished Product as are required to fulfill requirements for commercial sales, Non-Approval Trials and product sampling with respect to such Licensed Product in the Field in the Territory.

- 1.21 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a market-by-market and Licensed Product-by-Licensed Product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the Licensed Product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the profit sharing nor other payments made or required to be made hereunder shall be factor weighed (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must share profits from sales of such Licensed Product or make any other payments hereunder).
- 1.22 "Committee" means any of the JSC, JDC, JCC, JMC, JFC, any CRCC, and any other committee established by the Parties or by the Committees referenced above, each as described in Article III (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).
  - 1.23 "Competing Opt-Out Product" shall mean any Opt-Out Product having the same Target as a Licensed Product.
- 1.25 "Confidentiality Agreements" shall mean the confidentiality agreements between Regeneron and Sanofi Parent dated February 1, 2007 and October 23, 2007, respectively.
- 1.26 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Sanofi (based on information reported under Sections 5.4 and 9.5) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Commercial Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter, (c) Other Shared Expenses incurred by each Party for such Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.
  - 1.27 "Contract Sales Force" shall mean sales representatives employed by a Third Party.
- 1.28 "Contract Year" shall mean the period beginning on the Original Effective Date and ending on December 31, 2008, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.

1.	29	"Controlling	Party"	shall	mean	*******
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- 1.30 "Co-Promote" or "Co-Promotion" shall mean the joint marketing and promotion of Licensed Product(s) by the Parties (or their respective Affiliates) under the same trademark in a Major Market Country pursuant to the applicable Country/Region Commercialization Plan.
- 1.31 "Country/Region Commercialization Budget" shall mean the budget for a particular calendar year approved by the JCC for the applicable Country/Region Commercialization Plan.
- 1.32 "Country/Region Commercialization Plan" shall mean, for each Reporting Country/Region, the three (3) year rolling plan for Commercializing Licensed Products in the Field in such country or Region and the related Country/Region Commercialization Budget and a non-binding budget forecast for the next two (2) calendar years, approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country/Region Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.
- 1.33 "Country/Region Commercialization Committee", or "CRCC", shall mean the committee established by the JCC for a particular Reporting Country/Region as described in Section 3.5.
- 1.34 "Detail" shall mean, with respect to each Licensed Product in the Field, a selling presentation for such product by a representative of each Party's sales force, or another employee of each Party who may be deemed to be part of the Commercialization effort for such Licensed Product (e.g., such as a key account manager, etc.).

- 1.36 "Development Costs" shall mean costs incurred by a Party (for each Licensed Product, commencing with the first (1st) day of the month in which the Opt-In Notice (as such term is defined in the Discovery Agreement) for such Licensed Product is received by Regeneron directly in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the applicable Global Development Plan, including without limitation:
  - (a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining Registration Filings and Marketing Approvals necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;
    - (b) Development FTE Costs;
    - (c) Clinical Supply Costs;
  - (d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation (other than validation batches which are sold), (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up up to First Commercial Sale, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);
  - (e) any license fees and other payments under Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory subject to Sections 13.3(d) and 13.3(e) in this Agreement; and
    - (f) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.
- 1.37 "Development FTE Cost" shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs.

- - 1.39 "Development Plan" shall mean a Global Development Plan or an Initial Development Plan, as the context requires.
  - 1.40 "Discovery Program" shall have the meaning set forth in the Discovery Agreement.
  - 1.41 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.
- 1.42 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.
  - 1.43 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
  - 1.44 "Field" shall mean the treatment, prevention, palliation and/or diagnosis of any disease.
- 1.45 "Finished Product" shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or preclinical trials, as the case may be.
- 1.46 "First Commercial Sale" shall mean, with respect to a Licensed Product in a country in the Territory, the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.
- 1.47 "Formulated Bulk Product" shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.
- 1.48 "FTE" shall mean a full time equivalent employee (<u>i.e.</u>, one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes of Development shall be \*\*\*\*\*\*\*\* per year.
  - 1.49 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

- 1.50 "Global Commercialization Budget" shall mean the budget(s) for a particular Contract Year approved by the JCC for the applicable Global Commercialization Plan.
- 1.51 "Global Commercialization Plan" shall mean, with respect to a Licensed Product, the three (3) year rolling plan approved by the JSC for Commercializing such Licensed Product throughout the world, including the related Global Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Global Commercialization Plan shall set forth (if not otherwise set forth in the applicable Country/Region Commercialization Plan(s)) for a Licensed Product, the information, plans and forecasts set forth in Section 6.2.
  - 1.52 "Global Development Budget" shall mean the budget(s) for a particular Contract Year approved by the JSC for the applicable Global Development Plan.
- 1.53 "Global Development Plan" shall mean, with respect to a Licensed Product, the Initial Development Plan and the three (3) year rolling plan approved by the JSC for the worldwide Development of such Licensed Product, including the related Global Development Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, a Global Development Plan will not include Non-Approval Trials.
- 1.54 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" and/or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.
- 1.55 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.
  - 1.56 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.
  - 1.57 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- 1.58 "IND" shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.
  - 1.59 "Indication" means any disease.
  - 1.60 "Initial Development Plan" shall have the meaning set forth in the Discovery Agreement.

- 1.61 "Initial IND Filing Date" means, with respect to a Licensed Product, the date an IND for such Licensed Product is first filed.
- 1.62 "Investor Agreement" means the Investor Agreement, dated as of December 20, 2007, by and among Sanofi Parent, Sanofi, Aventis LLC, Sanofi Amerique and Regeneron, as amended as of the Effective Date, and as the same may be amended from time to time.
  - 1.63 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.
- 1.64 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information, including marketing and supply information, (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.
  - 1.65 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.
- 1.66 "Lead Regulatory Party" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.
- 1.67 "Legal Dispute" shall mean any dispute related to a Party's alleged failure to comply with this Agreement or the validity, breach, termination or interpretation of this Agreement.
- 1.68 "<u>License</u>" shall mean any license or other agreement to acquire rights from a Third Party, which license or other agreement has been approved by the JSC required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.
- 1.71 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.

- 1.72 "Marketing Approval" shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.
  - 1.73 "Manufacturing Plan" shall mean the manufacturing plan as prepared by the JMC as described in Section 8.5.
- 1.74 "Medical Post-Approval Cost" shall mean, for Licensed Product(s) in each country in the Territory, the product of (a) the number of office-based people supporting (i) the coordination of Non-Approval Trials, (ii) post-Approval non-clinical pharmacovigilance, (iii) the maintenance of Approvals, and (iv) Pricing Approvals (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan) and (b) the applicable Medical Post-Approval FTE Rate. The calculation of the number of people in (a) above will be designed to ensure the proper reporting and auditing of such information in accordance with this Agreement. For the avoidance of doubt, the activities of contract personnel shall be charged as an Out-of-Pocket Cost.
- 1.75 "Medical Post-Approval FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Post-Approval FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.
- 1.76 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Licensed Products in the Field in the Territory by or on behalf of a Party or its Affiliates or Sublicensees to Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:
  - (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Licensed Products;
  - (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
  - (c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;
  - (d) Third Party cash rebates and chargebacks related to sales of Licensed Products, to the extent allowed;
  - (e) retroactive price reductions that are actually allowed or granted;

- (f) compulsory refunds, credits and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;
- (g) freight, postage, shipment and costs (or wholesale fees in lieu of those costs) and customs duties incurred in delivering Licensed Products that are separately identified on the invoice or other documentation;
- (h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Licensed Products, which are separately identified on the invoice or other documentation; and
- (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 9.8 of this Agreement. Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Sanofi or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Licensed Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the First Commercial Sale of such Combination Product, the Parties shall agree through the JFC to the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates (as such term is defined in the Discovery Agreement) shall not be deemed Combination Products.

Solely for the purposes of Section 2.6(d) of this Agreement, the term "Licensed Product" as used in the definition of Net Sales shall refer to Opt-Out Products.

1.77 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by either Party or its Affiliates, or by the Parties or their Affiliates jointly, during the Term pursuant to this Agreement, to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.

- 1.78 "Non-Approval Trials" shall mean any post-marketing surveys, registries and clinical trials post-first Marketing Approval not intended to gain additional labeled Indications, but excluding any post-first Marketing Approval clinical trials required by Regulatory Authorities to maintain Marketing Approvals of existing labeled Indication(s).
  - 1.79 "Opt-In Right" shall have the meaning set forth in the Discovery Agreement.
- 1.80 "Opt-Out Product" shall mean a Licensed Product as to which this Agreement has been terminated in accordance with Section 19.2. For clarity, an Early Development Opt-Out Product shall not constitute an Opt-Out Product.
  - 1.81 "Original Effective Date" shall mean November 28, 2007.
- 1.82 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 7.6, 12.1(a), 12.2(e), 12.3(b), 13.1(c), 13.3(d), 17.1(c), and 17.1(d).
- 1.83 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with a Plan, if applicable.
- 1.84 "Party Information" shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party's or its Affiliates' technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement.
  - 1.85 "Patent Application" shall mean any application for a Patent.
  - 1.86 "Patent Rights" shall mean unexpired Patents and Patent Applications.
- 1.87 "Patents" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.
- 1.88 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.
- 1.89 "Phase 3 Trial" shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.

- 1.90 "Plan" shall mean any Country/Region Commercialization Plan, Global Commercialization Plan, Global Development Plan, Initial Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.
- 1.91 "Positive Phase 3 Trial Results" shall mean a Phase 3 Trial that meets its primary end-point as defined in the study protocol for such Phase 3 Trial, and the safety profile supports continued clinical testing in the applicable Indication and/or filing of an application for Marketing Approval.
- 1.92 "Pre-Launch Marketing Expenses" shall mean, with respect to a Licensed Product, on a country-by-country basis in the Territory, with respect to each Licensed Product, all Commercialization expenses to support such Licensed Product in the Field incurred beginning on the date which is the later of the date of
- 1.93 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.
  - 1.94 "Product Candidate" shall have the meaning set forth in the Discovery Agreement.
- 1.95 "Product Trademark" shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.
- 1.96 "Promotional Materials" shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.
- 1.97 "Quarter" or "Quarterly" shall refer to a calendar quarter, except that the first (1st) Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.
  - 1.98 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

- 1.99 "Regeneron Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.
- 1.100 "Regeneron Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.
  - 1.101 "Region" shall mean such countries or group of countries as determined by the JCC.
- 1.102 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.
- 1.103 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.
- 1.104 "Reporting Country/Region" shall mean each Major Market Country, and each other country or Region for which a Country/Region Commercialization Committee has been established by the JCC.
  - 1.105 "Rest of World" or "ROW" shall mean all Rest of World Countries.
  - 1.106 "Rest of World Country" shall mean any country in the Territory other than the United States.
- 1.107 "ROW CPI" shall mean the "EU15 CPI" (or its successor equivalent index), which is published monthly and available via *The Bloomberg Professional*, as published by Bloomberg L.P.

- 1.109 "Sales Force FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of pharmaceutical companies in the Field in the applicable country, and including an allocation of regional and country sales force management cost, to be approved six (6) months prior to the first Commercial Sale, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs, information systems and allocated costs, such as, for example, allocated overhead costs.
  - 1.110 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.
- 1.111 "Sanofi Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Sanofi or its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.
- 1.112 "Sanofi Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.
- 1.113 "Sanofi Stock Purchase Agreement" means the Stock Purchase Agreement dated as of the Effective Date by and between Sanofi Amerique, Aventis LLC and Regeneron.
- 1.114 "Shared Commercial Expenses" shall mean the sum of the following items, in each case to the extent directly attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country/Region Commercialization Plan or Global Commercialization Plan:

- (b) bad debt attributable to Licensed Products in the Field sold in the Territory;
- (c) Sales Force Cost;
- (d) Medical Post-Approval Cost;
- (e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;
- (f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion relate to both Licensed Products and other products developed or commercialized by Sanofi or its Affiliates as agreed upon in an approved Global Commercialization Plan or Country/Region Commercialization Plan;
- (g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost;
- (h) Out-of-Pocket Costs related to Pricing Approvals and the maintenance of all Approvals directly related to the Commercialization of Licensed Products in the Field in the Territory;
  - (i) Commercial Overhead Charge;
  - (j) Pre-Launch Marketing Expenses;
  - (k) Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Registration Filing of indications and line extensions; and
- (l) any other costs or expenses directly related to the Commercialization of a Licensed Product after First Commercial Sale of such Licensed Product and not included in clauses (a) through (k) above.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will be fairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Commercial Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

- 1.115 "Shared Phase 3 Trial Costs" shall mean Development Costs associated with Phase 3 Trials of any Licensed Product incurred after the receipt of first Positive Phase 3 Trial Results for such Licensed Product.
- 1.116 "Sublicensee" shall mean a Third Party or an Affiliate to whom Sanofi will have granted a license or sublicense under Sanofi's rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a "Sublicensee" will include a Third Party to whom Sanofi will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Sanofi a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.
- 1.117 "Target" shall mean any gene, receptor, ligand or other molecule (a) associated with a disease activity that may be modified by direct interaction with a Licensed Product or (b) to which a Licensed Product binds.
- 1.118 "Terminated Licensed Product" shall mean a Licensed Product as to which this Agreement has been terminated in accordance with its terms in accordance with Article XIX, and shall include any Opt-Out Product.
  - 1.119 "Termination Notice Period" shall mean the Sanofi Termination Notice Period or the Regeneron Termination Notice Period, as applicable.
  - 1.120 "Territory" shall mean all the countries and territories of the world.
  - 1.121 "Third Party." shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.
  - 1.122 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.
- 1.123 "<u>US CPI</u>" shall mean the Consumer Price Index All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).
- 1.124 "Valid Claim" shall mean (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a Patent Application, which claim has been pending less than five (5) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).

DEFINITION	SECTION/SCHEDULE
Acquired Entity	2.6(c)
Acquiring Party	2.6(c)
Agreement	Preamble
Alliance Manager	3.2(a)
Annual True-Up	SCHEDULE 2
Applicable ROW Percentages	SCHEDULE 2
Budget Dispute	Section 3.11(b)
Collaboration	Preamble
Collaboration Purpose	3.1(b)
Combination Product	1.76
Cost	SCHEDULE 1
Damages	17.1(a)
Default Interest Rate	9.9
Development Balance	SCHEDULE 2
Discovery Agreement	Preamble
Disputed Budget	Section 3.11(b)
Early Development Opt-Out Product	5.6
Effective Date	Preamble
Excluded Rights	4.3
Expert Panel	10.4(a)
First Year	5.3
Force Majeure	ARTICLE XVIII
Global Development Budget(s)	5.3
Governance Dispute	10.2
Incomplete Activity	5.3
Indemnified Party	17.2
Indemnifying Party	17.2
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JMC	3.1(a)
Joint Invention	12.1(b)
JSC	3.1(a)
Lead Litigation Party	13.1(c)
Manufacturing Cost	SCHEDULE 1
Manufacturing Notice	8.3(a)
Manufacturing Plan	8.5
Marketing Guidelines	3.4(b)(vi)

DEFENSE	
<u>DEFINITION</u>	SECTION/SCHEDULE
Maximum Regeneron Effort	6.5(e)(i)
Modified Clause	20.7
Non-Acquiring Party	2.6(c)
Non-Approval Trials	6.2(h)
Non-Incurred Amount	5.3
Opt-Out Partner	2.6(d)
Opt-Out Product Notice	2.6(c)
OverPaying Party	Section 13.3(e)
Party(ies)	Preamble
Patent Jurisdictions	12.2(a)
POC Principal Party	5.2
POC Time	5.2
Post-POC Principal Party	5.2
Publishing Party	16.3
Quarterly True-Up	SCHEDULE 2
Regeneron	Preamble
Regeneron Commitment Level	6.5(e)(i)
Regeneron Early Development Opt-Out Right	5.6
Regeneron Early Opt-Out Notice	5.6
Regeneron Indemnitees	17.1(a)
Regeneron Profit Split	SCHEDULE 2
Regeneron Reimbursement Amount	SCHEDULE 2
Regeneron Sole Inventions	12.1(a)
Regeneron Termination Notice Period	19.2(b)
Reimbursement Payment	SCHEDULE 2
Required Divestiture Notice Period	2.6(c)
Rest of World Profit Split	SCHEDULE 2
Royalty Term	9.3
ROW Profit Split	SCHEDULE 2
ROW Profit Split Annual True-Up	SCHEDULE 2
Sanofi	Preamble
Sanofi Amerique	Preamble
Sanofi Indemnitees	17.1(b)
Sanofi Parent	Preamble
Sanofi Sole Inventions	12.1(a)
Sanofi Termination Notice Period	19.2(a)
SDEA	7.4
Shared Phase 3 Trial Costs Balance	SCHEDULE 2
Sole Developer	2.6(d)
Sole Inventions	12.1(a)
Succeeding Year(s)	5.3
Target Labeling	7.2(d)
Target ROW Profit Split	7.2(d) SCHEDULE 2
Technical Development Matter	10.2
Term	19.1(a)

<u>DEFINITION</u>	SECTION/SCHEDULE
Third Party	2.6(c)
Third Party Acquisition	2.6(c)
U.S. Profit Split	SCHEDULE 2
US Profits	SCHEDULE 2
VelocImmune Royalties	Section 13.3(e)
Working Group	3.1(a)

## ARTICLE II COLLABORATION

- 2.1 Scope of Collaboration. Upon and subject to terms and conditions of this Agreement, the Parties will cooperate in good faith to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in such a manner so as to optimize the commercial potential of each Licensed Product. The Parties shall establish various Committees as set forth in Article III of this Agreement to oversee and/or coordinate the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in Article XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to operate effectively and efficiently under and in accordance with the terms and conditions of this Agreement.
- 2.2 <u>Compliance With Law</u>. Both Sanofi and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.
- 2.3 <u>Further Assurances and Transaction Approvals</u>. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.
- 2.4 <u>Compliance with Third Party Agreements</u>. Each Party agrees to comply with the obligations set forth in (a) the Licenses to which it is a party and to notify the other Party of any terms or conditions in any such License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement, including any sublicense under a License referenced in subsection (a) above, to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Neither Party may terminate or amend any License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.

2.5 <u>Plans</u>. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.

### 2.6 <u>Limitation on Exercise of Rights Outside of Collaboration</u>.

- (a) <u>Non-Compete</u>. Without limitation of and in addition and subject to Section 2.8 of the Discovery Agreement, during the Term, except as set forth in this Agreement or Section 2.8 of the Discovery Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Competing Product.
- (b) Regeneron Sole Development. If Regeneron presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Global Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then Regeneron may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the applicable Global Development Plan; provided, however, Regeneron must first present the proposed protocols and clinical trial designs to Sanofi for approval, such approval not to be unreasonably withheld or delayed and, for other than Non-Approval Trials, shall also present to Sanofi the related budgets for Clinical Supply Costs and Out-of-Pocket Costs and applicable FTE costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). Regeneron shall also provide to Sanofi drug safety data from such additional clinical trials in accordance with Section 7.4. The Sanofi representatives on the JDC may disapprove any such protocols or clinical trial designs for reasons of safety or Sanofi reasonably believes that the development as described in this Section 2.6(b) would have a material adverse effect on the overall development strategy for the Licensed Product and/or the commercial viability of such License Product, including the magnitude of sales for such Licensed Product. If, in compliance with this Section 2.6(b), Sanofi does not approve any such protocols or clinical trial designs for reasons as described herein, Regeneron may not proceed with the proposed clinical trials unless Regeneron disputes such disapproval and until the dispute has been resolved, as provided in Section 3.11(b) and, if necessary, Section 10.4, in Regeneron's favor. In the event that Regeneron conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article IV of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to Regeneron with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trial(s) to support an Approval in the Territory, then Sanofi shall be required to reimburse Regeneron for \*\*\*\*\*\*\*\*\* of the actual Out-of-Pocket Costs and Clinical Supply Costs and applicable FTE costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to Sanofi pursuant to this Section 2.6(b) and the other terms of this Agreement. Publication of any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b) shall be subject to Article XVI.

(c) <u>Company Acquisitions</u>. Notwithstanding Section 2.6(a), if as the result of an acquisition of a Third Party (such acquisition a "<u>Third Party Acquisition</u>) by a Par or one or more of its Affiliates (the "<u>Acquiring Party</u>"), the Acquiring Party acquires rights to a product that is a Competing Product (the "<u>Acquired Competing Product</u>") a Licensed Product (the "<u>Competing Licensed Product</u>"), the Acquiring Party, at its sole discretion, shall do one of the following: (W) present a proposal to the JDC to include the Acquired Competing Product in the Collaboration in accordance with Section 2.6(c)(i); (X) deliver to the other Party (the "<u>Non-Acquiring Party</u>.") a terminatio notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product; or (Y) transfer its rights in the Acquired Competing Product to a Third Party pursuant to Section 2.6(c)(iii).

(i) <u>Proposal for Inclusion</u>. If the Acquiring Party chooses this alternative, within ten (10) Business Days after the closing of such Third Party Acquisition, the Acquiring Party shall present a proposal to the JDC to include such Acquired Competing Product in the Collaboration based on the terms of this Agreement. As part o presentation, the Acquiring party shall provide the JDC with all information with respect to such Acquired Competing Product reasonably available to the Acquiring P and material to a decision by the Non-Acquiring Party's representatives on the JDC as to whether to approve the inclusion of such Acquired Competing Product in the Collaboration. The JDC shall, on or before the date which is twenty (20) Business Days after the closing of such Third Party Acquisition, decide whether to approve the inclusion of such Acquired Competing Product in the Collaboration under the terms of this Agreement. If the JDC timely approves the inclusion of such Acquired Competing Product in the Collaboration, then upon the closing of such Third Party Acquisition the Acquired Competing Product shall automatically be included in the Collaboration as a Licensed Product hereunder. If the JDC does not approve such inclusion, the Acquiring Party shall elect whether to deliver to the Non-Acquiring Patermination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product or transfer its rights to Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party in accordance with Section 2.6(c)(iii) below).

- (ii) <u>Termination of Licensed Product</u>. If the Acquiring Party chooses this alternative, the Acquiring Party shall deliver to the Non-Acquiring Party, within ten (Business Days after the decision of the JDC not to include the Acquired Competing Product in the Collaboration pursuant to Section 2.6(c)(i), a termination notice put to Section 19.2(a) or 19.2(b), as applicable, with respect to the Competing Licensed Product (the "<u>Opt-Out Product Notice</u>"). The provisions of Section 19.2(a) or 19.2 as applicable, and the provisions of Sections 19.7, 19.8 and Schedule 4 or 5, as applicable, shall then apply to such Competing Licensed Product. For the avoidance of doubt, such Competing Licensed Product shall then be an Opt-Out Product, and notwithstanding any other provision of this Agreement, the Acquiring Party shall be deemed (without any requirement of notice to the Non-Acquiring Party) to have irrevocably ceded all decision-making authority with respect to such Opt-Out Product the Non-Acquiring Party. In addition, if such Opt-Out Product is being marketed and sold at the time of the closing of the Third Party Acquisition, then during the San Termination Notice Period or Regeneron Termination Notice Period, as applicable, the following shall apply:
  - (1) In any Quarter in which the U.S. Profits are positive, the U.S. Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to Acquiring Party, and in any Quarter in which the ROW Profits are positive, the ROW Profit Split shall be zero percent (0%) to the Acquiring Party and one hundre (100%) to the Non-Acquiring Party.
  - (2) In any Quarter, in which U.S. Profits are negative, the U.S. Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Acquiring Party, and in any Quarter in which ROW Profits are negative, the ROW Profit Split shall be one hundred percent (100%) to the Acquiring Party and zer (0%) to the Non-Acquiring Party.
- (iii) <u>Transfer of Rights</u>. If the Acquiring Party chooses this alternative, the Acquiring Party shall commit in writing to the Non-Acquiring Party, within ten (10) Business Days after the closing of such Third Party Acquisition, to license or otherwise transfer rights to such Acquired Competing Product to a Third Party (without a consideration or payment to the Non-Acquiring Party) and/or cease all development, manufacturing and/or commercialization, as applicable, of such Acquired Compe Product within six (6) months after the closing of the Third Party Acquisition, and shall do so within such six (6) month period.

(d) Required Divestiture of Licensed Product. Notwithstanding any of the foregoing in this Section 2.6(d), in the event the Acquiring Party believes, based on the written advice of its counsel, that it is required by Law to divest its interest either in the Acquired Competing Product or the Competing Licensed Product, the Acquiring Party may terminate this Agreement with respect to such Competing Licensed Product pursuant to Section 19.2(a) or 19.2 (b), as appropriate, Section 2.6(c) (ii) and this Section 2.6(d), with regards to the Competing Licensed Product, or transfer its interest in the Acquired Competing Product pursuant to Section 2.6(c)(iii). If the Acquiring Party terminates this Agreement with respect to the Competing Licensed Product pursuant to this Section 2.6(d), it shall give the Non-Acquiring Party the maximum advance notice (up to twelve (12) months) of termination consistent with such divestiture requirement imposed by Law (the "Required Divestiture Notice Period"), following which the provisions of 2.6(c)(ii) shall apply and the Competing Licensed Product shall be an Opt-Out Product. During this period, the Acquiring Party will reasonably cooperate (at the Acquiring Party's sole cost and expense) with the Non-Acquiring Party to enable the Non-Acquiring Party to assume, within the Required Divestiture Notice Period, the continued Development, Manufacture and Commercialization of such Opt-Out Product in the Field in the Territory. The Acquiring Party shall also be responsible for, and shall promptly pay upon demand, all reasonable costs and expenses incurred by the Non-Acquiring Party in assuming such continued Development, Manufacture and Commercialization of such Opt-Out Product to the extent such costs and expenses, other than capital investments, would not have been incurred and/or would have been paid by the Acquiring Party, absent such Acquiring Party's termination with respect to such Opt-Out Product pursuant to Section 19.2(a) or (b). For the avoidance of doubt, if the Required Divestiture Notice Period is less than the twelve (12) months required by Section 19.2, the Acquiring Party shall have continuing payment obligations (though no performance obligations beyond those described above) to the Non-Acquiring Party with respect to such Opt-Out Product for the entire Sanofi Termination Notice Period (if Sanofi is the Acquiring Party) or Regeneron Termination Notice Period (if Regeneron is the Acquiring Party). Subject to the further provisions of this Section 2.6(d), in the case of any Opt-Out Product, the non-terminating Party (the "Sole Developer") shall have the right to Develop and Commercialize such Opt-Out Product, unless such Opt-Out Product is (or becomes) a Competing Opt-Out Product, in which case the Sole Developer may not (either directly or through an Affiliate or Third Party), Develop or Commercialize such Competing Opt-Out Product for a period of \*\*\*\*\*\*\* following the date it becomes a Competing Opt-Out Product (or, if shorter, such period ending on the date such Competing Opt-Out Product ceases to be a Competing Opt-Out Product), unless otherwise agreed by the terminating Party (the "Opt-Out Partner"). If an Opt-Out Product is Commercialized by the Sole Developer (either directly or through an Affiliate or Third Party) in compliance with this Section 2.6(d), then the Sole Developer shall pay the Opt-Out Partner royalties based on Net Sales of such Opt-Out Product and the stage of Development of the Licensed Product at the time it became an Opt-Out Product, at the royalty rate(s) described on Exhibit A. Notwithstanding the foregoing or any other provision of this Agreement, in the case of any Opt-Out Product, including any Competing Opt-Out Product, resulting from termination of this Agreement with respect to a Licensed Product pursuant to Section 19.2 in the circumstances described in Section 2.6(c), the Sole Developer shall have no obligation either to delay Developing or Commercializing, or to pay royalties with respect to, such Opt-Out Product.

(e) Clinical Trials for Combination Products. Notwithstanding anything in this Section 2.6(e) to the contrary, each Party and/or its respective Affiliates shall be entitled to (i) initiate, sponsor and/or conduct a clinical trial and/or (ii) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in an clinical trial, initiated, sponsored and/or conducted by any Third Party, in each of the foregoing cases with respect to the combination of any Party's (or its Affiliate's) product, together with any Competing Product that has been granted a Marketing Approval for at least one Indication in the applicable country, unless (A) a Licensed Product Developed under this Agreement has been granted a Marketing Approval in the applicable country for use in combination with such Party's (or its Affiliate's) product in the same Indication(s) as the one to be studied in the intended clinical trial with the Competing Product which is not approved in such Indication or (B) both the Competing Product and a Licensed Product Developed under this Agreement have been granted a Marketing Approval in the applicable country for use in combination with such Party (or its Affiliate's) product as the same Indication to be studied in the intended clinical trial with the Competing Product and the relevant labeling of both th Licensed Product and the Competing Product for such Indication is substantially similar. For any combination study with a Competing Product covered by this Section 2.6(e), the applicable Party shall notify the other Party prior to initiating such trial, such notice to include a brief synopsis of the protocol and a description of the Party's (c its Affiliate's) role(s) and responsibilities in connection with the study. Further, for any combination study with a Competing Product covered by this Section 2.6(e), each Party shall promptly provide the other Party with available results of such combination study, unless such disclosure is prohibited by Law or contract. Each Party and/or it Affiliates shall be entitled to use data from clinical trials permitted by this Section 2.6(e) to promote the combination of such Party product together with such Competing Product, unless a Licensed Product Developed has been granted a Marketing Approval in the applicable country for use in combination with such Third Party product, in the same Indication. Neither Party nor its respective Affiliates shall receive any compensation or other payments (either in cash or in kind) based on the development, promotion, or sale of a Competing Product. Neither Party will intentionally delay the commencement, enrollment or completion of a clinical study of a Licensed Product a result of any ongoing or pending clinical trial permitted by this Section 2.6(e). For the avoidance of doubt, neither Party nor its respective Affiliates shall use or disclose any Party Information or New Information subject to the confidentiality provisions of Article XVI in connection with any of the activities described in this Section 2.6(e).

(f) <u>Sanofi Rights</u>. Notwithstanding Section 2.6(a), if Sanofi or its Affiliate wishes to acquire or license rights to a Competing Product other than through the acquisition of a Third Party (which is covered in Section 2.6(c) above), and the applicable Licensed Product against the same Target as such Competing Product has not you commenced Development in any Phase 3 Trial in any indication, then during the Sanofi Termination Notice Period following Regeneron's receipt of Sanofi's termination notice for such Licensed Product under Section 19.2(a), Sanofi or its Affiliate shall have the right to acquire, license, Develop and Commercialize a Competing Product, either alone or through any Third Party, and the provisions of Section 19.2(a), 19.7, 19.8, and Schedule 4 shall then apply with respect to such Licensed Product.

### ARTICLE III MANAGEMENT

#### 3.1 Committees/Management.

- (a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), CRCCs to the extent provided in Section 3.5, and such other commercialization sub-committee as JCC shall deem to be appropriate, a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The JSC, JDC JFC and JMC shall each be established within thirty (30) days after the Effective Date. The JCC shall be established at least two (2) years prior to the anticipated filing day for Marketing Approval for the first Licensed Product under this Agreement. It is understood that the Parties may wish to establish multiple Committees reporting to the JSC, JDC, and JCC with responsibility for different Licensed Products. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate a the Committee which establishes the Working Group determines.
- (b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

## 3.2 Joint Steering Committee.

(a) <u>Composition and Purpose</u>. The JSC shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program for each Licensed Product, including the Manufacture of Licensed Products in the Field fo use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing thei responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.11 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager ("Alliance Manager") to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees and providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually review and approve the Global Development Plan(s) if any, Manufacturing Plan(s), Global Commercialization Plan(s) and Country/Region Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC, as the JSC deems appropriate and (v) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties.

## 3.3 Joint Development Committee.

- (a) <u>Composition and Purpose</u>. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the worldwide Development of each Licensed Product in th Field; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Global Development Plan(s) (and related Global Development Budget(s)) and (iii) to oversee the implementation of the Global Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).
  - (b) Specific Responsibilities. In particular, the JDC shall be responsible for:
    - (i) advising the JSC on the overall global Development strategy for each Licensed Product in the Field;
  - (ii) developing (or overseeing the development of), and updating at least annually, the Global Development Plan(s) (and related Global Development Budget(s described in Sections 5.2 and 5.3, for final approval by the JSC;

- (iii) reviewing and overseeing the implementation of, and compliance with, the Global Development Plan(s) (including the Global Development Budget(s));
- (iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;
- (v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans, and reviewing and approving protocols, statis analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under t Global Development Plan(s) and for Non-Approval Trials;
- (vi) reviewing and approving proposed target Licensed Product labeling and reviewing and, to the extent set forth herein, approving proposed changes to product labeling with respect to Licensed Products in the Field in accordance with Section 7.2;
  - (vii) developing a target profile for each Licensed Product;
  - (viii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;
- (ix) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems improvements in concert with the JCC;
- (x) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field:
- (xi) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan(s);
  - (xii) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.

#### 3.4 Joint Commercialization Committee.

(a) <u>Composition and Purpose</u>. The purpose of the JCC shall be to develop and propose to the JDC and JSC the strategy for the global Commercialization of Licensed Products in the Field in the Territory, and to oversee the implementation of the Global Commercialization Plans and the Commercialization operational aspects of the Collaboration on a country-by-country basis. The JCC shall be composed of at least two (2) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

- (b) JCC Responsibilities. In particular, the JCC shall be responsible for:
  - (i) developing and proposing to the JSC the global strategy for the Commercialization of each Licensed Product in the Field in the Territory;
- (ii) commencing no later than two (2) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing (or overseeing the development of), and updating not less frequently than once per Contract Year, the Global Commercialization Plan(s) and related Global Commercialization Budget(s) country-by-country basis for final approval by the JSC and (B) establishing, to the extent provided in Section 3.5, Country/Region Commercialization Committees to establish Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto and carry out the other activitie described in Section 3.5;
- (iii) Defining target groups to be covered by overall marketing efforts in the applicable country, including, without limitation,
  - (iv) Establishing the trade dress for each Licensed Product, consistent with the guidelines established by the JCC, in the applicable Major Market Country;
- (v) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan(s) for review by the JMC and approval by the JSC;
- (vi) for each Licensed Product, on a country-by-country basis for the Major Market Countries, developing and updating, as necessary, global promotional guid for branding, positioning, core messages and Promotional Material messages and Licensed Product pricing and rebate/discount guidelines; guidelines for determining percentage of sales force compensation linked to sales of such Licensed Product (collectively, the items referred to in this paragraph (vi) shall be referred to as the "Marketing Guidelines") as part of the Global Commercialization Plan;
- (vii) reviewing and overseeing compliance with the Global Commercialization Plan (including the related Global Commercialization Budget), and Country/Re Commercialization Plans (including the Country/Region Commercialization Budgets), to the extent applicable, for each Licensed Product, including ensuring that cou specific launch plans are consistent with the Marketing Guidelines, and reviewing and validating latest annual estimates for the current calendar year compared to the Global Commercialization Budget and Country/Region Commercialization Budgets;
- (viii) establishing or validating the number and position of Details required to meet market and sales forecasts and their conversion into the equivalent number Detailing FTEs according to applicable weighting factors, based upon sales force and market practices, on a country-by-country basis, consistent, however, with the applicable Marketing Guidelines;

- (ix) for each Licensed Product, selecting a Product Trademark in accordance with Section 11.2 and giving guidance on trade dress for such Licensed Product;
- (x) determining the launch date for each Licensed Product on a country-by-country basis in Major Market Countries;
- (xi) reviewing and approving \*\*\*\*\*\*\*\*\*\*\*\*\* and similar policies for each Licensed Product in the applicable Major Market Country, which shall toonsistent with the Marketing Guidelines;
- (xii) preparing short-term and long-term sales forecasts for each Licensed Product on a country-by-basis for Major Market Countries and reviewing such forec for the remaining countries;
- (xiii) \*, and (C) determining which such trials should be conducted, rejected or redesigned and whether any such trial should be referred to the JDC for consideration for inclusion in the applicable Global Development Plan;
  - (xiv) validating the contents, design and layout of packaging for each Licensed Product in the Field;
  - (xv) validating plans and policies regarding journal and other publications with respect to each Licensed Product in the Field in concert with the JDC;
- (xvi) formulating a life-cycle management strategy for each Licensed Product in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;
- (xvii) matters relating to Regeneron's Commitment Level with respect to a Licensed Product in a Co-Commercialization Country, including consenting to char therein; and
  - (xviii) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the JSC, JDC JFC or JMC.
- 3.5 <u>Country/Region Commercialization Committees</u>. The JCC will establish a Country/Region Commercialization Committee in each Major Market Country, and in each other Reporting Country/Region as and when determined by the JCC. The Country/Region Commercialization Committees will be responsible for establishing the Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto with respect to the applicable Reporting Countries/Region(s). The Country/Region Commercialization Committees will also serve as a forum to consider and discuss and, if so empowered by the JCC, decide, in a more detailed and focused manner with respect to the applicable Reporting Countries/Region(s), and make suggestions or recommendations to the JCC with respect to, the matters referred to in Section 3.4, as applicable, including the implementation of decisions with respect thereto made by the JCC as contemplated by such Section 3.4.

- 3.6 <u>Joint Finance Committee</u>. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article IX and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC, the JMC and the JCC, as needed.
- 3.7 <u>Joint Manufacturing Committee</u>. Working with the JDC and JCC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing process development and Manufacturing activities, including preparing and updating the Manufacturing Plan for approval by the JSC and carrying out such other responsibilities set forth in Article VIII, process and technology selection, process improvements and related intellectual property filing strategy and obtaining a common process for manufacturing, recalls, market withdrawals, and any other corrective actions related to any Licensed Product in the Territory, and for any other matters specifically assigned to the JMC by the JSC. For process development activities, the Joint Manufacturing Committee shall consult the appropriate expert functions within both Parties or their Affiliates as appropriate.
- 3.8 <u>Membership</u>. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi. Each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue final minutes within thirty (30) days thereafter.
- 3.9 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once every Quarter during the Term, commencing from and after the time such Committee is established as provided herein. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties or their Affiliates) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of any Licensed Product in the Field (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.
- 3.10 <u>Decision-Making</u>. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.

- 3.11 <u>Resolution of Governance Matters</u>. As provided in Section 10.2, this Section 3.11 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.
  - (a) <u>Generally</u>. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible, provided that, in the case of any matter which cannot be resolved by the JDC, JCC, CRCC, JMC, JFC or other relevant Committee established hereunder, at the request of either Party, such matter shall promptly, and in any event within ten (10) Business Days (or two (2) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution.

  - (c) Notwithstanding the foregoing, and subject to Section 10.4, Legal Disputes and disputes referred to in the third sentence of Section 2.6(b) which involve a Technical Development Matter shall be referred to the Executive Officers with no Party's Executive Officer having final decision making authority.
  - (d) <u>Interim Budgets</u>. Pending resolution by the Executive Officers of any referred dispute under Section 3.11(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committal approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.11(c).
  - (e) <u>Obligations of the Parties</u>. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreemer which restricts or prohibits a Party from taking any specified action.

### ARTICLE IV LICENSE GRANTS

- 4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.6) and any License to which Regeneron is a party, Regeneron hereby grants to Sanofi (a) the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop and import Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive (except as otherwise provided below in this Section 4.1) right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, except that the right and license granted pursuant to this clause (b) shall be co-exclusive (with Regeneron and its Affiliates) to the extent of Regeneron's right to Co-Promote Licensed Products and Regeneron's right to supply Licensed Products to Sanofi, as contemplated by this Agreement. Sanofi will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.4.
- 4.2 <u>Sanofi License Grants</u>. Subject to the terms and conditions of this Agreement and any License to which Sanofi or any of its Affiliates is a party, Sanofi hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-exclusive (with Sanofi and its Affiliates) right and license under the Sanofi Intellectual Property to the extent necessary to make, have made, use, develop and import Licensed Products for use in the Field in the Territory and to Co-Promote Licensed Products to the extent provided in this Agreement.
- 4.3 Newly Created Intellectual Property. In addition to the other licenses granted under this Article IV and subject to the other terms and conditions of this Agreement, to the extent permitted under any relevant Third Party agreement, each Party grants to the other Party and its Affiliates the perpetual, royalty-free, paid-up, non-exclusive, worldwide right and license, with the right to grant sublicenses, to use and practice for any and all purposes: all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights), other than Know-How jointly owned pursuant to Section 12.1(e) and other than Excluded Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans. As used above, the term "Excluded Rights" shall mean any Patents or Know-How claiming or covering composition (including any formulation) of a Licensed Product. For the avoidance of doubt, nothing in this Section 4.3 shall be construed to grant either Party any license to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

- 4.4 Sublicensing. Unless otherwise restricted by any License, Sanofi will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Sanofi may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any License, Regeneron will have the right to sublicense any of its rights under Section 4.2 with the prior written consent of Sanofi, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Sanofi's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement, Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article XVI, and will include, with respect to a Sublicensee of Sanofi, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Sanofi on the same basis as if such sales were Net Sales by Sanofi. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the applicable Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have an adverse effect on either Party or any of its Affiliates or any Party's Intellectual Property, then the harmed Party may cause the other Party or its Affiliate to exercise, and the other Party or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and the other Party, at the option of the other Party, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Each Party will forward to the other Party a complete copy of each applicable fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.
- 4.5 <u>No Implied License</u>. Except as expressly provided in this Article IV or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.
- 4.6 Retained Rights. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Regeneron expressly reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the further avoidance of doubt, Regeneron retains all rights in Regeneron Intellectual Property, Regeneron's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation the right to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Sanofi expressly reserves for itself and its Affiliates and Third Party licensees under the Sanofi Intellectual Property and Sanofi's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Sanofi retains all rights in Sanofi Intellectual Property, Sanofi's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation, the right to exploit Sanofi Intellectual Property and Sanofi's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

## ARTICLE V DEVELOPMENT ACTIVITIES

5.1 <u>Development of Licensed Products</u>. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Global Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices.

5.2 Global Development Plans. With respect to each Licensed Product, the JDC shall prepare and present a Global Development Plan for approval by the JSC, and the JSC shall approve a Global Development Plan for such Licensed Product, within three (3) months after the time such Licensed Product first becomes a Licensed Product in accordance with the terms of the Discovery Agreement and this Agreement, and shall, subject to the further provisions of this Section 5.2, determine which Party will take the lead in the Development of such Licensed Product, Prior to such JSC approval of the first Global Development Plan for any Licensed Product, the Parties shall Develop the Licensed Product in accordance with the applicable Initial Development Plan. An updated Global Development Plan for such Licensed Product will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Global Development Plan for a Licensed Product will set forth the plan for Development of such Licensed Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for such Licensed Product in the Field in the Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers. Each Global Development Plan will be reviewed and informally updated by the JDC not less frequently than once every six (6) months for the ensuing three (3) year period. Unless and to the extent otherwise agreed by the Parties with respect to a particular Licensed Product, (i) the Parties shall alternate, on a Licensed Product-by-Licensed Product basis, in being allocated principal responsibility for formulating, and carrying out, the principal Development activities for the applicable Licensed Product under the applicable Global Development Plan(s) from the time the applicable Product Candidate is advanced into Development in accordance with the Discovery Agreement (whereupon such Product Candidate automatically constitutes a Licensed Product) through proof of concept as defined in the Global Development Plan for the Licensed Product (the "POC Time") (with respect to any Licensed Product, the Party with such principal responsibility through the POC Time being referred to as the "POC Principal Party") and (ii) the Parties shall alternate being allocated principal responsibility for formulating, and carrying out, all clinical trials conducted subsequent to the POC Time for the applicable Licensed Product(s) under the applicable Global Development Plan(s) (with respect to a Licensed Product, the Party with such principal responsibility being referred to as the "Post-POC Principal Party"), with Sanofi being the Post-POC Principal Party for two (2), and Regeneron being the Post-POC Principal Party for one (1), out of each three (3) Licensed Products. The Parties shall cause their respective representatives on the JDC and the JSC, in preparing, updating and approving Global Development Plans, to allocate principal Development responsibilities thereunder as provided in this Section 5.2.

- 5.3 <u>Global Development Budgets</u>. Each Global Development Plan for a Licensed Product shall include a related Global Development Budget (each individually, a "<u>Global Development Budget</u>" and collectively, "<u>Global Development Budgets</u>") and each Global Development Budget shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Global Development Plan of which such Global Development Budget is a part in accordance with this Agreement. Amendments and updates to any Global Development Budget shall not be effective without the approval of the JSC.
- 5.4 <u>Development Reports</u>. Within forty-five (45) days after the end of each Quarter, commencing in the first Quarter in which Development activities commence hereunder with respect to the first Licensed Product, Regeneron and Sanofi shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Global Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter and shall be in such form, format and of such level of detail as approved by the JFC. At the next JSC meeting held following such forty-five (45) day period, the JSC will approve the final Development Costs which will be used in calculating the Global Development Balance.
- 5.5 <u>Review of Clinical Trial Protocols</u>. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by Regeneron pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials.
- 5.6 Regeneron Early Development Opt-Out. Within thirty (30) days of the date that Sanofi exercises its Opt-In Rights with respect to any Licensed Product thereby including such Licensed Product under this Agreement, Regeneron shall have a one-time right to opt-out of the further Development of such Licensed Product (such right of Regeneron, the "Regeneron Early Development Opt-Out Right", and each such Licensed Product as to which Regeneron has exercised the Regeneron Early Development Opt-Out Right, an "Early Development Opt-Out Product") by delivering written notice of such opt-out (a "Regeneron Early Opt-Out Notice") to Sanofi. Effective immediately upon the delivery by Regeneron to Sanofi of a Regeneron Early Opt-Out Notice with respect to a Licensed Product, (i) such Licensed Product shall automatically constitute an Early Development Opt-Out Product, (ii) the rights and licenses granted by Regeneron to Sanofi hereunder with respect to such Early Development Opt-Out Product shall automatically terminate, (iii) Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or the Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time the Regeneron Early Opt-Out Notice was delivered to Sanofi, to Develop, Manufacture and Commercialize in the Field in the Territory (and solely to the extent that such Regeneron Intellectual Property has, as of the date of the Regeneron Early Opt-Out Notice, actually been incorporated into such Early Development Opt-Out Product or otherwise claims or covers its use) the Early Development Opt-Out Product with respect to which such Regeneron Early Development Opt-Out Notice was delivered, (iv) Regeneron shall remain responsible for Regeneron shall, as promptly as reasonably practicable, transfer to Sanofi all clinical activities related to the Early Development Opt-Out Product, (vi) except as set forth in this Section 5.6, Regeneron shall have no further rights or obligations with respect to such Early Development Opt-Out Product, (vii) Sanofi shall be free to Develop and Commercialize such Early Development Opt-Out Product in the Field in the Territory free of any obligations to Regeneron hereunder, except for reimbursing Regeneron for any pass through costs to Third Party licensors of Regeneron Intellectual Property, to the extent attributable to the Development or Commercialization of Licensed Products Antibody that directly interacts with the same gene, receptor, ligand or other molecule to which such Early Development Opt-Out Product binds. Except as provided in this Section 5.6, a Party's obligations under this Agreement with respect to the Development of a Licensed Product shall terminate only upon termination of this Agreement with respect to such Licensed Product or in its entirety in accordance with, and only to the extent and upon the terms and conditions set forth in, Article XIX.

## ARTICLE VI COMMERCIALIZATION

6.1 Commercialization of Licensed Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC. Sanofi shall be the lead Party with respect to the Commercialization of Licensed Products in the Field. Sanofi shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field, and carry out the Commercialization activities in accordance with the applicable Global Commercialization Plan and the applicable Country/Region Commercialization Plans in a timely manner and conduct all such activities in compliance with applicable Laws. Except as otherwise provided in this Agreement, Sanofi shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory. Sanofi or its Affiliate shall invoice and book all sales of the Licensed Products in the Field in the Territory and shall appropriately record all such sales. Sanofi or its Affiliate shall also be responsible for the distribution of the Licensed Products in the Field in the Territory. Commencing with the initiation of Phase 3 Trials for a Licensed Product in the Field in the Territory, the Parties will commence regular ad hoc discussions concerning the Commercialization strategy for the Licensed Product.

(a) the overall global strategy for Commercializing such Licensed Product in the Field in the Territory, including target product profiles, branding, positioning, promotional materials and core messages for such Licensed Product;

- (c) the related Global Commercialization Budget;
- (d) anticipated launch dates for such Licensed Product for Major Market Countries;
- (e) market and sales forecasts for such Licensed Product in the Field in the Territory in a form to be agreed between the Parties;
- (f) strategies for the detailing and promotion of such Licensed Product in the Field in the Territory;
- (g) anticipated major advertising, public relations and patient advocacy programs for such Licensed Product in the Field in the Territory;
- (h) Non-Approval Trials; and
- (i) all other Marketing Guidelines.

#### 6.4 Commercialization Efforts; Sharing of Commercial Information.

- (a) Sanofi (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory is accordance with the Global Commercialization Plans, the Marketing Guidelines and, as applicable, the Country/Region Commercialization Plan(s). Without limiting the generality of the foregoing, (i) Sanofi will, as necessary, build, train and apply a field force necessary to Commercialize the Licensed Products in the Field in accordance with the applicable Global Commercialization Plans and Country/Region Commercialization Plans, (ii) Sanofi's, and in the Co-Commercialization Countries each Party's, sales representatives shall provide the FTE effort and detail the Licensed Products in the Field in accordance with the approved Country/Region Commercialization Plan (applicable), Global Commercialization Plan(s) and all applicable Laws.
- (b) Sanofi will provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, including, without limitation, information relating to anticipated launch dates, key market metrics, market research, and sales. Without limiting the foregoing, beginning in the Quarter of the First Commercial Sale in each Major Market Country, Sanofi will provide Regeneron, and with respect to each Co-Commercialization Country, Regeneron will provide Sanofi, on a quarterly basis, with reports of the activity within its field force in each such Major Market Country, which will include reasonable da from reports created by Sanofi or Regeneron for its internal management purposes.
- (c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information.
  - (d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.
  - 6.5 Co-Commercialization of Licensed Products.

- (b) <u>Co-Commercialization</u>. Sanofi and Regeneron (through their respective Affiliates where appropriate) shall Co-Commercialize Licensed Products under the applicable Product Trademarks in each Co-Commercialization Country in accordance with the then-current and applicable Country/Region Commercialization Plan. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts to Co-Commercialize the Licensed Products in the Co-Commercialization Countries, and carry out the activities assigned to it in the applicable Country/Region Commercialization Plan. Each Party shall ensure that its Co-Commercialization activities conform with the parameters in the applicable approved Country/Region Commercialization Plan and the applicable Global Commercialization Plan.
- (d) <u>Field Force Coordination</u>. The JCC or the applicable Committee shall coordinate the Co-Promotion of each Licensed Product by Sanofi, Regeneron, their respective local Affiliates and their respective sales representatives in each Co-Commercialization Country. The Parties will cooperate in the conduct of such activities wire respect to scheduling, geographical allocation, and Professional or other customer targeting in order to optimize profits under the applicable Country/Region Commercialization Plan. Without limiting the generality of the foregoing, in each Co-Commercialization Country the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted.

### (e) Co-Commercialization FTE Efforts.

- (ii) <u>Ophthalmology</u>. In the event that a Licensed Product receives Marketing Approval for an Indication related to ophthalmology, then, at Regeneron's option, Regeneron shall have the lead in the promotion of such Licensed Product in such Indication, provided, however, that the limitations set forth in Section 6.5(e)(i) shall a
- (f) <u>Training</u>. The Parties will coordinate sales force training efforts in Co-Commercialization Countries and will share training materials (and conduct joint training where appropriate) to facilitate joint sales force training efforts.
- (g) <u>Samples</u>. Sanofi shall provide Regeneron with Licensed Product samples for use in Co-Commercialization Countries as required in the applicable Country/Region Commercialization Plan. Sanofi and Regeneron (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable approved Country/Region Commercialization Plan and shall store and distribute samples in compliance with applicable Laws. Each Party (and its local Affiliates) will maintain tho records required by all applicable Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the Licensed Product samples or request.

#### 6.7 Sales and Licensed Product Distribution in the Territory; Other Responsibilities.

- (a) Sanofi (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Sanofi (or its Affiliate) also shall be responsible for (i) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (ii) handling all returns of Licensed Product sold under this Agreement and (iii) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory.
- (b) Sanofi (through its local Affiliates where appropriate), and with respect to the Co-Commercialization Countries, Regeneron (through its local Affiliates where appropriate), shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the determination of Sales Force Cost and Medical Post-Approval Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

## 6.9 Promotional Materials.

(a) Except as provided in and subject to Section 6.9(b): Sanofi will be responsible, consistent with the Marketing Guidelines, the Global Commercialization Plan and the Country/Region Commercialization Plans (as applicable) and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b)(vi for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the Territory, except where Regeneron shall perform such responsibilities as the Lead Regulatory Party. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Sanofi for use in the Territory.

- (b) The Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the Licensed Products which in each case, are approved by the JCC or the applicable Country/Region Commercialization Committee if so delegated by the JCC for the applicable Major Market Country Sanofi shall ensure that Regeneron's sales representatives are provided with reasonable quantities of Promotional Materials for use in a Co-Commercialization Country consistent with the Regeneron Commitment Level for such Co-Commercialization Country in accordance with the applicable approved Country/Region Commercialization Plan. All Promotional Materials generated for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties until such time as they have been reviewed and approved as set forth in this Section.
  - (c) Sanofi shall own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.
- 6.10 <u>Promotional Claims/Compliance</u>. Neither Party nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.
- 6.11 <u>Restriction on Bundling in the Territory</u>. If Sanofi or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Sanofi agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer, (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines.
- 6.12 <u>Inventory Management</u>. Sanofi shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.
  - 6.13 Medical and Consumer Inquiries. The JCC shall establish guidelines to handle medical questions or inquiries from consumers relative to Licensed Products.
- 6.14 <u>Market Exclusivity Extensions</u>. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Licensed Product in the Field may be marketed in such country.

6.15 <u>Post Marketing Clinical Trials</u>. Subject to the provision of this Agreement, the Parties shall comply with any clinical trials obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

#### ARTICLE VII CLINICAL AND REGULATORY AFFAIRS

#### 7.1 Ownership of Approvals and Registration Filings.

- (b) The Lead Regulatory Party shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.
- (c) The non-Lead Regulatory Party shall provide such assistance with respect to regulatory matters as is reasonably requested by the Lead Regulatory Party and consistent with the terms of this Agreement.

#### 7.2 Regulatory Coordination.

- (a) The Lead Regulatory Party shall oversee, monitor and coordinate applicable regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to each Licensed Product in the Field in each jurisdiction as to which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article VII. Without limiting the foregoing, the Lead Regulatory Party will be responsible for and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for each Licensed Product i the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.
- (b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of th Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities and (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the Territory. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory.

- (c) The Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities pertaining to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including, without limitation, all annual and periodic safety reports for Licensed Products in the Field), and consistent with applicable laws, to have up to two (2) representatives from the other Party attend and actively participate in all material, pre-scheduled meetings, telephone conferences and/or discussions with Regulatory Authorities to the extent such material meetings, telephone conferences and/or discussions pertain to the Development and/or Commercialization of any Licensed Product in the Field. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.
- (d) For each Licensed Product, the JDC shall develop and the JSC shall approve proposed target Licensed Product labeling ("Target Labeling") for use in the Territory.
- 7.3 <u>Regulatory Events</u>. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, which:
  - (a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;
  - (b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field anywhere in the Territory.

Information that shall be disclosed pursuant to this Section 7.3 shall include, but not be limited to the following matters with respect to Licensed Products:

- (i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;
- (ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the extent involving matters described in clauses (a), (b) or (c) of this Section 7.3;
  - (iii) receipt of a warning letter issued by a Regulatory Authority;
  - (iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and
  - (v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).
- 7.4 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning pharmacovigilence and risk management plans and product complaint reporting in all countries in which any Licensed Product is being developed, manufactured, or commercialized anywhere in the Territory. Without limitation to the foregoing, the Parties shall execute a Safety Data Exchange Agreement ("SDEA") setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse events/adverse drug reactions and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.
- 7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

7.6 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

## ARTICLE VIII MANUFACTURING AND SUPPLY

8.1 Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product. Until such time as Commercial Supply Requirements are being Manufactured, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements of Licensed Products in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Sanofi's prior written approval, such approval not to be unreasonably withheld or delayed, Sanofi or Third Parties to Manufacture such Formulated Bulk Product. If an entity other than Regeneron is to be used to Manufacture Formulated Bulk Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to Manufacture the applicable Licensed Product in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Party Manufacturers. The Formulated Bulk Product Manufactured by or on behalf of Regeneron for Clinical Supply Requirements will be billed to Sanofi by Regeneron at the Manufacturing Cost per Part I of Schedule 1 as a Development Cost. To the extent that Regeneron maintains manufacturing capacity available for the Manufacture of Clinical Supply Requirements, the cost of maintaining such capacity shall be included as a Development Cost to the extent it is not included as a Manufacturing Cost. For the avoidance of doubt, nothing in this Section 8.1 shall require Regeneron to expand its manufacturing capacity or use any manufacturing capacity acquired or constructed by Regeneron in the future to satisfy its obligations under this Section 8.1 other than those Regeneron manufacturing facilities in Rensselaer, New York that will be constructed pursuant to the Expansion Plan annexed to the Discovery Agreement.

8.2 <u>Finished Product Supply of Clinical Supply Requirements</u>. Regeneron will timely identify, and enter into an agreement with, a Third Party or Third Parties or Sanofi (or use its own facilities, if Regeneron has such capabilities) to perform the filling, packaging, labeling and testing of the Formulated Bulk Product and supply Finished Product for Clinical Supply Requirements for Licensed Products for use under this Agreement. If an entity other than Regeneron is to be used to perform filling, packaging, labeling or testing services related to Finished Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to perform such services in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Parties. Such Finished Product for Clinical Supply Requirements Manufactured on behalf of Regeneron will be billed to Sanofi at the Manufacturing Cost as a Development Cost, in accordance with Part I of Schedule 1.

### 8.3 Manufacture and Supply of Commercial Supply Requirements.

(b) Once Manufacture of Commercial Supply Requirements of a Licensed Product begins, or is scheduled to begin, Manufacture of Clinical Supply Requirements of such Licensed Product shall be coordinated with Manufacture of Commercial Supply Requirements of such Licensed Product. Formulated Bulk Product and/or Finished Product Manufactured by or on behalf of a Party for Commercial Supply Requirements, and for Clinical Supply Requirements that are Manufactured in coordination with the Commercial Supply Requirements, will be billed at the Manufacturing Cost described in Part II of Schedule 1 as a Commercial Supply Cost and Clinical Supply Cost, respectively. If a Party has commercial scale capacity available in anticipation of beginning to Manufacture Commercial Supply Requirements, the JMC shall decide if such Party shall Manufacture any Clinical Supply Requirements even before it begins to Manufacture Commercial Supply Requirements.

- (c) Any Third Party manufacturer of Commercial Supply Requirements or Clinical Supply Requirements will be required to enter into a separate confidentiality agreement with Regeneron prior to the transfer of the manufacturing operations from Regeneron to such Third Party. All of Regeneron's costs and expenses associated with the transfer of the manufacturing operations and related Know-How to the Third Party manufacturer (or Sanofi, to the extent that Sanofi manufactures all or part of the Commercial Supply Requirements or Clinical Supply Requirements) will be billed as a Development Cost.
- 8.4 <u>Supply Agreement</u>. The Parties shall enter into one or more clinical supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements, which shall contain terms consistent with this Agreement. At least \* of a Licensed Product, the Parties shall enter into separate commercial supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements and Commercial Supply Requirements after the First Commercial Sale, which shall contain terms consistent with this Agreement. Each supply agreement will include as an annex thereto a customary quality agreement containing terms and conditions regarding quality assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

- 8.6 <u>Manufacturing Shortfall</u>. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not, despite its using Commercially Reasonable Efforts, be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JMC and JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product (including the other Party) should be utilized.
- 8.7 <u>Manufacturing Compliance</u>. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article VIII or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of Licensed Products in the Field pursuant to this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Sanofi, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

## ARTICLE IX PERIODIC REPORTS; PAYMENTS

- 9.1 <u>Development Costs</u>. Sanofi shall be responsible for paying one hundred percent (100%) of the total Development Costs for each Licensed Product incurred by or on behalf of Sanofi, Regeneron and their respective Affiliates, except that Shared Phase 3 Trial Costs will be shared eighty percent (80%) by Sanofi and twenty percent (20%) by Regeneron. The Parties acknowledge that payments made by Sanofi pursuant to this Section 9.1 are being made as research and development expenses, as defined in Section 41 of the US Internal Revenue Code, and agree that any and all credits or deductions to which either Party may be entitled on account of research performed pursuant to such payments shall be allocated to Sanofi to the extent of such payments.
- 9.2 <u>Milestone Payments</u>. In addition to the other payments contemplated herein, Sanofi shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Sanofi shall have thirty (30) Business Days after the achievement of any such milestones to pay the corresponding amount to Regeneron, in each case, which shall not be reduced by any withholding or similar taxes.

- 9.4 Sharing of Profits from Licensed Products. Commencing on the Effective Date and continuing during the Term, the Parties shall share the U.S. Profit Split in the United States, and (ii) the Rest of World Profit Split in the Rest of World Countries, in each case, as described in Schedule 2.
  - 9.5 Periodic Reports. Sanofi and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:
    - (a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;
  - (b) Within twenty (20) days following the end of each month, commencing with the month in which First Commercial Sale occurs, Sanofi shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;
  - (c) Within forty-five (45) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, Sanofi shall deliver electronically to Regeneron a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;
  - (d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses or Shared Commercial Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses and/or Shared Commercial Expenses incurred by such Party in such Quarter on a country-by-country and Licensed Product-by-Licensed Product basis, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;
  - (e) Within forty-five (45) days after the end of each Quarter, commencing with the Quarter in which First Commercial Sale in a Reporting Country/Region occurs (or such earlier agreed upon calendar Quarter, if appropriate), Sanofi shall provide to Regeneron, in electronic form, for each Reporting Country/Region, and Regeneron shall provide to Sanofi, in electronic form, for each Co-Commercialization Country, a report summarizing in reasonable detail the marketing, detailing, selling and promotional activities undertaken by a Party (or its Affiliates) during the previous Quarter in such Reporting/Country Region and/or Co-Commercialization Country; and

(f) Within sixty (60) days following the end of each Quarter, Sanofi shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article IX and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.5 (including, as applicable, showing the calculation of the U.S. Profit Split and Rest of World Profit Split) and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.5 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

- 9.6 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Sanofi is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Regeneron within fifteen (15) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Sanofi within fifteen (15) days after its receipt of such Consolidated Payment Report from Sanofi. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Sanofi shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any License (to the extent attributable to the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such License, as the case may be.
- 9.7 <u>Invoices and Documentation</u>. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.
- 9.8 <u>Payment Method and Currency</u>. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rates for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.
- 9.9 <u>Late Payments</u>. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. All late payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, \*\*\*\* (such sum being referred to as the "<u>Default Interest Rate</u>").

- 9.10 Taxes. Except as set forth in Section 9.2, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence or other reasonable documentation of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.
- 9.11 <u>Adjustments to FTE Rates</u>. Notwithstanding anything herein to the contrary, upon the request of either Party, the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Sales Force FTE Rate, Medical Post-Approval FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.
- 9.12 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this Article IX, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.11(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

# ARTICLE X DISPUTE RESOLUTION

10.1 <u>Resolution of Disputes</u>. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 <u>Governance Disputes</u>. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article III ("<u>Governance Disputes</u>") shall be resolved pursuant to Article III and, to the extent such matters constitute Technical Development Matters, a dispute referred to in Section 14.2(b) or a Budget Dispute, Section 10.4, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "<u>Technical Development Matter</u>" shall mean any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).

10.3 <u>Legal Disputes</u>. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.11(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.

## 10.4 Expert Panel.

- (a) In the event of a dispute between the Parties concerning a Technical Development Matter, any Budget Dispute or a dispute referred to in Section 14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.11(b) (other than a Legal Dispute), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4 (for the avoidance of doubt, it is understood that, subject to Section 10.4(e), in the case of a Budget Dispute first submitted to the Expert Panel, the specific issue shall be limited to the overall commercial reasonableness of the Disputed Budget). Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.
- (b) Within fifteen (15) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

- (c) Within fifteen (15) days of the appointment of the second (2nd) expert, the two (2) appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third (3rd) expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.
- (d) Within seven (7) days of the appointment of the third (3rd) expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution (which, in the case of a Budget Dispute first submitted to the Expert Panel shall be a Party's proposed resolution that the Disputed Budget either is or is not overall commercially reasonable).

- (e) In rendering the final decision with respect to a Budget Dispute first submitted to the Expert Panel, the Expert Panel shall be limited to determining the overall commercial reasonableness of the Disputed Budget. If the Expert Panel determines that such Disputed Budget is overall commercially reasonable, then such Budget Dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the Expert Panel determines that such Disputed Budget is not overall commercially reasonable, then the Expert Panel shall, within fifteen (15) days after such determination, render a final decision as to what modifications could be made to such Disputed Budget in order for it to be overall commercially reasonable (a "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the Expert Panel shall order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the Disputed Budget in order for it to be overall commercially reasonable, at least seven days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision (which, for other than a Budget Modification Decision, shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions, and for a Budget Modification Decision, shall be rendered no later than seven days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two
- (f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.
- 10.5 <u>No Waiver</u>. Nothing in this Article X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

# ARTICLE XI TRADEMARKS AND CORPORATE LOGOS

- 11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.
- 11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory, unless such Product Trademark is prohibited by law in any country in the Territory or the JCC determines that a different Product Trademark should be used in particular countries or Regions to maximize the commercial potential of such Licensed Product. Once a Product Trademark has been selected by the JCC, the Parties shall enter into an agreement or, in the alternative, shall amend this Agreement as the Parties may agree, in order to address the Parties' respective rights and obligations with respect to such Product Trademark. Each Licensed Product in the Field shall be promoted and sold in the Territory under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

- 11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Sanofi (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory.
- 11.4 <u>Prosecution and Maintenance of Product Trademark(s)</u>. Sanofi will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Sanofi elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of its intention not to prosecute or maintain any such Product Trademark in such country in the Territory, and Regeneron shall have the right to do so on behalf of Sanofi for use with Licensed Products, subject to consultation and cooperation with Sanofi. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of Product Trademarks as provided in this Section 11.4 shall be shared by the Parties as part of Shared Commercial Expenses.

11.5 License to the Product Trademark(s). Sanofi hereby grants to Regeneron a co-exclusive license (non-exclusive only with respect to Regeneron) to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if applicable, Co-Promotion of Licensed Products, or other Regeneron Commercialization activities with respect to Licensed Products if agreed to by Sanofi or set forth in any Plans, subject to the terms and conditions of this Agreement. Consistent with Section 4.4 of this Agreement, neither Party shall license (or in the case of Regeneron, sublicense) rights to use, or otherwise transfer ownership of the Product Trademark(s) without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Sanofi shall only utilize the Product Trademark(s) on approved Promotional Materials, on the Licensed Products as needed and on or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Sanofi or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) in relation to a product that is a Licensed Product, or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version

11.6 <u>Use of Corporate Names</u>. Sanofi (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product), unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples, only for the time period and solely to the extent necessary to exhaust the existing inventory of Licensed Product (including packaging materials for such Licensed Product) and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

# ARTICLE XII NEWLY CREATED INVENTIONS AND KNOW-HOW

# 12.1 Ownership of Newly Created Intellectual Property.

- (a) Subject to Section 12.1(e), each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Sanofi, its Affiliates, employees, agents and consultants are referred to herein as "Sanofi Sole Inventions". Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as "Regeneron Sole Inventions". The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder. Any remuneration payable under applicable law to an inventor and costs associated with determining such remuneration shall be treated as Other Shared Expenses.
- (b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi or its Affiliate (or for which ownership vests in Sanofi or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of Law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole ("Joint Inventions").

- (c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.
- (d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.
- (e) Subject to the other terms and conditions of this Agreement (other than Section 12.1(a)), to the extent permitted under any relevant Third Party agreement, each Party agrees that all Know-How, other than Excluded Know-How Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans shall be Joint Inventions. Each Party agrees to execute all necessary documentation to reflect the foregoing. As used above, the term "Excluded Know-How Rights" shall mean any Know-How claiming or covering composition (including any formulation) of a Licensed Product, including, for the avoidance of doubt, any manufacturing and/or cell line related intellectual property. For further clarity, nothing in this Section 12.1(e) shall be construed to grant either Party any rights to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.
- (f) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article IV, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article XII shall relieve a Party or its Affiliates of their obligations under Article XVI with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

## 12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory. Regeneron shall undertake such activities using outside counsel reasonably acceptable to Sanofi except that all provisionals, the priority application based thereon and the corresponding PCT may be prepared and filed by Regeneron's in-house counsel. Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Regeneron Patent Rights: (i) Regeneron shall provide to Sanofi for review and comment a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and incorporate any reasonable comment from Sanofi within such thirty (30) day period unless Regeneron reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Regeneron shall provide Sanofi promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Sanofi promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent otherwise agreed in writing; and (iv) Regeneron shall consult with Sanofi a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Sanofi of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and Sanofi shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof, in Regeneron's name or Sanofi's name at Sanofi's sole discretion, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Sanofi that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret and Sanofi agrees in writing.

(b) Sanofi shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Sanofi Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Sanofi shall have the following obligations with respect to the filing, prosecution and maintenance of Sanofi Patent Rights: (i) Sanofi shall provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Sanofi and incorporate any reasonable comment from Regeneron unless Sanofi reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Sanofi shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Sanofi shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; and (iv) Sanofi shall consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Sanofi desires to abandon any Patent included in the Sanofi Patent Rights in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Sanofi Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Sanofi's name, unless, with respect to any such Patent Applications that are unpublished, Sanofi notifies Regeneron that Sanofi would prefer to maintain the subject matter of such Patent Application as a trade secret and Regeneron agrees in writing.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners through outside counsel reasonably acceptable to the non-Controlling Party, except that the Controlling Party may prepare and file all provisional applications, priority applications based thereon and the corresponding PCTs using in-house counsel. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and incorporate any reasonable comment provided by the non-Controlling Party within such thirty (30) day period (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all material communications received from or filed in patent offices with respect to such filings and the Parties use all reasonable efforts to reach agreement in a timely manner with respect to all material responses and amendments; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior written notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be treated as Other Shared Expenses.

## 12.3 Interference, Opposition and Reissue.

- (a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Sanofi Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms, provided that if such agreement cannot be reached promptly, such decisions will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties.
- (b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Sanofi Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be treated as Other Shared Expenses.

# ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION AND LICENSES

## 13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a Sanofi Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known, potential or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim.

(b) With respect to any such actual, suspected or potential infringement by virtue of a generic or potential generic competitor's activities in the Field in the Territory, including but not limited to, any ANDA filing, Paragraph IV Certification (or the equivalent for biologics) or other actual or potential infringement by a generic or potential generic competitor anywhere in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made by Sanofi with active assistance from and in consultation with Regeneron. Regeneron will provide reasonable assistance to Sanofi in prosecuting any suit, and if required by Law, will join in the suit. Although Sanofi has the right to select counsel of its own choice, it shall first consult with Regeneron and consider in good faith the recommendations of Regeneron. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties or according to the U.S. Profit Split and Rest of World Profit Split if and as applicable.

(c) With respect to all other such actual, potential or suspected infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully in an effort to determine a mutually agreeable course of action, provided if such agreement cannot be reached promptly, final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party." The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties.

- (d) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) or (c) related to activities in the Field in the Territory shall be treated as Other Shared Expenses.
- (e) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.
- 13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

## 13.3 Third Party Infringement Claims; New Licenses.

- (a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it using its own counsel; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party.
- (b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be treated as Other Shared Expenses.
- (d) License fees, royalties and other payments under Licenses to the extent attributable to, and based on, the Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be treated as Other Shared Expenses.

## ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

## 14.2 Audits and Adjustments.

- (a) Each Party shall have the right (at its own cost), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.
- (b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article X. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than seven and one-half percent (7.5%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article XVI.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 <u>GAAP/IAS/IFRS</u>. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with, at a Party's election, GAAP or IAS/IFRS.

# ARTICLE XV REPRESENTATIONS, WARRANTIES AND COVENANTS

- 15.1 <u>Due Organization, Valid Existence and Due Authorization; Financial Capability.</u> Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate (or, in the case of Sanofi Amerique, partnership) power and authority and has taken all corporate (or, in the case of Sanofi Amerique, partnership) action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article IV hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder.
- 15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.
  - 15.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:

- (a) Regeneron owns all right, title and interest in and to all Regeneron Patent Rights in existence as of the Effective Date;
- (b) Regeneron has the right and authority to grant the rights granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;
- (c) there is no pending litigation that alleges that any of Regeneron's activities relating to the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);
- (d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;
- (e) the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other rights of any Person;
- (f) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;
- (g) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings; and
- (h) Regeneron has enforceable written agreements with all of its employees and contractors who may participate in the conduct of the Collaboration or receive Confidential Information hereunder assigning to Regeneron ownership of all intellectual property rights created in the course of their employment or provision of services, as applicable.
- 15.4 <u>Disclaimer of Wartanties</u>. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) it will not during the Term grant any right or license to any Third Party in the Territory which would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) in the course of the Development or Commercialization of a Licensed Product in the Field under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

## ARTICLE XVI CONFIDENTIALITY

## 16.1 Confidential Information.

(a) Each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI and the provisions of Article XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Sanofi, Party Information provided to it under the Confidentiality Agreements is confidential and proprietary to such other Party. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI) that all New Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article XVI, each of Sanofi and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

- (b) Notwithstanding anything provided above, the restrictions provided in this Article XVI shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.
- (c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.
- (d) Notwithstanding anything provided above or elsewhere in this Agreement, Sanofi and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law
- 16.2 <u>Injunctive Relief</u>. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

16.3 <u>Publication of New Information</u>. During the Term, if either Sanofi or Regeneron (the "<u>Publishing Party</u>") desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).

16.4 Disclosures Concerning this Agreement. The Parties will mutually agree upon the contents of their respective press releases with respect to the execution of this Agreement and any Ancillary Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not ) issue any other press releases or public announcements concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Sanofi acknowledges that Regeneron as a publicly traded company may be legally obligated to make timely disclosures of material events relating to Licensed Products. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement and each Ancillary Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

# ARTICLE XVII INDEMNITY

## 17.1 Indemnity and Insurance.

- (a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:
  - (i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Sanofi, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or
    - (ii) material breach by Sanofi of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.
- (b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees, Sublicensees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:
  - (i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Sanofi or any other Sanofi Indemnitee; or
    - (ii) material breach by Regeneron of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.

- (c) In the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.
- (d) In the event of any Third Party product liability claim alleging that the Development or Commercialization of any Licensed Product in the Field causes damages for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.
- (f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Sanofi Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article VIII; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article VIII.
- 17.2 <u>Indemnity Procedure</u>. The Party entitled to indemnification under this Article XVII (an "<u>Indemnified Party</u>") shall notify the Party potentially responsible for such indemnification (the "<u>Indemnifying Party</u>") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).

- (a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written
- (b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.
- (c) The amount of any Damages for which indemnification is provided under this Article XVII will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.
- (d) If an Indemnified Party receives an indemnification payment pursuant to this Article XVII and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article XVII and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article XVII.

## ARTICLE XVIII FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

# ARTICLE XIX TERM AND TERMINATION

## 19.1 Term/Expiration of Term.

- (a) The "Term" of this Agreement commenced on the Original Effective Date and, unless this Agreement is earlier terminated in its entirety in accordance with this Article XIX, shall expire upon the later to occur of (i) the expiration of the Discovery Program, and (ii) such time as neither Party, nor either Party's Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent.
- (b) Upon expiration of the Term pursuant to Section 19.1(a) above, except as set forth in this Agreement, all licenses and rights with respect to Licensed Products shall automatically terminate and revert to the granting Party.

### 19.2 Termination Without Cause.

(a) By Sanofi. (i) Sanofi may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with the terms of the Discovery Agreement, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case on twelve (12) months' prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2(a), in the event of such termination by Sanofi of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2, this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Sanofi Termination Notice Period") and the terms of Schedule 4 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(a) or Schedule 4, during the Sanofi Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Products(s)) in the Field in accordance with Plans. During the Sanofi Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Sanofi hereunder and in any event upon the expiration of the Sanofi Termination Notice Period, whether or not any such notice is given by Regeneron, (i) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Sanofi Termination Notice Period), (ii) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall terminate, and (iii) Sanofi will promptly take the actions required by Schedule 4 and Regeneron will reasonably cooperate with Sanofi (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Sanofi Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Sanofi Termination Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Sanofi Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

(ii) In addition to Sanofi's termination rights set forth in Section 19.2(a)(i), from and after the twelfth (12<sup>th</sup>) anniversary of the First Commercial Sale of a Licensed Product in a country, Sanofi may, upon twenty-four (24) months' prior written notice to Regeneron, terminate this Agreement with respect to such Licensed Product in such country. If Sanofi exercises such right, the provisions of Section 19.2(a)(i) (except that the Sanofi Termination Notice Period referred to therein shall be twenty-four (24) months rather than twelve (12) months), and Sections 19.7(a) and 19.8 shall apply with respect to such Terminated Licensed Product in such country.

(b) By Regeneron. Regeneron may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with its terms, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case, on twelve (12) months' prior written notice to Sanofi. Except as otherwise provided below in this Section 19.2(b), in the event of such termination by Regeneron of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2(b), this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Regeneron Termination Notice Period") and the terms of Schedule 5 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(b) or Schedule 5, during the Regeneron Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Products(s)) in the Field in accordance with Plans. During the Regeneron Termination Notice Period, to the extent set forth or requested in one or more written notices from Sanofi to Regeneron hereunder and in any event upon the expiration of the Regeneron Termination Notice Period, whether or not any such notice is given by Sanofi, (i) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Regeneron Termination Notice Period), (ii) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Products(s) shall terminate, and (iii) Regeneron will promptly take the actions required by Schedule 5 and Sanofi will reasonably cooperate with Regeneron (for avoidance of doubt, such cooperation shall not require Sanofi to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Sanofi) to facilitate Sanofi's (or its nominee's) expeditious assumption during the Regeneron Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Regeneron Termination Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Regeneron Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety or for a particular Licensed Product or particular Licensed Products in the Field in the entire Territory, upon written notice to the other Party, if such other Party commits a material breach of its obligations under this Agreement with respect to such Licensed Product(s) as to which such notice of termination is given (or all Licensed Products if such notice of termination is with respect to this Agreement is in its entirety). Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above) material breach by a Party, as determined by a court of competent jurisdiction.

19.4 <u>Termination for Insolvency</u>. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill or Lock-Up. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Aventis Stock Purchase Agreement, to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of section 20.16 or of paragraphs (a) through (e) of Section Agreement, as applicable.

## 19.6 Termination of Discovery Agreement.

- (a) <u>By Regeneron</u>. Regeneron may terminate this Agreement in its entirety, effective upon written notice to Sanofi, if the Discovery Agreement has been terminated by Regeneron pursuant to Section 12.2, 12.3 or 12.4 thereof.
- (b) <u>By Sanofi</u>. Sanofi may terminate this Agreement in its entirety effective upon written notice to Regeneron, if the Discovery Agreement has been terminated by Sanofi pursuant to Section 12.2 or 12.3 thereof.

## 19.7 Effect of Termination.

(a) Except as provided in Section 19.2(b), and in Section 19.7(b) below, upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the provisions of Schedule 4 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s), and except to the extent required by Sanofi to fulfill its obligations pursuant to Schedule 4, (i) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Sanofi and its Affiliates to Regeneron referred to in Schedule 4 shall automatically come into full force and effect with respect to the Terminated Licensed Product(s). If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, or pursuant to Section 19.6(a) then Sanofi shall pay to Regeneron, in addition to any other amount payable by Sanofi to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to one hundred percent (100%) of the Development Costs incurred by Regeneron under the Global Development Plan during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

- (b) Upon termination of this Agreement by Regeneron pursuant to Section 19.2(b) or by Sanofi pursuant to Section 19.3 or 19.4, in its entirety, or for a particular Licensed Product or particular Licensed Products in the Field, the provisions of Schedule 5 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s) and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 5, (i) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Sanofi, (ii) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Regeneron referred to in Schedule 5 shall come into full force and effect with respect to the Terminated Licensed Product(s)
- 19.8 <u>Survival of Obligations</u>. Except as otherwise provided in this Article XIX, or Schedule 4 or Schedule 5, upon expiration, or upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the rights and obligations of the Parties hereunder with respect to the Terminated Licensed Product(s), in the applicable country or countries if such termination is pursuant to Section 19.2(a)(ii), shall terminate, and this Agreement shall cease to be of further force or effect to the extent of such termination, provided that notwithstanding any expiration or termination of this Agreement:
  - (a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero;
  - (b) subject to the provisions of this Article XIX, including Schedule 4 and Schedule 5 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article XVI, as well as other provisions (including, without limitation, Sections 7.4, 9.8, 9.9, 9.12, 10.3 and 10.4, the second sentence of Section 12.1(e) and Articles XII (with respect to Joint Inventions), XVI, XVII, XIX and XX) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and
    - (c) such expiration or termination and this Article XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

# ARTICLE XX MISCELLANEOUS

- 20.1 <u>Governing Law; Submission to Jurisdiction</u>. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article X, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- 20.2 <u>Waiver</u>. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.
- 20.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 6 attached hereto and shall be (a) delivered personally, (b) sent via a reputable nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.
- 20.4 Entire Agreement. This Agreement, together with the Discovery Agreement and, solely to the extent referred to herein, the Ancillary Agreements contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof, provided that the last sentence of Section 14.4 of the Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the Discovery Agreement.
- 20.5 <u>Amendments</u>. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.
- 20.6 <u>Interpretation</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words "herein" or "hereunder" relate to this Agreement.

20.7 <u>Severability</u>. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("<u>Modified Clause</u>"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.8 <u>Registration and Filing of the Agreement</u>. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 <u>Assignment</u>. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 <u>Affiliates</u>. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Sanofi Amerique guarantees to Regeneron the prompt and timely payment of amounts payable by Sanofi to Regeneron hereunder once those amounts have become legally due and payable. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

- 20.12 <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.
- 20.13 <u>Third-Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article XVII is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.
- 20.14 <u>Relationship of the Parties</u>. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.
- 20.15 <u>Limitation of Damages</u>. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS.
- 20.16 <u>Non-Solicitation</u>. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.
  - 20.17 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Sanofi, Sanofi Amerique and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

# AVENTIS PHARMACEUTICALS INC.

By /s/ John M. Spinnato

Name: John M. Spinnato

Title: VP & General Counsel, US Legal

By /s/ Christian Blin

Name: Christian Blin
Title: VP, R&D Finance

## SANOFI-AVENTIS AMERIQUE DU NORD

(solely for purposes of Section 15.1, 15.2 and 20.11).

By /s/ Jose Ferrer

Name: Jose Ferrer

Title: VP, Legal Operations

By /s/ Christian Blin

Name: Christian Blin
Title: VP, R&D Finance

# REGENERON PHARMACEUTICALS, INC.

By /s/ Murray Goldberg

Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

# EXHIBIT A

# Royalties For Opt-Out Products

Stage of Development at Opt-Out		Royalties on Net Sales
*******		****
*******		****
	1	

# Manufacturing Cost

\*\*\*\*\*\*\*\*\*\*

### Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the U.S. Profit Split for such Quarter payable to Regeneron (as set forth in Part I), plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron (as set forth in Part II), minus (c) the Development Compensation Payment for such Quarter payable to Sanofi (as set forth in Part III), plus or minus (d) the Regeneron Reimbursement Amount for such Quarter payable to either Regeneron or Sanofi (as set forth in Part IV).

In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

# I. U.S. PROFIT SPLIT

The "<u>U.S. Profit Split</u>" shall mean fifty percent (50%) of U.S. Profits in a Quarter. "<u>U.S. Profits</u>" in a Quarter shall mean aggregate Net Sales of all Licensed Products in the U.S. in the Quarter less the sum of (a) aggregate COGS in the U.S. in the Quarter, (b) aggregate Shared Commercial Expenses incurred by both Parties and allocable to the U.S. in the Quarter, and (c) aggregate Other Shared Expenses incurred by both Parties and allocable to, the U.S. in the Quarter.

An example of a calculation of the U.S. Profit Split in a Quarter would be:

\*\*\*\*\*\*\*\*

## II. REST OF WORLD PROFIT SPLIT

The Parties intend to share profits from Net Sales of Licensed Products in the Rest of World (or ROW) in each Contract Year (the "Rest of World Profit Split," defined below) based on the aggregate amount of such Net Sales in accordance with the Target ROW Profit Split (defined below). Since the full calculation cannot be done until aggregate Net Sales for the full Contract Year are known, each Quarter, the Parties will calculate an estimated profit split for the Quarter based on Net Sales for the Quarter in ROW and the Applicable ROW Percentages (defined below). Following the end of each Contract Year, the Parties will true-up the quarterly estimates of the Rest of World Profit Split to the Target ROW Profit Split through the ROW Profit Split Annual True-Up calculation (defined below).

The "Target ROW Profit Split" for any Contract Year shall mean a profit split whereby ROW Profits from ROW Net Sales of all Licensed Products up to \*\*\*\*\*\*\*\*\*\* in the Contract Year are split 65% Sanofi/35% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products from \*\*\*\*\*\*\*\*\*\* up to \$750 million in the Contract Year are split 60% Sanofi/40% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products greater than \$750 million in the Contract Year are split 55% Sanofi/45% Regeneron, with all profit splits calculated using the assumption that the ratio of ROW Profits to ROW Net Sales is the same on each dollar of ROW Net Sales in the Contract Year.

The "Applicable ROW Percentages" for the Quarter for each of Sanofi and Regeneron shall mean the percentages to be used to calculate each Party's Rest of World Profit Split for the Quarter, as illustrated in the example below. At the end of each Contract Year, as part of the calculation of the fourth Quarter Rest of World Profit Split, a "ROW Profit Split Annual True-Up" shall also be calculated to make each Party's Rest of World Profit Split for the Contract Year equal to the Target ROW Profit Split. Calculation of the Applicable ROW Percentages and Rest of World Profit Splits for a Quarter and ROW Profit Split Annual True-Up for a Contract Year are illustrated in the example below.

\*\*\*\*\*\*\*

Notwithstanding the method of calculation shown above, in any Quarter (or for any full Contract Year) in which the ROW Profits are negative, the Applicable ROW Percentages for such Quarter (or for such Contract Year after calculation of the ROW Profit Split Annual True-Up) shall be fifty-five percent (55%) for Sanofi and forty-five percent (45%) for Regeneron.

An example of a calculation of the Rest of World Profit Split in a Quarter would be:

\*\*\*\*\*\*\*\*\*

### III. DEVELOPMENT COMPENSATION PAYMENT

The "Regeneron Profit Split" in a Quarter shall mean the sum of (a) the U.S. Profit Split for such Quarter payable to Regeneron plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron.

The "Development Balance" as of the end of a Quarter shall mean (a) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plans for all Licensed Products from the Effective Date through the close of such Quarter, excluding any Shared Phase 3 Trial Costs, plus (b) thirty percent (30%) of the aggregate amount of Shared Phase 3 Trial Costs incurred by both Parties under the Global Development Plans for all Licensed Products from the Effective Date through the close of such Quarter, less (c) the aggregate amount of Development Compensation Payments included in the calculation of the Quarterly True-Up in all prior Quarters.

If both the Development Balance as of the end of a Quarter is greater than zero and the Regeneron Profit Split for the Quarter is greater than zero, the "Development Compensation <u>Payment</u>" for such Quarter shall equal the lower of (a) ten percent (10%) of the Regeneron Profit Split for the Quarter and (b) the Development Balance. Otherwise, the Development Compensation Payment for the Quarter shall equal zero.

An example of a calculation of the Development Compensation Payment in a Quarter would be:

Development Balance at the end of the Quarter	900
U.S. Profit Split payable to Regeneron	350
Rest of World Profit Split payable to Regeneron	380
Regeneron Profit Split	730
10% of the Regeneron Profit Split	73
Development Compensation Payment	73

For the avoidance of doubt, the Development Costs for and Opt-Out Product until the time such Opt-Out Product becomes an Opt-Out Product are included in the calculation of the Development Balance.

## IV. REGENERON REIMBURSEMENT AMOUNT

The "Regeneron Reimbursement Amount" for a Quarter shall mean (a) aggregate Shared Commercial Expenses incurred by Regeneron in the U.S. and ROW in the Quarter for all Licensed Products, plus (b) aggregate Other Shared Expenses incurred by Regeneron in the U.S. and ROW in the Quarter for all Licensed Products, plus (c) Development Costs incurred by Regeneron under a Global Development Plan in the Quarter for all Licensed Products, other than Shared Phase 3 Trial Costs, plus (d) aggregate Shared Phase 3 Trial Costs incurred by Regeneron under a Global Development Plan in the Quarter for all Licensed Products minus twenty percent (20%) of the aggregate Shared Phase 3 Trial Costs incurred by both Sanofi and Regeneron under a Global Development Plan in the Quarter for all Licensed Products (with the amount so calculated in this clause (d) called the "Shared Phase 3 Trial Costs Balance"). For clarity, if the Shared Phase 3 Trial Costs Balance is negative, it shall be subtracted from the amount otherwise payable to Regeneron as a Regeneron Reimbursement Amount, and if the total Regeneron Reimbursement Amount is negative, it shall be a negative number in the calculation of the Quarterly True-Up.

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Commercial Expenses in the U.S.	50
Regeneron Shared Commercial Expenses in ROW	100
Regeneron Other Shared Expenses in the U.S.	10
Regeneron Other Shared Expenses in ROW	10
Regeneron Development Costs under a Global Development Plan	80
Shared Phase 3 Trial Costs Balance	0
Regeneron Reimbursement Amount	250

# V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-Up in a Quarter would be:

U.S. Profit Split Payable to Regeneron	350
ROW Profit Split Payable to Regeneron	380
Development Compensation Payment	(73)
Regeneron Reimbursement Amount	250
Quarterly True-Up	907

In this example, Sanofi would pay Regeneron 907 in accordance with the terms set forth in Article 9.

## Sales Milestones

Aggregate annual Net Sales of all Licensed Products in Rest of World Countries Sales Milestone

US\$1 billion	*******
*****	*******
*****	*******
*****	******
****	******

For purposes of clarification, each of the foregoing milestone payments shall be made only once and only upon the first occurrence of each milestone. Aggregate annual Net Sales of Licensed Products shall be determined based on the aggregate Net Sales of all Licensed Products in Rest of World Countries in any rolling twelve (12) month period.

### **Termination Arrangements**

The rights and obligations set forth in this Schedule 4 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which, and, if applicable pursuant to Section 19.2(a)(ii), only in the country or countries in which, this Agreement has been terminated.

- 1. Sanofi shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information directly related to any Terminated Licensed Product(s), and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to any Terminated Licensed Product(s). In addition, at Regeneron's request, Sanofi shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, sales training materials, samples, and product inventory. Notwithstanding the foregoing, Sanofi may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.
- 2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than any royalties due for any Royalty Products under the Discovery Agreement and any amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Sanofi), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Sanofi Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing and Commercializing Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Sanofi Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Sanofi Intellectual Property retained by Sanofi).
- 3. Sanofi shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:
- (a) Sanofi shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Sanofi or its Affiliates or any of its Sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

- (b) Sanofi shall assign and transfer to Regeneron (or its nominee) Sanofi's entire right, title and interest in and to all Product Trademarks for any Terminated Licensed Product(s) and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Sanofi's corporate name and logos or any trade names except for the limited rights set forth herein.
- (c) Sanofi shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Sanofi, or such other format as may be reasonably requested by Regeneron.
- (d) Sanofi shall use Commercially Reasonable Efforts to assign to Regeneron any applicable Licenses and sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Regeneron.
- (e) Without limitation of Sanofi's other obligations under this Schedule 4, to the extent Sanofi or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Sanofi (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Regeneron shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Sanofi was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Regeneron notifies Sanofi that Regeneron is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.
- 4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the development, manufacture, and commercialization of the Terminated Licensed Product(s) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.
- 5. For the avoidance of doubt, except as expressly provided in the Discovery Agreement or this Agreement, Regeneron shall not be required to provide Sanofi any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 4; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Sanofi may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

### **Termination Arrangements**

The rights and obligations set forth in this Schedule 5 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which this Agreement has been terminated.

- 1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Sanofi or, at Sanofi's request, destroy, all documents containing New Information or Party Information of Sanofi and its Affiliates directly related to any Opt-Out Products, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to the Terminated Licensed Product(s). In addition, at Sanofi's request, Regeneron shall collect and transfer to Sanofi any remaining inventory of Promotional Materials, sales training materials, product samples and product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.
- 2. Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing, and Commercializing the Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Regeneron Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Regeneron Intellectual Property retained by Regeneron.
- 3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Sanofi to enable Sanofi (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:
- (a) Regeneron shall transfer and assign to Sanofi (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

- (b) Regeneron shall assign and transfer to Sanofi (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for the Terminated Licensed Product(s) and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.
- (c) Regeneron shall provide to Sanofi (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Sanofi.
- (d) Regeneron shall use Commercially Reasonable Efforts to assign to Sanofi any applicable Licenses and sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Sanofi.
- (e) Without limitation of Regeneron's other obligations under this Schedule 5, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Sanofi with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Sanofi shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Sanofi notifies Regeneron that Sanofi is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.
- 4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field hereunder to Sanofi (or its Sublicensee or Third Party designee) as soon as is reasonably possible.
- 5. For the avoidance of doubt, Sanofi shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 5; provided, however, that Sanofi shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Sanofi of such licenses or other rights.

## **Notices**

## (a) If to Sanofi or Sanofi Amerique:

Aventis Pharmaceuticals Inc 200 Crossing Boulevard Bridgewater New Jersey 08807 USA

Attention: President R&D Copy: General Counsel

With a copy to:

sanofi-aventis 174 Avenue de France Paris, France 75017 Attention: General Counsel

# (b) If to Regeneron:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 U.S.A. Attention: President Copy: General Counsel

With a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP One Beacon Street, 31<sup>st</sup> Floor Boston, Massachusetts 02108 Attention: Kent A. Coit

## Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

# I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this Amendment No. 1 to annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: June 2, 2010 By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

## Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

# I, Murray A. Goldberg, certify that:

- 1. I have reviewed this Amendment No. 1 to annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: June 2, 2010 By: /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary