May 7, 2015

Regeneron Reports First Quarter 2015 Financial and Operating Results

- First quarter 2015 EYLEA® (aflibercept) Injection global net sales increased 44% to $833 million (consisting of $541 million in the U.S. and $292 million in rest of world(1)) versus first quarter 2014
- First quarter 2015 non-GAAP net income(2) increased 28% to $336 million, or $2.88 per diluted share, versus first quarter 2014
- Raised estimated full year 2015 EYLEA U.S. net sales growth guidance to 30% - 35% over 2014

TARRYTOWN, N.Y., May 7, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2015 and provided an update on development programs.

Financial Highlights

($ in millions, except per share data)	Three Months Ended March 31,		
	2015	2014*	% Change
EYLEA U.S. net product sales	$ 541	$ 359	51 %
Total revenues	$ 870	$ 626	39 %
Non-GAAP net income (2)	$ 336	$ 263	28 %
Non-GAAP net income per share - diluted (2)	$ 2.88	$ 2.26	27 %
GAAP net income	$ 76	$ 68	12 %
GAAP net income per share - diluted	$ 0.66	$ 0.61	8 %

** See note (4) below for an explanation of revisions made to certain amounts previously reported for the three months ended March 31, 2014.*

"EYLEA started the year with strong performance, particularly in the U.S., where it is the leading FDA-approved anti-VEGF retinal therapy," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "In addition to continued sales and market share growth for EYLEA, this year marks an inflection point in our business with the upcoming FDA review and potential launch of Praluent for hypercholesterolemia as well as the continued advancement of our innovative pipeline, which we expect to include five late-stage programs across a range of serious diseases by the end of the year."

Business Highlights

EYLEA® (aflibercept) Injection for Intravitreal Injection

- In the first quarter of 2015, net sales of EYLEA in the United States increased 51% to $541 million from $359 million in the first quarter of 2014. Overall distributor inventory levels remained within the Company's one- to two-week targeted range.
- Bayer HealthCare commercializes EYLEA outside the United States. In the first quarter of 2015, net sales of EYLEA outside of the United States(1) were $292 million, compared to $218 million in the first quarter of 2014. In the first quarter of 2015, Regeneron recognized $89 million from its share of net profit from EYLEA sales outside the United States (after repayment of $14 million in development expenses), compared to $61 million in the first quarter of 2014 (after repayment of $14 million in development expenses).
- In March 2015, the U.S. Food and Drug Administration (FDA) approved EYLEA for the treatment of diabetic retinopathy in patients with diabetic macular edema (DME).
- In February 2015, the European Commission approved EYLEA for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO), which includes macular edema following branch retinal vein occlusion (BRVO), in addition to the previously-approved indication of macular edema secondary to central retinal vein occlusion (CRVO).
- In February 2015, the Company announced that results from the National Institutes of Health (NIH)-sponsored, Diabetic Retinopathy Clinical Research Network comparative effectiveness study in patients with DME (Protocol T) were published in *The New England Journal of Medicine*. In this study, EYLEA demonstrated significantly greater improvement on the primary endpoint of mean visual acuity letter score change at one year (EYLEA +13 letters; bevacizumab (Avastin®) +10; ranibizumab (Lucentis®) +11). These differences were driven by patients with moderate or worse vision loss at the start

of the trial (worse than 20/40); in these patients, EYLEA showed a statistically significant 7-letter (approximately 1.5 lines on an eye chart) improvement over bevacizumab and a 5-letter (1 line on an eye chart) improvement over ranibizumab (EYLEA +19 letters; bevacizumab +12; ranibizumab +14). The independently conducted, government-sponsored study was designed to compare three different anti-VEGF therapies, EYLEA, bevacizumab and ranibizumab, for the treatment of DME.

Pipeline Progress

Regeneron has fifteen fully human monoclonal antibodies generated using the Company's *VelocImmune*® technology in clinical development, including five in collaboration with Sanofi(5). Highlights from the antibody pipeline include:

Praluent® (alirocumab) is the Company's antibody targeting PCSK9 to lower LDL-cholesterol (LDL-C or "bad" cholesterol).

- In January 2015, the FDA accepted for priority review the BLA for Praluent, with a target action date of July 24, 2015. The FDA's Endocrinologic and Metabolic Drugs Advisory Committee is scheduled to meet on June 9, 2015 to discuss the BLA for Praluent.
- The European Medicines Agency (EMA) has also accepted for review the Marketing Authorization Application (MAA) for Praluent.
- In January 2015, the Company and Sanofi announced that the ODYSSEY CHOICE I and ODYSSEY CHOICE II studies, which evaluated every four-week dosing, met their primary efficacy endpoints. The trials compared the reduction from baseline in LDL-C at 24 weeks with Praluent versus placebo in patients with hypercholesterolemia.
- In February 2015, 18-month (78-week) results of the ODYSSEY LONG TERM Phase 3 trial of Praluent, involving 2,341 high risk patients with hypercholesterolemia, were published online in *The New England Journal of Medicine*. In this trial, Praluent 150 mg every two weeks reduced LDL-C by an additional 62% at week 24 when compared to placebo, the primary efficacy endpoint of the study, with consistent LDL-C lowering maintained over 78 weeks.
- The Phase 3 ODYSSEY program remains ongoing.

Sarilumab, the Company's antibody targeting IL-6R for rheumatoid arthritis, is currently being studied in the global Phase 3 SARIL-RA program. The Company and Sanofi plan to present new Phase 3 data in 2015 and submit a BLA in the United States by the end of 2015.

Dupilumab, the Company's antibody that blocks signaling of IL-4 and IL-13, is currently being studied in atopic dermatitis, asthma, nasal polyps in patients with chronic sinusitis, and eosinophilic esophagitis.

- Multiple Phase 3 studies of dupilumab in atopic dermatitis are currently underway.
- A Phase 3 study of dupilumab in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015. Results of the interim analysis of a dose-ranging Phase 2b of dupilumab in adult patients with uncontrolled persistent asthma will be presented at the American Thoracic Society meeting later this month.
- In the first quarter of 2015, a Phase 2 study of dupilumab in adolescents and children with atopic dermatitis was initiated.
- In the first quarter of 2015, a Phase 2 study of dupilumab in eosinophilic esophagitis was initiated.

Fasinumab, an antibody targeting Nerve Growth Factor (NGF), is expected to re-enter clinical development in mid-2015.

REGN2222, an antibody targeting the respiratory syncytial virus (RSV), is expected to enter pivotal trials in mid-2015(5).

REGN2176-3, a combination product comprised of an antibody to PDGFR-beta co-formulated with EYLEA for use in ophthalmology, entered Phase 2 clinical development in the second quarter of 2015.

REGN2810, an antibody targeting PD-1, entered Phase 1 clinical development for the treatment of cancer in the first quarter of 2015.

REGN1500, an antibody to Angptl-3, entered Phase 2 clinical development for the treatment of dyslipidemia in homozygous familial hypercholesterolemia in the first quarter of 2015.

REGN1033, the Company's antibody to GDF8/Myostatin, met the primary endpoint of an increase in lean body mass by bone density (DXA) scan at 12-weeks compared to placebo in a Phase 2 proof-of-concept study in elderly men and women with sarcopenia. The results of the secondary, functional endpoints were mixed. The most common adverse events were injection site reactions. The Company and Sanofi are in the process of analyzing the primary and secondary endpoints to determine the appropriate next steps. Data will be presented at a future medical meeting.

First Quarter 2015 Financial Results

Product Revenues: Net product sales were $545 million in the first quarter of 2015, compared to $362 million in the first quarter of 2014. EYLEA net product sales in the United States were $541 million in the first quarter of 2015, compared to $359 million in the first quarter of 2014.

Total Revenues: Total revenues, which include product revenues described above, increased by 39% to $870 million in the first quarter of 2015, compared to $626 million in the first quarter of 2014. Total revenues also include collaboration revenues of $297 million in the first quarter of 2015, compared to $256 million in the first quarter of 2014. Collaboration revenues in the first quarter of 2015 increased primarily due to higher reimbursement of the Company's development expenses under its antibody collaboration with Sanofi and an increase in the Company's net profit from commercialization of EYLEA outside the United States, partly offset by the Company's share of antibody collaboration commercialization costs primarily related to Praluent. In addition, collaboration revenues in the first quarter of 2015 and 2014 included $15 million and $30 million, respectively, of sales milestones earned from Bayer HealthCare. Refer to Table 4 for a summary of collaboration revenue.

In addition, in February 2015, the Company and Sanofi entered into an amended ZALTRAP® agreement which amended and restated the companies' ZALTRAP collaboration agreement. In connection with the amended ZALTRAP agreement, the Company recorded $20 million of revenue within technology licensing and other revenue primarily related to manufacturing ZALTRAP commercial supplies for Sanofi and revenues earned based on a percentage of net sales of ZALTRAP.

Research and Development (R&D) Expenses: GAAP R&D expenses were $343 million in the first quarter of 2015, compared to $287 million in the first quarter of 2014. The higher R&D expenses in the first quarter of 2015 were principally due to higher costs related to manufacturing Praluent drug supplies, higher headcount to support the Company's increased R&D activities, and higher development costs primarily related to dupilumab. In addition, in the first quarter of 2015, R&D-related non-cash share-based compensation expense was $60 million, compared to $43 million in the first quarter of 2014.

Selling, General, and Administrative (SG&A) Expenses: GAAP SG&A expenses were $159 million in the first quarter of 2015, compared to $103 million in the first quarter of 2014. The increase was primarily due to higher expenses associated with the Branded Prescription Drug Fee, and higher headcount and headcount-related costs. In addition, in the first quarter of 2015, SG&A-related non-cash share-based compensation expense was $42 million, compared to $32 million in the first quarter of 2014.

Income Tax Expense: GAAP income tax expense was $201 million in the first quarter of 2015, compared to $113 million in the first quarter of 2014. The effective tax rate was 72.5% for the first quarter of 2015, compared to 62.2% for the first quarter of 2014. The effective tax rate for the first quarter of 2015 was negatively impacted primarily by (i) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, (ii) the non-tax deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities. GAAP income tax expense in the first quarter of 2015 and 2014 was principally a non-cash expense, due primarily to the utilization of net operating loss and tax credit carryforwards, and deductions related to employee stock option exercises.

Non-GAAP and GAAP Net Income: The Company reported non-GAAP net income of $336 million, or $3.28 per basic share and $2.88 per diluted share, in the first quarter of 2015, compared to non-GAAP net income of $263 million, or $2.66 per basic share and $2.26 per diluted share, in the first quarter of 2014.

The Company reported GAAP net income of $76 million, or $0.74 per basic share and $0.66 per diluted share, in the first quarter of 2015, compared to GAAP net income of $68 million, or $0.69 per basic share and $0.61 per diluted share, in the first quarter of 2014.

A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

2015 Financial Guidance[(3)]

The Company's updated full year 2015 financial guidance consists of the following components:

EYLEA U.S. net product sales	30% - 35% growth over 2014 *(previously 25% - 30% growth over 2014)*
Non-GAAP unreimbursed R&D [(2)]	$525 million - $575 million *(reaffirmed)*
Non-GAAP SG&A [(2)]	$650 million - $725 million *(reaffirmed)*
Cash tax as a % of non-GAAP pre-tax income [(2)]	10% - 20% *(reaffirmed)*
Capital expenditures	$650 million - $750 million *(previously $650 million - $800 million)*

(1) Regeneron records net product sales of EYLEA in the United States. Outside the United States, EYLEA net product sales comprise sales by Bayer HealthCare in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer HealthCare. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within "Bayer HealthCare collaboration revenue" in its Statements of Operations.

(2) This press release uses non-GAAP net income, non-GAAP net income per share, non-GAAP unreimbursed R&D, non-GAAP SG&A, and cash tax as a percentage of non-GAAP pre-tax income, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The Company believes that the presentation of these non-GAAP measures is useful to investors because they exclude, as applicable: (i) non-cash share-based compensation expense, which fluctuates from period to period based on factors that are not within the Company's control, such as the Company's stock price on the dates share-based grants are issued; (ii) non-cash interest expense related to the Company's convertible senior notes since this is not deemed useful in evaluating the Company's operating performance; (iii) loss on extinguishment of debt, since this non-cash charge is based on factors that are not within the Company's control; and (iv) income tax expense for 2014, which was principally a non-cash expense due primarily to utilization of net operating loss and tax credit carry-forwards, and deductions related to employee stock option exercises. In 2015, income tax expense adjustments consider the tax effect of reconciling items and an adjustment from GAAP tax expense to the amount of taxes that are paid or payable in cash in respect of the current period. As there is a significant difference between the Company's effective tax rate and actual cash income taxes paid or payable, GAAP income tax expense is not deemed useful in evaluating the Company's operating performance. Non-GAAP unreimbursed R&D represents non-GAAP R&D expenses reduced by R&D expense reimbursements from the Company's collaboration partners. Management uses these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the Company's historical GAAP to non-GAAP results is included in Table 3 of this press release.

(3) The Company's 2015 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(4) Applicable amounts previously reported for the three months ended March 31, 2014 and as of December 31, 2014 have been revised to reflect a correction to the Company's accounting for certain stock option awards. These revisions consisted entirely of non-cash adjustments and had no impact on the Company's previously reported non-GAAP financial measures, including non-GAAP net income and non-GAAP net income per share. Refer to the Company's Form 10-Q for the quarterly period ended March 31, 2015 (Note 4 of the Notes to Condensed Consolidated Financial Statements) for further details.

(5) In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its first quarter 2015 financial and operating results on Thursday, May 7, 2015, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International). A link to the webcast may be accessed from the "Events and Presentations" page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for 30 days.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. Several Regeneron programs are based on human genetics findings. For additional information about the Company, please visit www.regeneron.com.

Forward-Looking Statement

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, including without limitation Praluent, sarilumab, dupilumab, fasinumab, REGN2222, REGN2176-3, REGN2810, REGN1500, and REGN1033; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as EYLEA), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and

product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), such as the comparative effectiveness study in patients with DME discussed in this news release, on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance, including without limitation those relating to EYLEA U.S. net product sales, non-GAAP unreimbursed R&D, non-GAAP SG&A, cash tax as a percentage of non-GAAP pre-tax income, and capital expenditures; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2014 and its Form 10-Q for the quarterly period ended March 31, 2015. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

This press release and/or the financial results attached to this press release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of historical non-GAAP financial measures.

Contact Information:

Manisha Narasimhan, Ph.D.	Hala Mirza
Investor Relations	Corporate Communications
914-847-5126	914-847-3422
manisha.narasimhan@regeneron.com	hala.mirza@regeneron.com

TABLE 1

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2015	December 31, 2014*
Assets:		
Cash and marketable securities	$ 1,225,469	$ 1,360,634
Accounts receivable - trade, net	1,015,962	739,379
Accounts receivable from Sanofi and Bayer HealthCare	322,500	278,020
Inventories	133,863	128,861
Deferred tax assets	351,610	338,256
Property, plant, and equipment, net	1,110,597	974,309
Other assets	38,572	74,520
Total assets	$ 4,198,573	$ 3,893,979
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 519,049	$ 620,137
Deferred revenue	234,161	250,301
Facility lease obligations	329,851	312,291
Convertible senior notes	144,082	146,773
Stockholders' equity	2,971,430	2,564,477
Total liabilities and stockholders' equity	$ 4,198,573	$ 3,893,979

** Certain revisions have been made to the previously reported December 31, 2014 amounts. See note (4) above.*

TABLE 2

REGENERON PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2015	**2014***
Revenues:		
Net product sales	$ 544,573	$ 362,378
Sanofi collaboration revenue	173,356	130,508
Bayer HealthCare collaboration revenue	123,846	125,312
Technology licensing and other revenue	27,837	7,542
	869,612	625,740
Expenses:		
Research and development	343,113	287,379
Selling, general, and administrative	158,991	103,227
Cost of goods sold	42,570	27,473
Cost of collaboration and contract manufacturing	41,385	16,099
	586,059	434,178
Income from operations	283,553	191,562
Other income (expense):		
Investment and other income	81	937
Interest expense	(6,169)	(11,613)
Loss on extinguishment of debt	(942)	—
	(7,030)	(10,676)
Income before income taxes	276,523	180,886
Income tax expense	(200,502)	(112,581)
Net income	$ 76,021	$ 68,305
Net income per share - basic	$ 0.74	$ 0.69
Net income per share - diluted	$ 0.66	$ 0.61
Weighted average shares outstanding - basic	102,227	98,709
Weighted average shares outstanding - diluted	114,519	112,151

** Certain revisions have been made to the previously reported amounts for the three months ended March 31, 2014. See note (4) above.*

TABLE 3

REGENERON PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME (Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2015	**2014***
GAAP net income	$ 76,021	$ 68,305
Adjustments:		
R&D: Non-cash share-based compensation expense	59,502	43,304
SG&A: Non-cash share-based compensation expense	42,175	31,964
COGS: Non-cash share-based compensation expense	2,082	517
Interest expense: Non-cash interest related to convertible senior notes	2,248	5,924
Other expense: Loss on extinguishment of debt	942	—
Non-cash income taxes	152,568	112,581
Non-GAAP net income	$ 335,538	$ 262,595
Non-GAAP net income per share - basic	$ 3.28	$ 2.66

Non-GAAP net income per share - diluted [(a)]	$ 2.88	$ 2.26
Shares used in calculating:		
Non-GAAP net income per share - basic	102,227	98,709
Non-GAAP net income per share - diluted [(b)]	116,506	117,186

** Certain revisions have been made to the amounts previously reported for the three months ended March 31, 2014. See note (4) above.*

(a) For diluted non-GAAP net income per share calculations, excludes $0.4 million and $1.7 million, respectively, of interest expense for the three-month periods ended March 31, 2015 and 2014, related to the contractual coupon interest rate on the Company's 1.875% convertible senior notes, since these securities were dilutive.

(b) Weighted average shares outstanding includes the dilutive effect, if any, of employee stock options, restricted stock awards, convertible senior notes, and warrants.

TABLE 4

REGENERON PHARMACEUTICALS, INC.
COLLABORATION REVENUE (Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2015	**2014**
Sanofi collaboration revenue:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	$ (3,212)
Regeneron's share of losses in connection with commercialization of antibodies	$ (22,405)	—
Reimbursement of Regeneron research and development expenses	169,506	127,914
Reimbursement of Regeneron commercialization-related expenses	8,458	—
Other	17,797	5,806
Total Sanofi collaboration revenue	173,356	130,508
Bayer HealthCare collaboration revenue:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	89,426	61,159
Sales milestones	15,000	30,000
Cost-sharing of Regeneron development expenses	3,911	20,860
Other	15,509	13,293
Total Bayer HealthCare collaboration revenue	123,846	125,312
Total collaboration revenue	$ 297,202	$ 255,820

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/regeneron-reports-first-quarter-2015-financial-and-operating-results-300079165.html

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media