



## Regeneron and Sanofi To Accelerate and Expand Investment for Cemiplimab and Dupilumab Development Programs

January 8, 2018 at 7:04 AM EST

TARRYTOWN, N.Y. and PARIS, Jan. 8, 2018 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi will accelerate and expand investment for the clinical development of the PD-1 (programmed cell death protein 1) antibody cemiplimab in oncology, and the IL-4/IL-13 pathway-blocking antibody dupilumab in Type 2 allergic diseases. Both of these breakthrough therapies have the potential to benefit a number of different patient populations, and this strategic investment will enable the companies to evaluate cemiplimab and dupilumab in broader clinical development programs.

Under the terms of the expansion, the investment in cemiplimab will be increased to a minimum of \$1.64 billion, an increase of approximately \$1 billion over the [initial 2015 agreement](#), and Sanofi and Regeneron will continue to equally fund cemiplimab development. The companies will also continue their investment in other immuno-oncology programs under their existing Immuno-oncology Discovery Agreement. Investigational cemiplimab is being studied as monotherapy and in combination with other therapies in a wide range of cancers including advanced skin cancers, non-small cell lung cancer, cervical cancer and lymphomas, with more studies in other indications planned to begin in 2018. The companies expect to submit U.S. and EU regulatory applications for cemiplimab in advanced cutaneous squamous cell carcinoma in the first quarter of 2018.

The additional investment in the dupilumab development program will help accelerate planned new studies in chronic obstructive pulmonary disease, peanut allergy and grass allergy, as well as in patients who have multiple allergic conditions. These areas are in addition to ongoing dupilumab clinical development in pediatric atopic dermatitis, pediatric asthma, eosinophilic esophagitis and nasal polyposis. Dupixent® (dupilumab) is approved for the treatment of adults with moderate-to-severe atopic dermatitis in the U.S. and EU, and a U.S. supplemental biologics license application was submitted for uncontrolled, persistent asthma for patients aged 12 and over in the fourth quarter of 2017. The additional investment will also accelerate and expand development of REGN3500, an IL-33 antibody, with studies expected to be conducted in atopic dermatitis, asthma and chronic obstructive pulmonary disease. The increased funding for dupilumab and REGN3500 will be pursuant to the existing Antibody License and Collaboration Agreement between the companies.

"Cemiplimab has demonstrated strong pivotal clinical results in advanced cutaneous squamous cell carcinoma and is a core backbone of our immuno-oncology development program, both as a monotherapy and in combination with other therapies. The increased funding will enable us to investigate this important new therapy in a variety of cancers as rapidly as possible," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "Similarly, dupilumab has the potential to be a pipeline in a single product given its unique activity on the IL-4/13 pathway, which is a critical driver of Type 2 allergic inflammation. We look forward to rapidly advancing a broad development program to further investigate the potential of dupilumab to help multiple different patient populations in need."

Regeneron has agreed to grant a limited waiver of the "lock-up" in the Amended and Restated Investor Agreement between the companies, so that Sanofi may sell a small percentage of the Regeneron common stock it owns to fund a portion of the cemiplimab and dupilumab development expansion. This waiver will allow Sanofi to sell in private transactions to Regeneron up to an aggregate of 1.4 million shares of Regeneron common stock through the end of 2020, representing approximately 6 percent of the 23.9 million shares of Regeneron common stock Sanofi currently owns. As of October 20, 2017, there were 107.4 million shares of Regeneron capital stock outstanding. If Regeneron decides not to purchase the shares, Sanofi will be allowed to sell those shares on the open market, subject to certain volume and timing limitations. Further details on the updated agreements are available in Regeneron's current report on [Form 8-K filed today](#).

Cemiplimab and dupilumab were invented by Regeneron using the company's proprietary *VelocImmune*® technology that yields optimized fully-human antibodies. Other than the approved uses of Dupixent, cemiplimab, dupilumab and REGN3500 are under clinical investigation and their safety and efficacy have not been fully evaluated by any regulatory authority.

### IMPORTANT SAFETY INFORMATION

**Do not use** if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

**Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:**

- have eye problems
- have a parasitic (helminth) infection
- have asthma
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.

- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your healthcare provider.

**DUPIXENT can cause serious side effects, including:**

- **Allergic reactions.** Stop using DUPIXENT and go to the nearest hospital emergency room if you get any of the following symptoms: fever, general ill feeling, swollen lymph nodes, hives, itching, joint pain, or skin rash.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.

**The most common side effects** include injection site reactions, eye and eyelid inflammation, including redness, swelling and itching, and cold sores in your mouth or on your lips.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed. If your healthcare provider decides that you or a caregiver can give DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. **Do not** try to inject DUPIXENT until you have been shown the right way by your healthcare provider.

Please click [here](#) for the full Prescribing Information. The patient information is available [here](#).

**INDICATION**

DUPIXENT is used to treat adult patients with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children. DUPIXENT is administered by subcutaneous injection every two weeks after an initial loading dose

**About Regeneron Pharmaceuticals, Inc.**

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, and infectious and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its unique *VelociSuite*<sup>®</sup> technologies, including *VelocImmune*<sup>®</sup> to yield optimized fully human antibodies, and ambitious initiatives such as The Regeneron Genetics Center, one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com) or follow @Regeneron on Twitter.

**About Sanofi**

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

**Sanofi Forward-Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential*

of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

### **Regeneron Forward-Looking Statements and Use of Digital Media**

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), 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 (including without limitation cemiplimab (REGN2810) for the treatment of various cancer indications; dupilumab in various Type 2 allergic diseases; and REGN3500, an IL-33 antibody, in atopic dermatitis, asthma, and chronic obstructive pulmonary disease); 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, such as cemiplimab, dupilumab, and REGN3500; 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; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, such as cemiplimab and dupilumab, including the potential regulatory approval of dupilumab in patients aged 12 and over with uncontrolled persistent asthma based on the supplemental Biologics License Applications discussed in this news release; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in later studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs (such as the clinical programs relating to cemiplimab, dupilumab, and REGN3500 referenced in this news release), and business, including those relating to patient privacy; 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) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labelling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; 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; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), 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, including without limitation the patent litigation proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended September 30, 2017. 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

### **Contacts Sanofi:**

#### **Media Relations**

Ashleigh Koss  
Tel: +1 (908) 981 8745  
[ashleigh.koss@sanofi.com](mailto:ashleigh.koss@sanofi.com)

#### **Investor Relations**

George Grofik  
Tel: +33 (0)1 53 77 45 45  
[ir@sanofi.com](mailto:ir@sanofi.com)

**Contacts Regeneron:**

**Media Relations**

Arleen Goldenberg

Tel: +1 (914) 847-3456

Mobile: +1 (914) 260-8788


[arleen.goldenberg@regeneron.com](mailto:arleen.goldenberg@regeneron.com)

**Investor Relations**

Manisha Narasimhan, Ph.D.

Tel: +1 (914) 847-5126

[Manisha.narasimhan@regeneron.com](mailto:Manisha.narasimhan@regeneron.com)

 View original content: <http://www.prnewswire.com/news-releases/regeneron-and-sanofi-to-accelerate-and-expand-investment-for-cemiplimab-and-dupilumab-development-programs-300578910.html>

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media