



## **Regeneron and Sanofi Announce Sarilumab Biologics License Application Accepted for Review by US FDA**

January 8, 2016

TARRYTOWN, N.Y. and PARIS, Jan. 8, 2016 /PRNewswire/ -- [Regeneron Pharmaceuticals, Inc. \(REGN\)](#) and Sanofi today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for sarilumab. Per the Prescription Drug User Fee Act (PDUFA), the target action date is October 30, 2016. Sarilumab is an investigational, human monoclonal antibody directed against the IL-6 receptor that is intended for the treatment of patients with active, moderate-to-severe rheumatoid arthritis (RA). IL-6 is the most abundant cytokine in the serum and synovial fluid of patients with RA and levels correlate with both disease activity and joint destruction.

The BLA for sarilumab contains data from approximately 2,500 adults with active, moderate-to-severe RA who had an inadequate response to previous treatment regimens, including seven studies from the global SARIL-RA Phase 3 program.

The goal of the ongoing global clinical development program is to evaluate the safety and efficacy of subcutaneous sarilumab, either as monotherapy or in combination with conventional disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (MTX), in reducing the signs and symptoms and inhibiting the radiographic progression of RA.

The safety and efficacy of sarilumab have not been fully evaluated by any regulatory authority.

### **About Sanofi**

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### **About Regeneron Pharmaceuticals, Inc.**

Regeneron (NASDAQ: REGN) 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 high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com) or follow @Regeneron on Twitter.

### **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, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, 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, 2014. 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 sarilumab; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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 the SARIL-RA clinical development program; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation sarilumab; 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) 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; 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2014 and its Form 10-Q for the quarter ended September 30, 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.

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**

**Jack Cox**

Tel: +33 (0)1 53 77 94 74

[jack.cox@sanofi.com](mailto:jack.cox@sanofi.com)

**Investor Relations**

**Sebastien Martel**

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)

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/regeneron-and-sanofi-announce-sarilumab-biologics-license-application-accepted-for-review-by-us-fda-300201389.html>

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media