Regeneron and Sanofi Announce Topline Results of Phase 3 Monotherapy Study Demonstrating Superiority of Sarilumab vs. Adalimumab in Patients with Active Rheumatoid Arthritis

March 11, 2016

TARRYTOWN, N.Y. and PARIS, March 11, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that a Phase 3 monotherapy study met its primary endpoint demonstrating that sarilumab was superior to adalimumab (marketed by AbbVie as HUMIRA®) in improving signs and symptoms in patients with active rheumatoid arthritis (RA) at Week 24. The study, called SARIL-RA-MONARCH, also met important secondary endpoints including other measures assessing improvements in signs and symptoms of RA and physical function. Sarilumab is an investigational, human IL-6 receptor antibody.

"In this study, sarilumab monotherapy provided stronger efficacy than adalimumab monotherapy. Adalimumab is one of the most commonly used biologic medicines in RA," said Janet van Adelsberg, M.D., Senior Director, Clinical Sciences, Immunology and Inflammation, Regeneron. "This is the first time an IL-6 receptor blocker delivered subcutaneously has demonstrated superiority over adalimumab monotherapy in RA."

The SARIL-RA-MONARCH study enrolled 369 adult patients with active RA who were inadequate responders to, intolerant of, or inappropriate candidates for methotrexate (MTX). Patients were randomized to receive either subcutaneous sarilumab monotherapy (200 mg every 2 weeks) or adalimumab monotherapy (40 mg every 2 weeks); patients who did not respond adequately to adalimumab could increase to weekly dosing.

"Despite the availability of a wide range of treatment options, we believe that new therapies are needed to further address unmet needs of RA patients," said Dr. Simon Cooper, MBBS VP, Global Project Head, Immunology and Inflammation, Sanofi. "These data suggest that sarilumab, if approved, may be an option for patients unable to tolerate or take methotrexate, and we look forward to sharing further details at an upcoming medical congress."

The primary endpoint was change from baseline in DAS28-ESR at 24 weeks, which demonstrated a statistically significant difference in favor of sarilumab (-3.25 for sarilumab compared to -2.22 for adalimumab, p less than 0.0001). The study also met clinically important secondary endpoints including improvements in signs and symptoms of RA as measured by patients achieving a 20 percent improvement in the American College of Rheumatology (ACR) criteria (72 percent for sarilumab vs. 58 percent for adalimumab, p less than 0.01). Additional positive secondary endpoints included ACR50 and ACR70 response, and improvement in physical function, as measured by the Health Assessment Questionnaire - Disability Index (HAQ-DI) as compared to adalimumab (p less than 0.01 for all of these measures). DAS28-ESR is a measure of disease activity in RA, which includes the evaluation of 28 joints in the body for tenderness and swelling, a general health assessment, and ESR, a laboratory measure for inflammation.

The incidence of adverse events (64 percent for both groups), serious adverse events (5 percent for sarilumab vs. 7 percent for adalimumab), infections (29 percent for sarilumab vs. 28 percent for adalimumab), and serious infections (1 percent for both groups) were generally similar between groups. Neutropenia, which was not associated with infections, was more common with sarilumab (14 percent for sarilumab vs.1 percent for adalimumab), as has been seen in previous studies with IL-6 inhibitors. Injection site erythema (8 percent sarilumab vs. 3 percent adalimumab) was also more common with sarilumab.

About Sarilumab
Sarilumab is a human monoclonal antibody directed against the IL-6 receptor that inhibits the inflammatory activity in RA mediated by the IL-6 signaling pathway. IL-6 is the most abundant cytokine in the serum and synovial fluid of patients with RA, and levels of IL-6 correlate with both disease activity and joint destruction.

In January, the companies announced that the U.S. Food and Drug Administration (FDA) accepted for review the biologics license application (BLA) for sarilumab with a target action date of October 30, 2016. The BLA submission is supported by 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 outcome of SARIL-RA-MONARCH is not part of the ongoing review by the FDA. The regulatory submission is planned in the EU in Q3 2016.

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 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, 2015. 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; 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 (including possible regulatory approval of sarilumab by the U.S. Food and Drug Administration based on the Biologics License Application discussed in this news release); 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; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, 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 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, 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	**Investor Relations**
Jack Cox	**Sébastien Martel**
Tel: +33 (0)1 53 77 46 46	Tel: +33 (0)1 53 77 45 45
mr@sanofi.com	ir@sanofi.com

Contacts Regeneron:

Media Relations	
Arleen Goldenberg	**Investor Relations**
Tel: +1 (914) 847-3456	**Manisha Narasimhan, Ph.D.**
Mobile: +1 (914) 260-8788	Tel: +1 (914) 847-5126
arleen.goldenberg@regeneron.com	manisha.narasimhan@regeneron.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/regeneron-and-sanofi-announce-topline-results-of-phase-3-monotherapy-study-demonstrating-superiority-of-sarilumab-vs-adalimumab-in-patients-with-active-rheumatoid-arthritis-300234309.html

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media