Regeneron and Sanofi Present Results from Pivotal Phase 3 Study of Sarilumab at American College of Rheumatology Annual Meeting

November 8, 2015 at 7:00 AM EST

TARRYTOWN, N.Y. and PARIS, Nov. 8, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced results from a pivotal Phase 3 study of sarilumab, an investigational, human antibody against the IL-6 receptor. The results of the study, SARIL-RA-TARGET, are being presented today at an oral session during the American College of Rheumatology (ACR) Annual Meeting in San Francisco, California. The study met both its co-primary endpoints of improvements in signs and symptoms of rheumatoid arthritis (RA) and improvements in physical function, as well as secondary efficacy endpoints.

"Rheumatoid arthritis can be a debilitating disease that has a significant impact on a patient, and despite the availability of a wide range of treatments, new agents are still needed to address unmet patient needs including failure to respond to therapy," said Dr. Roy Fleischmann, clinical professor in the Department of Internal Medicine at the University of Texas Southwestern Medical Center and lead study author. "These data suggest that sarilumab, if approved, may be a potential option for patients with moderate-to-severe RA."

The SARIL-RA-TARGET trial enrolled 546 RA patients who were inadequate responders or intolerant of TNF-alpha inhibitors (TNF-IR). Patients were randomized to one of three treatment groups self-administered subcutaneously (SC) every other week (Q2W): sarilumab 200 milligrams (mg), sarilumab 150 mg, or placebo, in addition to non-biologic disease modifying anti-rheumatic drugs (DMARD) therapy. Top-line results were previously announced in May 2015.

Both sarilumab groups showed clinically relevant and statistically significant improvements compared to placebo in both co-primary endpoints:

- Improvement in physical function at week 12, as measured by mean change from baseline in the Health Assessment Questionnaire-Disability Index (HAQ-DI). The HAQ-DI measures patients' abilities to perform a standard set of daily physical activities. The change from baseline to week 12 in HAQ-DI was -0.49, -0.50, and -0.29 in the sarilumab 200 mg (p=0.0004), sarilumab 150 mg (p=0.0007), and placebo groups, respectively.
- Improvements in signs and symptoms of RA at week 24, as measured by the proportion of patients achieving an ACR20 response (ACR20) were 61 percent in the sarilumab 200 mg group; 56 percent in the sarilumab 150 mg group; and 34 percent in the placebo group, all in combination with DMARD therapy (p less than 0.0001).

Secondary efficacy endpoints that will be presented during the ACR oral session include the following:

- Proportion of patients achieving an ACR50 response at week 24 were 41 percent in the sarilumab 200 mg group, 37 percent in the sarilumab 150 mg group, and 18 percent in the placebo group (p less than 0.0001).
- Proportion of patients achieving an ACR70 response at week 24 were 16 percent in the sarilumab 200 mg group (p=0.0056), 20 percent in the sarilumab 150 mg group (p=0.0002), and 7 percent in the placebo group.
- The mean change from baseline to week 24 in disease activity score in 28 joints using C-reactive protein (DAS28-CRP), which evaluates the disease activity of RA, were as follows: -2.82, -2.35 and -1.38 in the sarilumab 200 mg, sarilumab 150 mg, and placebo groups, respectively.
- The proportion of patients achieving DAS28-CRP less than 2.6 at week 24 were as follows: 29 percent, 25 percent, and 7 percent in the sarilumab 200 mg, sarilumab 150 mg, and placebo groups, respectively.
- The change from baseline to week 24 in clinical disease activity index (CDAI), which also evaluates the disease activity of RA, were as follows: -30.43, -27.14, and -23.9 in the sarilumab 200 mg, sarilumab 150 mg, and placebo groups, respectively.
- The change from baseline to week 24 in HAQ-DI were as follows: -0.58, -0.52 and -0.34 in the sarilumab 200 mg, sarilumab 150 mg, and placebo groups, respectively.

Treatment-emergent adverse events (TEAEs) were more frequent in the sarilumab groups (65 percent and 66 percent in sarilumab 200 mg and 150 mg vs 50 percent in placebo respectively). The incidence of serious adverse events (SAEs) was higher than placebo in the sarilumab 200 mg group (5 percent vs. 3 percent) and was similar to placebo in the 150 mg group (3 percent). Infection was the most frequently reported adverse event (30, 22 and 27 percent in the 200 mg, 150 mg and placebo groups respectively). Serious infections occurred in 2 patients in the sarilumab 200 mg group, 1 patient in the sarilumab 150 mg group and 2 patients on placebo. The most frequent events leading to treatment discontinuation were infection and neutropenia. Adverse events and laboratory changes were consistent with observations from the MOBILITY study and with the mechanism of action of sarilumab.

During the same oral session at ACR, data from the SARIL-RA-ASCERTAIN/1309 studies will also be presented. In total, 14 abstracts were accepted for presentation at the meeting. This includes additional abstracts detailing data from the sarilumab clinical trial program: SARIL-RA-MOBILITY and SARIL-RA-EXTEND.

Sanofi and Regeneron recently submitted a Biologics License Application (BLA) for sarilumab to the U.S. Food and Drug Administration (FDA).

Sanofi and Regeneron will host an IR Thematic Conference Call for the financial community focusing on sarilumab on Monday, November 9 at 7:00 a.m. PDT. The conference call will include a presentation followed by a Q&A session. It will be accessible through an audio webcast at www.sanofi.com and www.regeneron.com and also via the following telephone numbers: France, +33 (0) 1 70 77 09 40; UK, +44 (0) 207 107 1613; and USA, +1 855 402 7761.

The investigational agent described above is currently under clinical development, and its safety and efficacy have not been evaluated by any regulatory authority.

About Sarilumab
Sarilumab (REGN88/SAR153191) is a human monoclonal antibody directed against the IL-6 receptor (IL-6R).[5] Sarilumab binds with high affinity to the IL-6 receptor. It blocks the binding of IL-6 to its receptor and interrupts the resultant cytokine-mediated inflammatory signaling. Sarilumab was developed using Regeneron's *VelocImmune*® antibody technology.

About Sanofi
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new 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 policies 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
Carrie Brown
Tel: +1 (908) 981-6486
Mobile: +1 (908) 247-6006
Carrie.Brown@sanofi.com

Investor Relations
Sebastien Martel
Tel: +33 (0)1 53 77 45 45
IR@sanofi.com

Contacts Regeneron:

Media Relations
Arleen Goldenberg
Tel: +1 (914) 847-3456
Mobile: +1 (914) 260-8788
arleen.goldenberg@regeneron.com

Investor Relations
Manisha Narasimhan, Ph.D.
Tel: +1 (914) 847-5126
manisha.narasimhan@regeneron.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/regeneron-and-sanofi-present-results-from-pivotal-phase-3-study-of-sarilumab-at-american-college-of-rheumatology-annual-meeting-300174459.html

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media