



Regeneron and Sanofi Announce Positive Topline Results from Phase 3 Studies with Sarilumab in Patients with Rheumatoid Arthritis

May 21, 2015

TARRYTOWN, N.Y. and PARIS, May 21, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi announced today that a Phase 3 study of sarilumab, an investigational, fully human IL-6 receptor antibody, met its co-primary efficacy endpoints of a greater improvement in signs and symptoms of rheumatoid arthritis (RA) at 24 weeks and physical function at 12 weeks, compared to placebo. The study, called SARIL-RA-TARGET, evaluated the efficacy and safety of two subcutaneous sarilumab doses versus placebo, added to non-biologic disease modifying anti-rheumatic drugs (DMARD) therapy in RA patients who were inadequate responders to or intolerant of TNF-alpha inhibitors (TNF-IR).

The SARIL-RA-TARGET trial enrolled 546 TNF-IR patients who 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 DMARD therapy. Both sarilumab groups showed clinically relevant and statistically significant improvements compared to the placebo group in both co-primary endpoints (p lesser than 0.001):

(1) Improvement in signs and symptoms of RA at 24 weeks, as measured by the American College of Rheumatology score of 20 percent improvement (ACR20), were as follows: 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.

(2) Improvement in physical function, as measured by change from baseline in the Health Assessment Question-Disability Index (HAQ-DI) at week 12.

The most frequently reported adverse events included infections (30, 22 and 27 percent in the 200 mg, 150 mg and placebo groups respectively) and injection site reactions (8, 7, 1 percent in the 200 mg, 150 mg and placebo groups respectively). Serious infections were uncommon (1, 0.6 and 1 percent in the 200 mg, 150 mg and placebo groups respectively). Reduction in neutrophil count was the most common lab abnormality. No unexpected safety findings were observed.

Two additional trials from the Phase 3 program, SARIL-RA-EASY and SARIL-RA-ASCERTAIN, also met their primary endpoints:

- SARIL-RA-EASY enrolled 217 patients and was designed to evaluate the technical performance and usability of the sarilumab autoinjector device. There were no product technical failures with the autoinjector, the primary endpoint of the study.
- SARIL-RA-ASCERTAIN was a 202 patient safety calibrator study, designed to assess the safety of two subcutaneous doses of sarilumab and tocilizumab infusion in combination with DMARDs in patients with RA who were TNF-IR. There were no clinically meaningful differences between the treatment groups in serious adverse events and serious infections.

Detailed results from all three SARIL-RA trials will be presented at future medical congresses.

About Sarilumab

Sarilumab (REGN88/SAR153191) is the first fully human monoclonal antibody directed against the IL-6 receptor (IL-6R). 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.

The investigational agent described above is currently under clinical development, and its safety and efficacy have not been 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 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 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. For additional information about the company, please visit www.regeneron.com.

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

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"), 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 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.

Contacts Sanofi:

Media Relations

Jack Cox

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

Mobile: +33 (0) 6 78 52 05 36

Jack.Cox@sanofi.com

Investor Relations

Sébastien 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-announce-positive-topline-results-from-phase-3-studies-with-sarilumab-in-patients-with-rheumatoid-arthritis-300086919.html>

SOURCE Regeneron Pharmaceuticals, Inc.