Sanofi and Regeneron Announce New, Detailed Data from Positive Sarilumab Phase 3 Rheumatoid Arthritis Trial at EULAR

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PARIS and TARRYTOWN, N.Y., June 12, 2014 /PRNewswire/ -- Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) and Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today presented positive results from a phase 3 trial of investigational drug sarilumab in rheumatoid arthritis (RA) patients who were inadequate responders to methotrexate (MTX) therapy. New data presented at the meeting showed that sarilumab increased major clinical response rates defined as achieving an ACR70 for at least 24 consecutive weeks and showed sustained improvement in signs and symptoms of RA after 52 weeks, which were secondary endpoints of the trial.

As previously announced, in this study, called SARIL-RA-MOBILITY, sarilumab met all three co-primary endpoints, demonstrating improvement in disease signs and symptoms at 24 weeks, physical function at 16 weeks and inhibition of joint damage progression at 52 weeks. These data will be presented today at the European League Against Rheumatism Annual Congress (EULAR 2014) Congress in Paris, France.

"Despite notable advances, many RA patients continue to struggle with debilitating signs and symptoms, underscoring a clear need for additional options," said Dr. Mark Genovese, Professor, Stanford University Medical Center and lead investigator in the study. "Sarilumab showed efficacy in this study at two different doses, both delivered subcutaneously every other week. We look forward to the results of ongoing trials in this comprehensive registration program."

The SARIL-RA-MOBILITY Phase 3 trial enrolled 1,197 adult patients with active, moderate-to-severe rheumatoid arthritis, who were inadequate responders to MTX therapy. Patients were randomized to one of three treatment groups dosed subcutaneously every other week, sarilumab 150 milligrams (mg), sarilumab 200 mg, or placebo, all in combination with MTX.

Both sarilumab groups showed statistically significant improvements compared to the placebo group in all three co-primary endpoints (p &< 0.0001).

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). These results were 58 percent, 66 percent, and 33 percent in the sarilumab 150 mg, sarilumab 200 mg, and placebo groups respectively, all in combination with MTX.
2. Improvement in physical function at Week 16 as measured by Health Assessment Questionnaire - Disability Index (HAQ-DI). Newly presented HAQ-DI results were -0.53, -0.55, and -0.29 in the sarilumab 150 mg, sarilumab 200 mg, and placebo groups respectively, all in combination with MTX.
3. Inhibition of progression of structural damage at Week 52, as measured by change in the van der Heijde modified total Sharp score (mTSS). These results were 0.90, 0.25, and 2.78 in the sarilumab 150 mg, sarilumab 200 mg, and placebo groups respectively, all in combination with MTX. The group receiving the 200 mg dose of sarilumab + MTX had a reduction of approximately 90 percent in the radiographic progression assessed by the mTSS compared to the radiographic progression with placebo + MTX at week 52.

Also newly presented, both sarilumab groups also showed improvement on the major clinical response secondary endpoint:

- Sarilumab combined with MTX demonstrated statistically significantly greater effect than MTX alone in achieving a major clinical response, defined as reducing signs and symptoms of RA by 70% or more, as measured by improvement of the American College of Rheumatology score (ACR70 response), for at least 24 consecutive weeks. These results were 13 percent, 15 percent and 3 percent in the sarilumab 150 mg, sarilumab 200 mg, and placebo groups, respectively (p &< 0.0001).

Both doses also demonstrated a sustained response in improvement of signs and symptoms of RA compared to placebo at 52 weeks as measured by the ACR20 response. These results were 54 percent, 59 percent, and 32 percent in the sarilumab 150 mg, sarilumab 200 mg, and placebo groups, respectively.

In the SARIL-RA-MOBILITY trial, there was a higher incidence of treatment-emergent adverse events leading to withdrawal in the sarilumab treatment groups compared to placebo (12.5 percent in 150 mg, 13.9 percent in 200 mg and 4.7 percent in placebo). Infections were the most frequently reported adverse events and were reported with a higher incidence in the sarilumab groups compared to placebo, all in combination with MTX (40.1 percent for 150 mg, 39.6 percent for the 200 mg group and 31.1 percent for placebo). The incidence of serious infections was 2.6 percent in the 150 mg + MTX group, 4.0 percent in the 200 mg + MTX group, and 2.3 percent in the placebo + MTX group.

Among patients treated with sarilumab, a dose-dependent decrease in mean neutrophil counts was observed. Serious infections were not associated with grades 3 and 4 neutropenia in this study. Increases in mean LDL cholesterol, and transaminases were observed. These safety findings were consistent with those observed in prior investigational studies with sarilumab.

The sarilumab Phase 3 program, known as SARIL-RA, has six ongoing clinical studies and is targeted to enroll approximately 2,800 RA patients.

About Sarilumab

Sarilumab (REGN88/SAR153191) is the first fully-human monoclonal antibody directed against the IL-6 receptor (IL-6R). Sarilumab is a subcutaneously delivered inhibitor of IL-6 signaling, which 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 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 markets medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, 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, 2013. 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, 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-MOBILITY study and the other SARIL-RA trials; 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; 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, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property 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, 2013 and its Form 10-Q for the quarter ended March 31, 2014. 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.

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