



Sanofi and Regeneron Announce Patient Enrollment in Two Phase 3 Trials with Sarilumab in Rheumatoid Arthritis (RA)

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PARIS and TARRYTOWN, N.Y., May 15, 2013 /PRNewswire/ -- Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the COMPARE and ASCERTAIN trials of sarilumab, the first fully human monoclonal antibody directed against the IL-6 receptor, which is delivered by subcutaneous injection every other week, have enrolled their first patients.

The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe rheumatoid arthritis (RA) who are inadequate responders to either methotrexate (MTX) or tumor necrosis factor alpha (TNF-alpha) inhibitor therapy. The SARIL-RA program is comprised of the following five trials: SARIL-RA MOBILITY, SARIL-RA TARGET, SARIL-RA COMPARE, SARIL-RA ASCERTAIN, and an open-label extension trial, SARIL-RA EXTEND. The program is targeted to enroll approximately 2,600 patients with moderate-to-severe rheumatoid arthritis. The primary objective of the overall Phase 3 program is to determine the safety and efficacy of sarilumab in reducing the signs and symptoms of RA, as well as inhibiting disease progression, in a broad range of patients. Two doses of sarilumab are being studied in the SARIL-RA program: 150 milligrams (mg) every other week and 200mg every other week.

The SARIL-RA ASCERTAIN trial is a multi-center, randomized, double-blind, active-calibrator, Phase 3 trial of 24 weeks that will assess the safety and tolerability of sarilumab and tocilizumab, both in combination with MTX, in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors. The primary endpoint of this study is safety.

"Despite the advances that TNF-alpha inhibitors have made in the management of patients with RA, up to 40 percent of patients are inadequately controlled, as assessed by DAS 28 score, or are unable to tolerate the first TNF-alpha inhibitor prescribed," said George D. Yancopoulos, M.D., Ph. D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "The COMPARE trial will explore whether these patients would be better served by switching to a different mechanism of action, IL-6 inhibition, rather than administering another TNF-alpha inhibitor."

The SARIL-RA COMPARE trial is a multi-center, randomized, double-blind, active-control, Phase 3 trial evaluating the safety and efficacy of sarilumab plus MTX compared to etanercept (a TNF-alpha inhibitor) plus MTX in adult patients with moderate-to-severe RA who demonstrate an inadequate response to adalimumab as their first TNF-alpha inhibitor therapy. COMPARE is designed to evaluate whether sarilumab is superior to etanercept when used in combination with MTX in this patient population. The primary endpoint of the study is the change in Disease Activity Score 28 based on C-reactive protein (DAS28-CRP) at 24 weeks. COMPARE is an international trial that expects to include 700 patients at approximately 300 sites.

"What is unique about the COMPARE study is that it will examine patients with RA who have not responded to their first TNF-alpha inhibitor and compare the safety and efficacy of a second TNF-alpha inhibitor versus a different class of therapy, an IL-6R inhibitor, sarilumab," said Jorge Insuasty, M.D., Vice President, Global R&D and Deputy to the President for Development, Sanofi. "The initiation of the SARIL-RA COMPARE and ASCERTAIN studies represents a significant step in the Phase 3 SARIL-RA clinical development program."

"The full SARIL-RA phase 3 clinical program is a robust program aimed to provide informative data on the anti-IL6R class of therapies. The COMPARE study will bring new data to the forefront in answering a key question," said Dr. Mark Genovese, Professor of Medicine, Division of Immunology and Rheumatology, Stanford University.

About Sarilumab

Sarilumab (REGN88/SAR153191) is the first fully human monoclonal antibody directed against the alpha subunit of the IL-6 receptor complex (IL-6R Alpha). Sarilumab is a high-affinity, subcutaneously delivered inhibitor of IL-6 signaling. It blocks the binding of IL-6 to its receptor and interrupts the resultant cytokine-mediated inflammatory signaling cascade. Sarilumab was developed using Regeneron's *VelocImmune*[®] antibody technology.

About the SARIL-RA Program

The SARIL-RA Phase 3 program consists of 5 studies and is targeted to enroll approximately 2,600 adults with moderate-to-severe rheumatoid arthritis who have not had sufficient results with other treatment regimens. The goal of the program is to evaluate the safety and efficacy of sarilumab in combination with methotrexate (MTX) in reducing the signs and symptoms and inhibiting the radiographic progression of RA.

1. The SARIL-RA MOBILITY trial (N=1197) is evaluating sarilumab in combination with MTX as treatment in adults with moderate-to-severe active RA with an inadequate response to MTX. SARIL-RA MOBILITY is fully enrolled and results are anticipated in first-half 2014.
2. The SARIL-RA TARGET trial (N=522) is currently recruiting and is evaluating sarilumab in combination with non-biologic, disease-modifying anti-rheumatic drugs (DMARDs) as treatment in adults with moderate-to-severe active RA who have had inadequate response to, or were intolerant of, one or more TNF-alpha inhibitors.
3. The SARIL-RA COMPARE trial (N=700) is currently recruiting and is evaluating the strategy of using IL-6 inhibition with sarilumab + MTX in patients who have had an inadequate response to open-label adalimumab + MTX after 16 weeks of therapy. Those patients identified as inadequate responders will then be randomized to a second TNF-alpha inhibitor (etanercept) + MTX or sarilumab (150mg or 200mg) + MTX.
4. The SARIL-RA ASCERTAIN trial (N=200) is currently recruiting and is evaluating sarilumab and tocilizumab in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors.

5. The SARIL-RA EXTEND trial (N=2100) is a long-term safety study of sarilumab; it is open to patients who complete the MOBILITY, TARGET or ASCERTAIN studies.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic systemic autoimmune disease affecting approximately 0.5% - 1% of the global adult population. Abnormal immune response causes inflamed, thickened synovium, the membrane that lines the joints. The inflammatory process can damage the bone and cartilage of the joint and the surrounding tissues. RA-related inflammation can involve the heart and the lung. In 10 percent of patients with RA, the liver is affected. Complications of RA include anemia and leukopenia. At times, RA can be very painful and affect a person's ability to carry out everyday tasks. Most people with RA experience periods when their symptoms worsen (flares or active disease), separated by periods in which the symptoms improve.

About Sanofi

Sanofi, a global and diversified 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, oncology, rheumatoid arthritis, allergic 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, 2012. 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. 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; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; 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 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, 2012 and Form 10-Q for the quarter ended March 31, 2013. 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, unless required by law.

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