Sanofi and Regeneron Report Positive Phase 2b Trial Results with Sarilumab in Rheumatoid Arthritis

July 12, 2011

PARIS and TARRYTOWN, N.Y., July 12, 2011 /PRNewswire/ -- Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced results from Phase 2b trials in rheumatoid arthritis (RA) and ankylosing spondylitis (AS) with sarilumab (REGN88/SAR153191), a novel, high-affinity, subcutaneously administered, fully-human antibody targeting the interleukin-6 receptor (IL-6R).

The Phase 2b MOBILITY trial in rheumatoid arthritis demonstrated that patients treated with sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA compared to patients treated with MTX alone. The MOBILITY study is a 306-patient, dose-ranging, multi-national, randomized, multi-arm, double-blind, placebo-controlled study, that compared five different dose regimens of sarilumab in combination with MTX to placebo plus MTX. The primary endpoint of the study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks.

In the MOBILITY trial, there was a dose response observed in patients receiving sarilumab in combination with MTX. An ACR20 response after 12 weeks was seen in 49.0% of patients receiving the lowest sarilumab dose regimen and 72.0% of patients receiving the highest dose regimen compared to 46.2% of patients receiving placebo and MTX (p=0.02, corrected for multiplicity, for the highest sarilumab dose regimen). The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities. The types and frequencies of adverse events were consistent with those previously reported with IL-6 inhibition. The incidence of serious adverse events among the five sarilumab treatment groups and placebo group were comparable.

Sarilumab also demonstrated significant benefit compared to placebo in secondary endpoints, including ACR 50, ACR 70, and DAS 28 scores, additional measures of clinical activity used in RA trials.

"Following these encouraging Phase 2b results in rheumatoid arthritis, the companies are currently discussing the dose(s) of sarilumab to advance into the Phase 3 portion of the MOBILITY trial," said Elias Zerhouni, President, Global Research & Development, Sanofi.

"The MOBILITY results provide evidence that IL-6R blockade with sarilumab represents a promising new anti-inflammatory investigational therapy for reducing RA disease symptoms. We are very pleased that the first of our novel VelocImmune® derived antibodies is poised to enter Phase 3 development," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Research Laboratories.

In the Phase 2b ALIGN trial in ankylosing spondylitis (AS), sarilumab did not demonstrate significant and clinically meaningful improvements in signs and symptoms of active AS compared to placebo in patients who had inadequate response to NSAIDs. Sarilumab was generally well tolerated. The most common adverse events reported more frequently in active treatment arms included infections and neutropenia.

Full data of both Phase 2b trials will be submitted for presentation at an upcoming scientific conference.

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, sub-cutaneously delivered, specific 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 VelocImmune® antibody technology.

About the MOBILITY Trial

The MOBILITY trial is a randomized, double-blind, placebo-controlled, multicenter, two-part, dose ranging and confirmatory study with an operationally seamless design, evaluating efficacy and safety of sarilumab on top of MTX in patients with active RA who are inadequate responders to MTX therapy. The primary objective of part A of the dose ranging MOBILITY trial was to demonstrate that sarilumab on top of MTX is effective in reducing the signs and symptoms of RA at 12 weeks. The five doses tested were 100 milligrams (mg) and 150 mg every week and 100 mg, 150 mg and 200 mg every other week. The primary objective of part B of the MOBILITY trial will be to demonstrate that sarilumab on top of MTX is effective in reducing the signs and symptoms of RA at 24 weeks. Further details about the MOBILITY trial are available at http://clinicaltrials.gov/ct2/results?term=SAR+153191+mobility.

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 an inflamed, thickened synovium, the membrane that lines the joint. As synovitis expands, 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% of patients with RA the liver is affected. Complications of RA include anemia and leucopenia. 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. Studies suggest that blockade of IL-6 signaling, one of several key cytokines involved in the inflammatory processes related to RA, may reduce inflammation of the joints, prevent long-term damage and relieve certain systemic effects of RA such as decreased hemoglobin, fatigue and osteoporosis.

About the ALIGN Trial

The 300-patient ALIGN trial is a randomized, double-blind, placebo-controlled, dose ranging study to evaluate the efficacy and safety of sarilumab in

patients with AS who had an inadequate response to NSAIDs. The primary outcome measure of the trial was the percentage of patients who achieved a 20% improvement in AS International Working Group Criteria for improvement (ASAS20) at 12 weeks. The secondary endpoints included ASAS40 response, partial remission, and changes in disease activity, safety and tolerability. In the ALIGN trial, the same dose regimens were tested as in part A of the MOBILITY trial. Further details about the ALIGN trial can be found at http://clinicaltrials.gov/ct2/results?term=SAR153191+align.

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, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

About Regeneron Pharmaceuticals, Inc.

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase III clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at 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 labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products 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 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, 2010. 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 financial 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 product candidates and research and clinical programs now underway or planned, 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 product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the Sanofi Group and Bayer HealthCare, to be canceled or terminated without any 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, 2010 and Form 10-Q for the quarter ended March 31, 2011 . Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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