



## Sanofi and Regeneron Report Positive Proof-of-Concept Data for Dupilumab, an IL-4R alpha Antibody, in Atopic Dermatitis

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PARIS and TARRYTOWN, N.Y., March 2, 2013 /PRNewswire/ -- Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that pooled data from two Phase 1b trials with dupilumab (REGN668/SAR231893), an investigational, high-affinity, subcutaneously administered, fully-human antibody targeting the alpha subunit of the interleukin 4 receptor (IL-4R alpha), were presented at the 71st Annual Meeting of the American Academy of Dermatology (AAD) in Miami.

The primary objective of the Phase 1b studies was to assess the safety profile of dupilumab. Other exploratory endpoints included pharmacokinetic, biomarker, and efficacy parameters. The efficacy data showed that treatment with four weekly subcutaneous injections of dupilumab at either 150 milligrams (mg) or 300mg per week, significantly improved the signs and symptoms of patients with moderate-to-severe atopic dermatitis (AD) whose disease was not adequately controlled with topical medications. Specifically, patients treated with dupilumab had significant improvements in body surface area (BSA) score, Investigator Global Assessment (IGA) score, and Eczema Area Severity Index (EASI) from baseline to week 4 compared to placebo (p < 0.05 vs. placebo for all measures and doses). The significant improvements in BSA, IGA, and EASI scores were maintained at week 8 in the 300mg dose group (p < 0.05 vs. placebo). A responder analysis demonstrated that at week 4, 54.5% of patients treated with the 150mg dose and 71.4% of patients treated with the 300mg dose achieved a reduction in EASI score of 50% or greater compared to 18.8% with placebo (p < 0.05). The most common adverse events (AEs) were nasopharyngitis (19.6% vs 12.5% for placebo) and headache (11.8% vs 6.3% for placebo).

"Despite existing therapies, a significant proportion of patients with moderate-to-severe atopic dermatitis continue to suffer from inflamed skin and intractable itch, which significantly impacts their quality of life," said Dr. Eric Simpson, Associate Professor, Director of Clinical Studies, Oregon Health and Science University, Portland, Oregon, USA, and Principal Investigator of the study. "The early phase results with this biologic therapy, which has a novel mechanism of action, are encouraging to those of us who treat these patients and warrant further clinical investigation."

"Through blockade of IL-4R alpha, dupilumab modulates signaling of both the IL-4 and IL-13 pathway, which have been implicated in the pathophysiology of allergic disease," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "We look forward to presenting additional data from a 12-week, Phase 2a trial in atopic dermatitis, as well as starting a larger Phase 2b trial with dupilumab in patients with atopic dermatitis, later this year."

Presented today in a late-breaking clinical trials session at the AAD meeting, the Phase 1b trials included 67 patients randomized to three different doses of dupilumab (75mg, n=8; 150mg, n=22; 300mg, n=21) and placebo (n=16). The primary objective of the Phase 1b studies was to assess the safety profile of dupilumab. Other endpoints included pharmacokinetic, biomarker, and efficacy parameters. Following the 4-week treatment period, patients in the studies were followed for an additional 4 weeks for a total of 8 weeks.

### About IL-4R and the IL-4/IL-13 Pathway

Atopic dermatitis and some types of asthma are characterized by the induction of a specific type of an immune response that is driven by a subset of immune cells called Type 2 helper T cells, or Th2 cells. IL-4 and IL-13 are key cytokines that are required for the initiation and maintenance of this Th2 immune response. Both IL-4 and IL-13 signaling occurs through two different IL-4 receptors (Type I and II), which both contain a common IL-4R alpha subunit.

### About Dupilumab (SAR231893/REGN668)

Dupilumab is a fully human monoclonal antibody directed against IL-4R alpha and is administered via subcutaneous injection. By blocking IL-4R alpha dupilumab modulates signaling of both IL-4 and IL-13, drivers of a Th2 immune response. Dupilumab was created using Regeneron's pioneering *VelocImmune*® technology and is being co-developed with Sanofi. Dupilumab is currently being studied in both atopic dermatitis and asthma.

### About Atopic Dermatitis

Atopic dermatitis (AD) is a chronic, immune-mediated, inflammation of the skin that is characterized by poorly defined erythema (redness) with edema (swelling), weeping in the acute stage, and skin thickening (lichenification) in the chronic stage. Chronic and/or relapsing lesions, along with pruritus (itching) and scratching are the hallmarks of the disease. The prevalence of AD is estimated to be between 1% and 3% of adults. For many patients, topical therapies are not effective for keeping the disease under control and the only approved systemic therapies to treat AD are prednisone and cyclosporine (in Europe). Moderate-to-severe atopic dermatitis can negatively impact patients' lives and is associated with a high burden to society both in terms of direct costs of medical care and prescription drugs, as well as loss of productivity.

## **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, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit [www.regeneron.com](http://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 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, 2011. 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 Dupilimab; 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 canceled 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. 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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