



Regeneron and Sanofi Announce Positive Phase 2 Top-line Dupilumab Results in Patients with Chronic Sinusitis with Nasal Polyps

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TARRYTOWN, N.Y. and PARIS, Sept. 30, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) today announced that a Phase 2a proof-of-concept study of dupilumab, an investigational therapy that blocks IL-4 and IL-13 signaling, met all primary and secondary endpoints in patients with moderate-to-severe chronic sinusitis with nasal polyps (CSwNP) who did not respond to intranasal corticosteroids.

"These data suggest the potential of dupilumab for use in the treatment of another allergic inflammatory condition," said Gianluca Pirozzi, M.D., PhD, Vice President, Global Project Head at Sanofi. "Based on these results, we plan to move forward with further clinical development of dupilumab in patients with chronic sinusitis with nasal polyps, in addition to the ongoing development in atopic dermatitis and in asthma."

In the study, dupilumab resulted in a statistically-significant improvement in the size of nasal polyps, as measured by endoscopic Nasal Polyp Score (NPS), the primary endpoint of the study. Statistically significant improvements in all secondary efficacy endpoints were also observed, including objective measures of sinusitis by CT scan, nasal air flow, and patient-reported symptoms (sense of smell, congestion, postnasal drip, runny nose and sleep disturbance). In a pre-specified exploratory analysis, dupilumab-treated patients who also had asthma demonstrated significant improvements in asthma control. The safety profile was consistent with previous studies. The most common AEs with dupilumab were injection site reactions, nasopharyngitis, oropharyngeal pain, epistaxis, headache and dizziness.

"There is growing recognition that patients suffering from one type of allergic disease often have additional allergic conditions. For example, many patients with chronic sinusitis with nasal polyps also have asthma or atopic dermatitis and vice versa," said Neil Graham, M.D., Vice President, Program Management at Regeneron. "The new data reported today, together with prior Phase 2 data with dupilumab in asthma and atopic dermatitis, support the growing body of scientific evidence that these conditions may result from a core allergic inflammatory process driven by the IL-4/IL-13 pathway."

The randomized, double-blind, placebo-controlled study enrolled 60 adult patients with moderate-to-severe CSwNP. Patients in the study received 300 milligrams (mg) of dupilumab or placebo administered once per week (QW) subcutaneously for 16 weeks, following an initial loading dose of 600 mg. All patients in the study also received a standard-of-care nasal corticosteroid spray. Patients were eligible for the study if they continued to have severe CSwNP despite standard treatment for at least one month. Fifty percent of patients in the study had received prior surgery for their condition.

Asthma was also present in 58 percent of CSwNP patients in the study. The conditions are often co-morbid and symptoms/exacerbations are frequently interdependent.

Detailed results of the study will be presented at an upcoming medical conference.

About Dupilumab and IL-4/IL-13 Signaling

Dupilumab, a fully-human monoclonal antibody, is directed against the IL-4 receptor alpha subunit, which blocks signaling from both IL-4 and IL-13. IL-4 and IL-13 are key cytokines that are required for the initiation and maintenance of the Th2 (Type 2 helper T-cell) immune response, which is believed to be a critical pathway in allergic inflammation.

Dupilumab was created using Regeneron's pioneering VelocImmune® technology and is being co-developed with Sanofi in atopic dermatitis, asthma and CSwNP. Dupilumab is an investigational agent under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority.

About Chronic Sinusitis with Nasal Polyps

CSwNP causes mucosal inflammation and polyps in the nasal cavity and sinuses, which result in long-term symptoms of nasal obstruction and congestion, reduction in or loss of sense of smell, and facial pain. Nasal polyps can block normal drainage from the sinuses and patients with nasal obstruction related to nasal polyposis have a 2-fold higher risk of sleep dysfunction. About 75 percent of CSwNP patients have a decreased sense of smell. The estimated prevalence of CSwNP is 3 percent to 5 percent (in Europe and US), and many patients do not respond to the only currently available therapy (intranasal corticosteroids). In the U.S., approximately 200,000 CSwNP patients have sinus surgery to improve breathing, nasal drainage and remove inflamed mucosal tissue. CSwNP is often associated with asthma. Approximately 30 percent of patients with CSwNP have asthma.

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

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 commercializes 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, 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 dupilumab; 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 current and contemplated future clinical trials evaluating dupilumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, including without limitation dupilumab for the treatment of chronic sinusitis with nasal polyps; ongoing regulatory obligations and oversight impacting Regeneron's research and clinical programs and business, including those relating to patient privacy; 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 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, 2013 and its Form 10-Q for the quarter ended June 30, 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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