May 18, 2015

Regeneron and Sanofi Announce Positive Pivotal Phase 2b Dupilumab Data in Asthma Presented at the American Thoracic Society 2015 International Conference

Phase 3 Clinical Trial in Uncontrolled Persistent Asthma Underway

TARRYTOWN, N.Y. and PARIS, May 18, 2015 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today shared positive results from an interim analysis of a pivotal Phase 2b study of dupilumab in adult patients with moderate-to-severe asthma, who are uncontrolled despite treatment with inhaled corticosteroids and long-acting beta agonists (ICS/LABA). As previously reported, the study met its primary endpoint of improving lung function in asthma patients with high blood eosinophil counts (HEos, greater than or equal to 300 eosinophilic cells/microliter). Such high counts are thought to be a marker for patients more likely to have "atopic" or "allergic" asthma. New data presented on secondary endpoints at the American Thoracic Society 2015 International Conference included positive results in study patients with low blood eosinophil counts (LEos, less than 300 eosinophilic cells/microliter), who are thought to be less likely to suffer from "allergic" asthma and thus less likely to respond to TH2 targeted therapies. Dupilumab is an investigational therapy that inhibits signaling of IL-4 and IL-13, two cytokines required for the TH2 (or Type 2) immune response.

Based on discussions with the U.S. Food and Drug Administration (FDA), this Phase 2b study may be considered one of two pivotal efficacy studies required for a potential dupilumab biologics license application (BLA) in asthma. The companies also announced the initiation of a Phase 3 clinical trial of dupilumab in patients with uncontrolled persistent asthma, known as LIBERTY ASTHMA QUEST, which will serve as the second required pivotal efficacy study. The global, placebo-controlled Phase 3 study will enroll more than 1,600 patients with uncontrolled persistent asthma and will evaluate two doses of dupilumab, 200 milligrams (mg) and 300 mg, subcutaneously administered every other week (Q2W).

The new results focused on LEos asthma patients. In this population, patients treated with either 200 mg or 300 mg Q2W doses of dupilumab showed a greater than 8 percent improvement in forced expiratory volume over one second (FEV1, a standard measure of lung function) at Week 12 (p less than 0.001), in comparison to placebo, both in combination with ICS/LABA. Additionally, the 200 mg and 300 mg Q2W doses of dupilumab in combination with ICS/LABA showed 68 percent and 62 percent reductions, respectively, in adjusted annualized rate of severe exacerbations in the LEos population (p less than 0.01 and p less than 0.05), in comparison to placebo in combination with ICS/LABA.

These results are consistent with previously reported positive results in HEos asthma patients and the overall patient population, in which the two Q2W doses (200 mg and 300 mg) of dupilumab in combination with ICS/LABA demonstrated a statistically significant 12 to 15 percent improvement in FEV1 over placebo at Week 12 and a 64 to 75 percent improvement in annualized rate of severe exacerbations over placebo.

Dupilumab also significantly reduced mean fractional exhaled nitric oxide (FeNO) across both Q2W doses tested (200 and 300 mg) and the three patient populations (overall, LEos and HEos), in a roughly dose-dependent manner. FeNO is recommended by the American Thoracic Society clinical practice guidelines to assess airway inflammation, since higher than normal levels of nitric oxide may be released when a patient has a chronic airway disease, such as asthma.

The most common adverse event was injection site reaction, which was more frequent in the dupilumab dose groups (13 to 25 percent) compared to placebo (12 percent). Other common adverse events in the study included upper respiratory tract infection (10 to 13 percent dupilumab; 13 percent placebo), headache (5 to 10 percent dupilumab; 8 percent placebo), nasopharyngitis (3 to 10 percent dupilumab; 6 percent placebo) and bronchitis (5 to 8 percent dupilumab; 8 percent placebo). The incidence of infections was balanced across treatment groups (42 to 45 percent dupilumab; 46 percent placebo), as was the incidence of serious adverse events (3 to 7 percent dupilumab; 5 percent placebo).

"Despite available treatments, many patients with asthma continue to have symptoms and recurring attacks, which have a serious and detrimental impact on their daily lives," said Sally Wenzel, M.D., lead investigator from The University of Pittsburgh, Division of Pulmonary, Allergy and Critical Care Medicine. "In the study, dupilumab added to standard-of-care therapy demonstrated fewer exacerbations and improved lung function across both the high and low baseline eosinophil groups. We look forward to the continued clinical development of dupilumab as a potential option for a broad population of patients with uncontrolled asthma."

The slide set presented at ATS can be found on Regeneron's website here. Dupilumab is an investigational agent under clinical development and its safety and efficacy have not been fully evaluated by any regulatory agency.

These results were based on a pre-specified interim analysis, which occurred when all patients had reached Week 12 of the 24-week treatment period; the average treatment duration at the time of the analysis was 21.4 weeks. The primary endpoint of the study was improvement from baseline in FEV1 at Week 12 in the HEos group. Final analyses on exacerbations and safety will be conducted after 24 weeks of treatment and a 16-week follow-up period.

About the Phase 2b Study
The double-blind, placebo-controlled, 24-week, dose-ranging study enrolled 776 adult patients with moderate-to-severe uncontrolled asthma, as defined by the Global Initiative for Asthma 2014 Guidelines. Trial participants were randomized to receive one of four doses of dupilumab (300 mg every other week, 200 mg every other week, 300 mg monthly, 200 mg monthly) or placebo. Approximately 42 percent of patients had high eosinophils across the dose groups. During the treatment period, patients continued their stable medium- or high-dose inhaled corticosteroid and long-acting beta agonist (ICS/LABA) combination product. Patients could have administered inhaled rescue medication as needed during the study. A severe exacerbation event during the study was defined as a deterioration of asthma requiring the use of systemic corticosteroids for three or more days, or hospitalization or an emergency room visit.

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 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. Several Regeneron programs are based on human genetics findings. 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, 2014. 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 Pharmaceuticals, Inc. ("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; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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 Phase 3 LIBERTY ASTHMA QUEST clinical trial evaluating dupilumab in patients with uncontrolled persistent asthma; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's

late-stage product candidates, including without limitation dupilumab; 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 and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the 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, 2014 and its Form 10-Q for the quarter ended March 31, 2015. Any forward-looking statements are made based on management's current beliefs and judgment, and 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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