Sanofi and Regeneron Announce that Dupilumab Used with Topical Corticosteroids (TCS) was Superior to Treatment with TCS Alone in Long-term Phase 3 Trial in Inadequately Controlled Moderate-to-Severe Atopic Dermatitis Patients

- These data, along with previous Phase 3 studies, will be part of a U.S. regulatory submission for dupilumab, which is on track for Q3 of 2016 -

Paris, France, and Tarrytown, N.Y. - June 3, 2016 - Sanofi and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that a one-year Phase 3 study, known as LIBERTY AD CHRONOS, evaluating investigational dupilumab met its primary and key secondary endpoints. In the study, dupilumab with topical corticosteroids (TCS) was compared to TCS alone in moderate-to-severe atopic dermatitis (AD) adult patients. Patients enrolled in the study were inadequately controlled by topical corticosteroids (TCS) with or without topical calcineurin inhibitor (TCI). Dupilumab with TCS significantly improved measures of overall disease severity at 16 and 52 weeks, when compared to placebo with TCS.

"These are the first long-term Phase 3 data that demonstrated dupilumab with topical corticosteroids was superior to topical corticosteroids alone, and provided sustained efficacy, significantly improving measures of overall disease severity, skin clearing, itching, and quality of life through one year of treatment," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. *"Although topical corticosteroids are standard therapies for atopic dermatitis, they are non-specific anti-inflammatory agents, while dupilumab is a targeted therapy that specifically blocks the IL-4/IL-13 signaling pathway. Our collective clinical data demonstrate that this pathway is a root cause in atopic dermatitis, asthma and nasal polyposis and we continue to evaluate the potential of this pathway in these atopic and allergic diseases."*

"Dupilumab is an innovative first-in-class investigational agent that has shown significant efficacy and a favorable safety profile in two pivotal Phase 3 studies in monotherapy for moderate-to-severe atopic dermatitis, and now in concomitant administration with topical corticosteroids," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. *"These one-year data strengthen the earlier 16-week results, suggesting that dupilumab impacts the aberrant activation of the IL-4/IL-13 pathway which resulted in significant efficacy without the side effects associated with immune-suppressing therapies. We will continue to advance dupilumab for patients worldwide suffering from inadequately controlled moderate-to-severe atopic dermatitis, with the first regulatory submission planned in the U.S. for the third quarter of this year."*

The primary endpoint results at week 16 were the following:

- 39 percent of patients who received either dupilumab 300 mg weekly or dupilumab 300 mg every two weeks with TCS achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 12 percent of patients receiving placebo with TCS (p less than 0.0001).
- 64 percent of patients who received dupilumab 300 mg weekly with TCS, and 69 percent of patients who received dupilumab 300 mg every two weeks with TCS achieved EASI-75, compared to 23 percent of patients receiving placebo with TCS (p less than 0.0001).

The secondary endpoint 52-week results were the following:

- 40 percent of patients who received dupilumab 300 mg weekly with TCS, and 36 percent of patients who received dupilumab 300 mg every two weeks with TCS achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 12.5 percent of patients receiving placebo with TCS (p less than 0.0001).
- 64 percent of patients who received 300 mg weekly with TCS, and 65 percent of patients who received 300 mg every two weeks with TCS achieved EASI-75, compared to 22 percent with placebo with TCS (p less than 0.0001).

Patients were less likely to discontinue therapy in the dupilumab with TCS groups compared to placebo with TCS group (15 percent in both dupilumab groups; 33 percent placebo).

The overall rate of adverse events was comparable between the dupilumab with TCS groups (83 percent for the weekly dose and 88 percent for the every two weeks dose) and the placebo with TCS group (84 percent). The rate of serious adverse events was comparable between the dupilumab with TCS groups (3 and 4 percent) and placebo with TCS group (5 percent). Serious and/or severe infections were numerically higher in the placebo with TCS group (1 percent in both dupilumab groups and 2 percent placebo). Adverse events that were noted to have a higher rate with dupilumab included injection site reactions (20 and 16 percent dupilumab; 9 percent placebo) and conjunctivitis (19 and 13 percent dupilumab; 8 percent placebo); 22 percent of patients on placebo, and 23 and 28 percent of patients on dupilumab reported a history of allergic conjunctivitis at study entry.

More detailed results, including long-term efficacy and safety data from CHRONOS will be submitted for presentation at a future medical congress.

The U.S. Food and Drug Administration (FDA) granted dupilumab Breakthrough Therapy designation in AD in November 2014. Dupilumab is currently under clinical development and its safety and efficacy have not been fully evaluated by any regulatory authority. If approved, dupilumab would be commercialized by Regeneron and Sanofi Genzyme, the specialty care global business of Sanofi.

The LIBERTY AD Phase 3 clinical program consists of five trials of patients with moderate-to-severe AD at sites worldwide.

About the LIBERTY CHRONOS TRIAL

A total of 740 adult patients with moderate-to-severe AD were enrolled in CHRONOS. All patients were inadequately controlled with topical medications and were assessed via the 5-point Investigator's Global Assessment (IGA) scale, ranging from 0 (clear) to 4 (severe); entry criteria required a baseline score of 3 or 4. Patients were also assessed using the Eczema Area and Severity Index (EASI) and other measures. All patients initiated daily treatment with a medium potency TCS or low potency TCS on areas of the body where medium potency TCS is considered unsafe. Patients were randomized in a 3:1:3 fashion into the following treatment groups: dupilumab 300 mg subcutaneously once per week (n=319), dupilumab 300 mg subcutaneously every two weeks (n=106), or placebo (n=315). This design allowed sufficient power for the efficacy endpoints in both dupilumab groups while increasing the available safety data on the more frequent dosing regimen. In the U.S., the primary efficacy endpoint of the study was the percent of patients who achieved IGA 0 or 1 at 16 weeks. In Europe and Japan there was an additional co-primary endpoint: the percent of patients achieving an EASI 75 score at week 16. The primary analysis was pre-specified to occur 52 weeks after approximately 85 percent of patients were randomized into the study.

About Atopic Dermatitis

Atopic dermatitis – a serious form of eczema – is a chronic inflammatory disease characterized by itchy, inflamed skin that can be present on any part of the body.[1,2] Though

symptoms appear externally, atopic dermatitis is characterized by underlying inflammation.[3] About 70 percent of people with atopic dermatitis have a family history of other common atopic diseases, such as asthma or hay fever.[2,8] In many cases, atopic dermatitis is characterized by pruritus (itchiness) and skin lesions.[9,10,11] The intense itching, scratching and skin damage associated with the disease can cause secondary infections that may require additional treatments. In addition, the physical manifestations of the disease can lead to anxiety, depression, and feelings of social isolation.[12,13,14,15,16] Based on a survey of 200 physicians, there are approximately 1.6 million patients in the U.S. that have been diagnosed with moderate-to-severe atopic dermatitis, and are currently being treated but still are living with inadequately controlled disease.[7]

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) 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 high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 initiatives 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, 2015. 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 and Use of Digital Media

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" or the "Company"), 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 clinical development programs evaluating dupilumab; the likelihood and timing of possible regulatory approval (including U.S. regulatory approval) and commercial launch of Regeneron's late-stage product candidates, such as dupilumab for atopic dermatitis or other indications; 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, such as dupilumab; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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, 2015 and its Form 10-Q for the quarterly period ended March 31, 2016. 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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