October 1, 2016

# Regeneron and Sanofi Announce Positive Dupixent® (dupilumab) Phase 3 Atopic Dermatitis Data Published in the New England Journal of Medicine

## Data to be presented today during a late breaking abstract session at the 25th Annual European Academy of Dermatology and Venereology (EADV) Congress

TARRYTOWN, N.Y. and PARIS, Oct. 1, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announce that detailed results from LIBERTY AD SOLO 1 and SOLO 2, two placebo-controlled Phase 3 studies evaluating investigational Dupixent® (dupilumab) in adult patients with inadequately controlled moderate-to-severe atopic dermatitis (AD), were published in the *New England Journal of Medicine* (NEJM). The studies met their primary endpoints evaluating the extent and severity of the disease. In addition, both trials met key secondary endpoints measuring reduction in itch, improvement in patient-reported anxiety and depression symptoms, and certain quality of life measures. Dupixent inhibits signaling of IL-4 and IL-13, two key cytokines required for the type 2 (including Th2) immune response, which is believed to be a major driver in AD, and certain atopic or allergic diseases including asthma and nasal polyposis, where Dupixent is being evaluated in ongoing clinical studies.

"These results support the growing body of evidence for Dupixent as a potential new treatment option for patients with moderate-to-severe atopic dermatitis who are struggling to control their disease. The Phase 3 SOLO 1 and SOLO 2 clinical trials are the first large pivotal studies where a systemic investigational therapy has demonstrated a significant reduction in the signs and symptoms of atopic dermatitis, and showed improvement in studied quality of life measures," said Eric Simpson, M.D., M.C.R., Oregon Health & Science University, and lead author of the NEJM paper. "Additionally, the reduction of itch intensity is important because itching is one of the most burdensome symptoms for patients and can impact other aspects of their lives, such as sleep."

The NEJM paper provides data on key endpoints including:

- At 16 weeks for SOLO 1 and SOLO 2, respectively, 37 and 36 percent of adult patients who received Dupixent 300 mg weekly, and 38 and 36 percent of patients who received Dupixent 300 mg every two weeks, achieved clearing or near-clearing of skin lesions as measured by the 5-point Investigator's Global Assessment (IGA) scale, compared to 10 and 8 percent with placebo (p less than 0.001). This was the primary endpoint of the study in the U.S. and one of the primary endpoints in the EU.
- At 16 weeks for SOLO 1 and SOLO 2, respectively, 52 and 48 percent of adult patients who received Dupixent 300 mg weekly, and 51 and 44 percent of patients who received Dupixent 300 mg every two weeks, achieved a 75 percent or greater reduction in their Eczema Area and Severity Index score (EASI-75) compared to 15 and 12 percent with placebo (p less than 0.001). This was the key secondary endpoint in the U.S. and one of the primary endpoints in the EU.
- At 16 weeks for SOLO 1 and SOLO 2, respectively, the percent improvement in EASI from baseline was 72 and 69 percent in patients who received the 300 mg weekly dose, and 72 and 67 percent for patients who received Dupixent 300 mg every two weeks, compared to 38 and 31 percent for placebo (p less than 0.001).
- The reduction in the daily intensity of patient-reported itch, as measured by the Pruritus Numerical Rating Scale (NRS), was a secondary endpoint that was met at 2 weeks, 4 weeks and 16 weeks. The Pruritus NRS ranges from 0 (no itch) to 10 (worst itch imaginable). At 16 weeks, for SOLO 1 and SOLO 2, respectively, 40 and 39 percent of patients who received Dupixent 300 mg weekly and 41 and 36 percent of patients who received Dupixent 300 mg every two weeks achieved a four-point or greater reduction in their NRS score compared to 12 and 10 percent with placebo (p less than 0.001).

Other positive secondary endpoints discussed in the NEJM paper include improvement in patient-reported anxiety and depression symptoms and certain quality of life measures as evaluated by Scoring Atopic Dermatitis (SCORAD), Hospital Anxiety and Depression Scale (HADS), Patient-Oriented Eczema Measure (POEM), and Dermatology Life Quality Index (DLQI).

For the 16-week treatment period, the overall rate of adverse events (65-73 percent Dupixent and 65-72 percent placebo) was comparable between the Dupixent groups and the placebo groups. The proportion of patients who completed the treatment period was 88-94 percent for Dupixent and 80.5-82 percent for placebo. The rate of serious adverse events was 1-3 percent for Dupixent and 5-6 percent for placebo. Serious or severe infections were similar in the Dupixent and placebo groups in both studies (1 percent Dupixent and 1 percent placebo). Adverse events that were noted to have a higher rate

with Dupixent treatment across both studies included injection site reactions (8-19 percent Dupixent; 6 percent placebo) and conjunctivitis (1-5 percent Dupixent; 1 percent placebo). No patients discontinued therapy due to injection site reactions and one patient discontinued therapy due to conjunctivitis.

The Dupixent Biologics License Application (BLA) was recently accepted for Priority Review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of March 29, 2017. The FDA granted Dupixent Breakthrough Therapy designation in uncontrolled moderate-to-severe atopic dermatitis in 2014. The European Medicines Agency (EMA) and FDA have conditionally accepted Dupixent as the trade name for dupilumab.

Dupixent is currently under clinical development and its safety and efficacy have not been fully evaluated by any regulatory authority. In addition to AD, Dupixent is being evaluated in asthma, nasal polyposis and eosinophilic esophagitis. If approved, Dupixent would be commercialized by Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi.

Regeneron and Sanofi will host an Investor Relations Thematic Conference Call for the financial community focusing on Dupixent following the late breaking data presentation at EADV at the following time: 7:00 a.m. ET (New York), 12:00 p.m. BST (London), 1:00 p.m. CEST (Paris and Vienna). To access this call, dial (888) 771-4371 (U.S.), 0805 102 604 (France), or 0808 238 9578 (UK). The conference call will include a presentation followed by a Q&A session and will be accessible through an audio webcast at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website.

**About the LIBERTY AD SOLO 1 and SOLO 2 TRIALS**

The Liberty AD Phase 3 clinical program consists of five trials of patients with moderate-to-severe atopic dermatitis (AD) at sites worldwide. A total of 1,379 adult patients with moderate-to-severe AD were enrolled in the identically designed SOLO 1 and SOLO 2 trials. Patients were enrolled if they were not adequately controlled with topical medications, or if topical treatment was not medically advisable. All patients 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. Patients were randomized into one of three treatment groups: Dupixent 300 mg subcutaneously once per week, Dupixent 300 mg subcutaneously every two weeks, or placebo for 16 weeks following an initial Dupixent loading dose of 600 mg subcutaneously, or placebo.

**About Moderate-to-Severe Atopic Dermatitis**

Moderate-to-severe atopic dermatitis, a serious, chronic form of eczema, is characterized by rashes and can include intense itching, skin dryness, cracking, redness, crusting, and oozing. Even though atopic dermatitis symptoms appear on the skin, they are fueled by a continuous cycle of underlying inflammation triggered in part by a malfunction in the immune system. People living with the physical symptoms of atopic dermatitis may also feel self-conscious and embarrassed about their appearance and may experience anxiety, depression, and feelings of social isolation.

**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 eye diseases, high LDL cholesterol and a rare inflammatory condition, and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, atopic dermatitis, pain, oncology, 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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, 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 Dupixent® (dupilumab); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, such as Dupixent for the treatment of adult patients with inadequately controlled moderate-to-severe atopic dermatitis and other potential indications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation Dupixent; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; 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 Dupixent; 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; 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 (or their respective affiliated companies, as applicable), 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 June 30, 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).*

**Contacts Sanofi:**

**Media Relations**
**Jack Cox**
Tel: +33 (0) 1 53 77 94 74
jack.cox@sanofi.com

**Investor Relations**
**George Grofik**
Tel: +33 (0) 1 53 77 94 69
ir@sanofi.com

**Contacts Regeneron:**

**Media Relations**
**Ilana Tabak**
Tel: + 1 (914) 847-3836
Mobile: +1 (914) 450-6677
ilana.tabak@regeneron.com

**Investor Relations**
Manisha Narasimhan, Ph.D.
Tel: +1 (914) 847-5126
Manisha.narasimhan@regeneron.com