REGENERON

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Regeneron and Sanofi Announce Presentation of Positive Data from Long-Term Pivotal Phase 3 CHRONOS Study of DUPIXENT® (dupilumab) in Moderate-to-Severe Atopic Dermatitis

Late-breaking oral abstract to be presented today at the Annual Meeting of the American Academy of Dermatology

TARRYTOWN, N.Y. and PARIS, March 4, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today presented detailed results from the one-year Phase 3 CHRONOS study, which showed that patients receiving the investigational drug DUPIXENT with topical corticosteroids (TCS) achieved significantly improved measures of overall disease severity compared to TCS alone in adults with uncontrolled moderate-to-severe atopic dermatitis (AD). The data will be presented today as a late-breaking oral abstract at the Annual Meeting of the American Academy of Dermatology (AAD) taking place in Orlando, Florida.

"These new results build upon previous positive Phase 3 monotherapy data. In the CHRONOS study, DUPIXENT used with topical corticosteroids showed significantly greater clearance of skin lesions and overall disease severity compared to topical corticosteroids alone, which are commonly prescribed for moderate-to-severe atopic dermatitis," said Andrew Blauvelt, M.D., President of Oregon Medical Research Center and principal investigator of the study. "This study provides positive long-term data for DUPIXENT, which is important given atopic dermatitis is a chronic inflammatory disease. Additionally, the presentation highlights the critical role of IL-4 and IL-13 as drivers of this atopic condition."

Patients were eligible for participation in the CHRONOS study if their disease was uncontrolled by topical medicines including corticosteroids with or without calcineurin inhibitors. Patients were randomized to receive DUPIXENT 300 mg weekly with TCS, DUPIXENT 300 mg every two weeks with TCS, or placebo with TCS. DUPIXENT with TCS significantly improved measures of overall disease severity at 16 and 52 weeks when compared to placebo with TCS.

As previously announced in June 2016, the primary endpoint results at week 16 and secondary endpoint 52-week results were the following:

- At 16 weeks, 39 percent of patients who received either DUPIXENT 300 mg weekly with TCS or DUPIXENT 300 mg every two weeks with TCS achieved clear or almost clear skin (IGA 0 or 1), compared to 12 percent of patients receiving placebo with TCS (p less than 0.0001).
- At 16 weeks, 64 percent of patients who received DUPIXENT 300 mg weekly with TCS, and 69 percent of patients who received DUPIXENT 300 mg every two weeks with TCS achieved EASI-75, a 75 percent reduction on an index measuring eczema severity, compared to 23 percent of patients receiving placebo with TCS (p less than 0.0001).
- At 52 weeks, 40 percent of patients who received DUPIXENT 300 mg weekly with TCS, and 36 percent of patients who received DUPIXENT 300 mg every two weeks with TCS achieved clear or almost clear skin (IGA 0 or 1), compared to 12.5 percent of patients receiving placebo with TCS (p less than 0.0001).
- At 52 weeks, 64 percent of patients who received DUPIXENT 300 mg weekly with TCS, and 65 percent of patients who received DUPIXENT 300 mg every two weeks with TCS achieved EASI-75, compared to 22 percent with placebo with TCS (p less than 0.0001).

New data being presented at the meeting show that:

- At 16 weeks, the mean percent improvement in EASI from baseline was 77 percent for patients who received DUPIXENT weekly with TCS and for patients who received DUPIXENT every two weeks with TCS, compared to 42 percent for patients receiving placebo with TCS (p less than 0.0001).
- At 16 weeks, the mean percent improvement from baseline in the intensity of patient-reported itch, as measured by the Pruritus Numerical Rating Scale (NRS), was 55 percent for patients who received DUPIXENT weekly with TCS and 58 percent for patients who received DUPIXENT every two weeks with TCS, compared to 29 percent for patients receiving placebo with TCS (p less than 0.0001).
- At 16 weeks, 77 percent of patients who received DUPIXENT weekly with TCS or DUPIXENT every two weeks with TCS achieved a ≥4-point improvement in the severity of their AD, as measured by the Patient Oriented Eczema Measure (POEM), a tool that quantifies the illness as experienced by the patients, compared to 37 percent of patients receiving placebo with TCS (p less than 0.0001).
- At 16 weeks, 74 percent of patients who received DUPIXENT weekly with TCS and 81 percent of patients who received DUPIXENT every two weeks with TCS achieved a ≥4-point improvement in aspects of their quality of life, as

measured by the Dermatology Life Quality Index (DLQI), compared to 43 percent of patients receiving placebo with TCS (p less than 0.0001). The DLQI is a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person.

- At 52 weeks, the mean percent improvement in EASI from baseline was 80 percent for patients who received DUPIXENT weekly with TCS and 78 percent for patients who received DUPIXENT every two weeks with TCS, compared to 46 percent for patients receiving placebo with TCS (p less than 0.0001).
- At 52 weeks, the mean percent improvement from baseline in the intensity of patient-reported itch, as measured by the NRS, was 54 percent for patients who received DUPIXENT weekly with TCS and 56 percent for patients who received DUPIXENT every two weeks with TCS, compared to 27 percent for patients receiving placebo with TCS (p less than 0.0001).
- At 52 weeks, 65 percent of patients who received DUPIXENT weekly with TCS and 76 percent of patients who received DUPIXENT every two weeks with TCS achieved a ≥4-point improvement in the severity of their AD, as measured by POEM, compared to 26 percent of patients receiving placebo with TCS (p less than 0.0001).
- At 52 weeks, 63 percent of patients who received DUPIXENT weekly with TCS and 80 percent of patients who received DUPIXENT every two weeks with TCS achieved a ≥4-point improvement their quality of life, as measured by the DLQI, compared to 30 percent of patients receiving placebo with TCS (p less than 0.0001).

In the CHRONOS trial, 85 percent of patients who received DUPIXENT weekly with TCS and 86 percent of patients who received DUPIXENT every two weeks with TCS completed the 52-week treatment, compared to 67 percent of patients in the placebo group. Patients who received DUPIXENT with TCS had higher rates of injection site reactions (19 percent DUPIXENT weekly, 15 percent DUPIXENT every two weeks and 8 percent TCS alone) and cases of conjunctivitis (19 percent DUPIXENT weekly, 14 percent DUPIXENT every two weeks and 8 percent TCS alone).

The DUPIXENT Biologics License Application (BLA) was accepted for Priority Review by the U.S. Food and Drug Administration (FDA) with a target action date of March 29, 2017. The FDA granted DUPIXENT Breakthrough Therapy designation in uncontrolled moderate-to-severe AD in 2014. The European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) on December 8, 2016.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. If approved, DUPIXENT would be commercialized by Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi.

About Atopic Dermatitis
AD is the most common form of eczema and is characterized by unpredictable flare-ups. It is a chronic inflammatory disease with symptoms often appearing on the skin. Moderate-to-severe AD is characterized by rashes and can include intense, persistent and debilitating itching, skin dryness, cracking, redness, crusting, and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating.

It's estimated approximately 300,000 people in the United States are living with uncontrolled moderate-to-severe AD and despite their current treatment, are most in need of new treatment options. Despite currently available therapies, there still remains an unmet need for treatments that help those adults struggling to manage their moderate-to-severe AD.

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) is a leading science-based biopharmaceutical company 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, atopic dermatitis, asthma, pain, cancer and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 Consumer Healthcare. 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.

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 uncontrolled moderate-to-severe atopic dermatitis (including possible regulatory approval of Dupixent by the U.S. Food and Drug Administration and the European Medicines Agency) 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 (such as Dupixent) 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, Bayer, and Teva Pharmaceutical Industries Ltd. (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, including without limitation the patent litigation relating to Praluent® (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. 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, 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).

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.

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