REGENERON

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Regeneron and Sanofi Announce FDA Approval of DUPIXENT® (dupilumab), the First Targeted Biologic Therapy for Adults with Moderate-to-Severe Atopic Dermatitis

DUPIXENT will be available later this week to U.S. patients suffering from this chronic and debilitating form of eczema

TARRYTOWN, N.Y. and PARIS, March 28, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the U.S. Food and Drug Administration (FDA) approved DUPIXENT® (dupilumab) Injection, the first and only biologic medicine approved for the treatment of adults with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable.

"People with moderate-to severe atopic dermatitis cope with intense, sometimes unbearable symptoms that can impact them for most of their lives," said Julie Block, President and Chief Executive Officer, National Eczema Association. "To date, there have been few options available to treat people with moderate-to-severe atopic dermatitis who have uncontrolled disease. That's why today's approval of Dupixent is so important for our community. Now we have a treatment that is expected to help address patients suffering from this devastating disease."

DUPIXENT is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in AD. DUPIXENT comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose. DUPIXENT can be used with or without topical corticosteroids. It should not be used in patients who are allergic to dupilumab or any of the ingredients in DUPIXENT.

AD, the most common form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin. Moderate-to-severe AD is characterized by rashes often covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating. Of the adults with uncontrolled moderate-to-severe AD in the United States, it is estimated that 300,000 are most in need of new treatment options.

"DUPIXENT is the result of years of tireless research by our scientists into the underlying causes of allergic and atopic diseases. In atopic dermatitis, DUPIXENT was shown to help clear the skin and manage the intense itch caused by the disease," said George D. Yancopoulos, M.D., Ph.D., Founding Scientist, President, and Chief Scientific Officer, Regeneron. "Today's approval would not be possible without the dedication of the clinical investigators and the participation of the patients who took part in the global LIBERTY AD clinical program."

DUPIXENT was evaluated by the FDA with Priority Review, which is reserved for medicines that represent potentially significant improvements in safety or efficacy in treating serious conditions. This followed the FDA's 2014 Breakthrough Therapy designation for DUPIXENT for inadequately controlled moderate-to-severe AD. Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs developed for serious or life-threatening conditions. DUPIXENT represents the first time this designation was granted for a dermatological disease, other than in dermatologic cancers.

"We strive to transform scientific innovation into therapeutic solutions that make a meaningful difference to people's lives," said Olivier Brandicourt, M.D., Chief Executive Officer, Sanofi. "The approval of DUPIXENT offers new hope for adults with moderate-to-severe AD in the United States, and we look forward to working with regulatory authorities around the world to bring this important new medicine to patients globally."

Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi, will market DUPIXENT in the United States. DUPIXENT is expected to be available to patients and providers in the U.S. later this week.

Regeneron and Sanofi recognize that DUPIXENT can only help those uncontrolled moderate-to-severe AD patients that were prescribed the medicine if they can both access the medicine and use it properly. Therefore, the companies have launched *DUPIXENT MyWay™, a* comprehensive and specialized program that provides support and services to patients throughout every step of the treatment process.

DUPIXENT MyWay™ will help eligible patients who are uninsured, lack coverage, or need assistance with their out-of-

pocket costs. Additionally, *DUPIXENT MyWay™* offers personalized support from registered nurses and other specialists who are available 24/7 to speak with patients and help them navigate the complex insurance process. For more information, please call 1-844-DUPIXENT (1-844-387-4936) or visit www.DUPIXENT.com.

The Wholesale Acquisition Cost (WAC) of DUPIXENT in the United States is $37,000 annually. Actual costs to patients, payers and health systems are anticipated to be lower as WAC pricing does not reflect discounts, rebates or patient assistance programs.

LIBERTY AD Clinical Program and Results
The approval of DUPIXENT was based on data from the global LIBERTY AD clinical program, which included three randomized Phase 3 pivotal trials known as SOLO 1, SOLO 2 and CHRONOS (enrolled 2,119 total adult patients). The studies examined the use of DUPIXENT either alone (SOLO 1 or SOLO 2, 1,379 adult patients enrolled) or with topical corticosteroids (CHRONOS, 740 adult patients enrolled) in patients with inadequately controlled moderate-to-severe AD. In all these studies, DUPIXENT alone or with topical corticosteroids met the primary and key secondary endpoints, specifically:

- In the SOLO 1 and SOLO 2 studies, treatment with DUPIXENT as monotherapy significantly improved measures of skin clearing and overall extent and severity of disease:
  - At 16 weeks, for SOLO 1 and SOLO 2, respectively, 38 and 36 percent of patients who received DUPIXENT 300 mg every two weeks achieved clear or almost clear skin as measured by the 5-point Investigator's Global Assessment (IGA) scale (primary endpoint), compared to 10 and 9 percent with placebo.
  - At 16 weeks, for SOLO 1 and SOLO 2, respectively, 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) from baseline, a key secondary endpoint, compared to 15 and 12 percent with placebo.
  - At 16 weeks, for SOLO 1 and SOLO 2, respectively, 41 and 36 percent of patients who received DUPIXENT 300 mg every two weeks achieved a greater than or equal to 4 point improvement in the daily intensity of patient-reported itch, as measured by the Pruritus Numerical Rating Scale (NRS), compared to 12 and 10 percent with placebo.

- In the CHRONOS study, treatment with DUPIXENT with topical corticosteroids (TCS) significantly improved measures of overall disease severity at 16 and 52 weeks, when compared to placebo with TCS:
  - At 16 weeks, 39 percent of patients who received DUPIXENT 300 mg every two weeks with TCS achieved clear or almost clear skin (IGA 0 or 1), the primary endpoint, compared to 12 percent of patients receiving placebo with TCS.
  - At 16 weeks, 69 percent of patients who received DUPIXENT 300 mg every two weeks with TCS achieved EASI-75 (key secondary endpoint), a 75 percent reduction on an index measuring eczema severity, compared to 23 percent of patients receiving placebo with TCS.
  - At 16 weeks, 59 percent of patients who received DUPIXENT 300 mg every two weeks with TCS achieved a greater than or equal to 4 point improvement in the daily intensity of patient-reported itch, as measured by the NRS, compared to 20 percent of patients receiving placebo with TCS.
  - The study also met additional key secondary endpoints at 52 weeks, showing that 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 13 percent of patients receiving placebo with TCS.

The most common adverse events that were noted to be greater than or equal to one percent with DUPIXENT treatment included injection site reactions, eye and eye lid inflammation including redness, swelling and itching, and cold sores in the mouth or on the lips.

In December 2016, the European Medicines Agency accepted for review Sanofi's and Regeneron's marketing authorization application (MAA) for DUPIXENT for adults with uncontrolled moderate-to-severe AD.

Dupilumab Program Overview
Dupilumab is currently being evaluated in a comprehensive development program for AD that includes studies in children with severe AD (6 months to 11 years of age) and adolescents with moderate-to-severe AD (12 to 17 years of age). In October 2016, the FDA granted dupilumab Breakthrough Therapy designation for both populations. These potential uses are investigational and have not been evaluated by any regulatory authority.

Dupilumab is also being studied in other inflammatory diseases that are believed to be driven by IL-4 and IL-13 cytokines, including persistent uncontrolled asthma (Phase 3, results expected later this year), nasal polyposis (Phase 3) and eosinophilic esophagitis (Phase 2). These potential uses are investigational and the safety and efficacy have not been evaluated by any regulatory authority. For more information on dupilumab clinical trials please visit www.clinicaltrials.gov.

IMPORTANT SAFETY INFORMATION

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems
- have a parasitic (helminth) infection
- have asthma
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your healthcare provider.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions**. Stop using DUPIXENT and go to the nearest hospital emergency room if you get any of the following symptoms: fever, general ill feeling, swollen lymph nodes, hives, itching, joint pain, or skin rash.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.

The most common side effects include injection site reactions, eye and eyelid inflammation, including redness, swelling and itching, and cold sores in your mouth or on your lips.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed. If your healthcare provider decides that you or a caregiver can give DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. **Do not** try to inject DUPIXENT until you have been shown the right way by your healthcare provider.

Please click here for the full Prescribing Information. The patient information is available here.

INDICATION

DUPIXENT is used to treat adult patients with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children.

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, atopic dermatitis and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, 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) Injection; 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 in jurisdictions outside the United States 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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2016. 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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