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Press Release

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

Dupixent® (dupilumab) showed positive Phase 3 results in adolescents with inadequately controlled moderate-to-severe atopic dermatitis

- U.S. regulatory submission for patients ages 12-17 planned for third quarter 2018

Paris and Tarrytown, NY – May 16, 2018 – A pivotal Phase 3 trial evaluating Dupixent® (dupilumab) to treat moderate-to-severe atopic dermatitis in adolescents (ages 12-17) met its primary and key secondary endpoints. In the trial, treatment with Dupixent as monotherapy significantly improved measures of overall disease severity, skin clearing, itching, and certain health-related quality of life measures. Dupixent is the first and only biologic to show positive results in this patient population.

> *"Moderate-to-severe atopic dermatitis can place a particularly significant burden on adolescents, who have to deal with oozing skin lesions with unrelenting, intense itching during their formative years," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "Dupixent blocks the IL-4/IL-13 pathway, which is emerging as a central driver of Type 2 allergic inflammation. We are committed to investigating the potential for Dupixent across Type 2 inflammatory diseases with high unmet need including atopic dermatitis, asthma, eosinophilic esophagitis, nasal polyps, chronic obstructive pulmonary disease, and food allergy."*

Patients treated with Dupixent had significant improvement in disease severity at 16 weeks

The primary endpoints were the proportion of patients achieving Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and 75% improvement in Eczema Area and Severity Index (EASI-75, co-primary endpoint outside of the U.S.) at 16 weeks. Results included:

- 24% of patients who received weight-based dosing of Dupixent every two weeks (200 mg or 300 mg) and 18% of patients who received a fixed dose of Dupixent every four weeks (300 mg) achieved the primary endpoint – clear or almost-clear skin (IGA; score of 0 or 1) – compared with 2% with placebo (p less than 0.0001, and p=0.0007, respectively).

- 41.5% of patients who received Dupixent every two weeks and 38% of patients who received Dupixent every four weeks achieved 75% or greater skin improvement (EASI-75) compared to 8% with placebo (p less than 0.0001).
- There was a 66% improvement in the Dupixent every two weeks group and, 65% improvement in the Dupixent every four weeks group in average percent change from baseline in EASI score compared with a 24% improvement in the placebo group (p less than 0.0001).
- There was a 48% improvement in the Dupixent every two weeks group and 45.5% improvement in the Dupixent every four weeks group in average percent change from baseline in the pruritus numerical rating scale (NRS) compared with a 19% improvement in the placebo group (p less than 0.0001).

"Current treatment options for these adolescent patients such as topical steroids, oral steroids, and non-steroidal immunosuppressants can have significant side effects," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. "We continue to explore Dupixent's role in targeting Type 2 inflammation as an underlying cause of atopic dermatitis to potentially provide adolescents, some of whom have lived with this disease their entire lives, a therapy that treats more than just their symptoms."

Dupixent safety profile was consistent with that seen in adults

For the 16-week treatment period, the overall rate of adverse events was comparable between the Dupixent groups and placebo (72% for Dupixent every two weeks, 64% for Dupixent every four weeks and 69% for placebo). There were no serious adverse events or events leading to treatment discontinuation in either Dupixent treatment group.

Adverse events that were observed at a higher rate with Dupixent included injection site reactions (8.5% for Dupixent every two weeks, 6% for Dupixent every four weeks compared with 3.5% for placebo) and conjunctivitis (10% for Dupixent every two weeks, 11% for Dupixent every four weeks compared with 5% for placebo). Skin infections were numerically lower in the Dupixent groups (11% for Dupixent every two weeks, 13% for Dupixent every four weeks compared with 20% for placebo).

Detailed results from this trial will be presented at a future medical meeting. These data will be submitted to regulatory authorities later this year. In 2016, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for Dupixent for the treatment of moderate-to-severe (12 to 17 years of age) and severe (6 months to 11 years of age) atopic dermatitis.

The safety and efficacy of Dupixent in the adolescent atopic dermatitis population have not been fully evaluated by any regulatory authority.

About the Dupixent Trial in Adolescent Patients

The pivotal, Phase 3, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent monotherapy in adolescent patients with moderate-to-severe atopic dermatitis. The trial enrolled 251 patients who were 12 years to 17 years of age with moderate-to-severe atopic dermatitis whose disease could not be adequately controlled with topical medications or for whom topical treatment was medically inadvisable. In total, 92% of these patients suffered from at least one concurrent allergic condition such as allergic rhinitis, asthma or food allergy.

The primary endpoint of this trial was the proportion of patients with an IGA score of 0 or 1 at Week 16. The IGA is a 5-point scale ranging from 0 (clear) to 4 (severe) that measures overall severity of skin lesions. A co-primary endpoint outside of the U.S. and a key secondary endpoint in the U.S. was the proportion of patients who achieved 75% or greater skin improvement as measured by the EASI-75 at Week 16. EASI is a tool used to measure the extent and severity of the disease.

Patients were randomized into one of three treatment groups for the controlled period of 16 weeks: the first group was treated with Dupixent subcutaneous injection 200 mg or 300 mg every two weeks, based on weight (with an initial dose of 400 mg or 600 mg respectively). The second group was treated with 300 mg Dupixent every four weeks (with an initial dose of 600 mg), and the third group was treated with placebo every two weeks.

About Moderate-to-Severe Atopic Dermatitis

Atopic dermatitis, a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin.[i,ii,iii,iv] Moderate-to-severe atopic dermatitis is characterized by rashes often covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing.[v] Itch is one of the most burdensome symptoms for patients and can be debilitating.[vi] In addition, patients with moderate-to-severe atopic dermatitis experience a substantial burden of disease, including painful skin lesions and intense pruritus.[vi]

Dupilumab Development Program

Sanofi and Regeneron are studying dupilumab in a broad range of clinical development programs for diseases driven by Type 2 inflammation, including asthma (Phase 3), pediatric atopic dermatitis (Phase 3, ages 6 months - 11 years), nasal polyps (Phase 3) and eosinophilic esophagitis (Phase 2). Future trials are planned for chronic obstructive pulmonary disease, grass allergy and food allergy (including peanut). These potential uses are investigational and the safety and efficacy have not been evaluated by any regulatory authority. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

For more information on dupilumab clinical trials please visit www.clinicaltrials.gov.

About Dupixent® (dupilumab)

Dupixent is currently approved in the U.S. for the treatment of adults with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Dupixent is also approved for use in certain patients with moderate-to-severe atopic dermatitis in a number of other countries, including the countries of the European Union, Canada, and Japan. The safety and efficacy of Dupixent in the adolescent atopic dermatitis population have not been fully evaluated by any regulatory authority.

In addition, the potential use of Dupixent for the treatment of certain adults and adolescents with inadequately controlled moderate-to-severe asthma is currently under regulatory review in the U.S. and European Union, and the safety and efficacy for this use have not been fully evaluated by any regulatory authority.

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. Dupixent is administered by subcutaneous injection at different injection sites every two weeks after an initial loading dose. Dupixent is intended for use under the guidance of a healthcare provider. A patient may self-inject Dupixent after training in subcutaneous injection technique using the pre-filled syringe.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

About Regeneron Pharmaceuticals, Inc

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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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, 2017. 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) 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 dupilumab for the treatment of moderate-to-severe atopic dermatitis in adolescents, pediatric atopic dermatitis, asthma, nasal polyps, eosinophilic esophagitis, chronic obstructive pulmonary disease, grass allergy, food allergy, and other potential indications; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in later studies and lead to therapeutic applications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation dupilumab; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as dupilumab) 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 proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, 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, 2017 and its Form 10-Q for the quarterly period ended March 31, 2018. 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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vi Zuberbier T et al. Patient perspectives on the management of atopic dermatitis. J Allergy Clin Immunol vol. 118, pp. 226-232, 2006.