SANOFI

Press Release

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

Dupixent® (dupilumab) showed positive topline results in Phase 3 trial of children aged 6 to 11 years with severe atopic dermatitis

* U.S. FDA submission for children planned for 4Q 2019

PARIS and TARRYTOWN, NY – August 6, 2019 – A pivotal Phase 3 trial evaluating Dupixent® (dupilumab) to treat severe atopic dermatitis in children aged 6 to 11 years met its primary and secondary endpoints. Dupixent is the first and only biologic to show positive results in this pediatric atopic dermatitis population.

The topline data show that for children with severe atopic dermatitis (covering nearly 60% of their skin surface on average), adding Dupixent to standard-of-care topical corticosteroids (TCS) significantly improved measures of overall disease severity, skin clearing, itching and health-related quality of life, compared to TCS alone. In addition, the safety data were consistent with the previously documented safety profile of Dupixent in older populations, including a numerically lower rate of skin infections compared to placebo.

> *"The results from this trial, the first to assess a biologic medicine in children under 12 with atopic dermatitis, are very important because of the significant unmet needs in this patient population. Children in the trial had suffered from severe atopic dermatitis for most of their lives*," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. *"The trial showed that Dupixent significantly improved outcomes and quality of life, with no new safety signals.*

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP).

> "*In this trial, children with severe atopic dermatitis had uncontrolled disease covering, on average, nearly 60% of their skin. The unrelenting symptoms of this disease, which impact not just the child but the whole family, include widespread rashes, intense and persistent itching, and skin lesions,"* said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. *"Symptoms of severe atopic dermatitis can take a toll on children both physically and emotionally. We are encouraged by these results, which demonstrate that Dupixent improved skin lesions, reduced itching, cleared the skin and importantly, improved health-related quality of life measures for these young patients."*

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

Results at 16 weeks included:

- 33% of patients who received Dupixent every four weeks (300 mg) and 30% of patients who received Dupixent every two weeks (100 mg or 200 mg, based on weight) achieved clear or almost clear skin (IGA; score of 0 or 1), compared to 11% for placebo ($p<0.0001$ and $p=0.0004$, respectively).
- 70% of patients who received Dupixent every four weeks and 67% of patients who received Dupixent every two weeks achieved 75% or greater skin improvement (EASI-75), compared to 27% for placebo ($p<0.0001$ for both).
- The average EASI score improvement from baseline was 82% in the Dupixent every four weeks group and 78% in the Dupixent every two weeks group, compared to 49% for placebo ($p<0.0001$ for both).
- Dupixent demonstrated significant itch relief, and also improved measures of patient-reported outcomes, such as anxiety, depression and health-related quality of life of parents and family members.

For the 16-week treatment period, the overall rates of adverse events were 65% for Dupixent every four weeks, 67% for Dupixent every two weeks and 73% for placebo. Adverse events that were more commonly observed with Dupixent included conjunctivitis (7% for Dupixent every four weeks, 15% for Dupixent every two weeks and 4% for placebo), nasopharyngitis (13% for Dupixent every four weeks, 7% for Dupixent every two weeks and 7% placebo) and injection site reactions (10% for Dupixent every four weeks, 11% for Dupixent every two weeks and 6% for placebo). Additional prespecified adverse events included skin infections (6% for Dupixent every four weeks, 8% for Dupixent every two weeks and 13% for placebo) and herpes viral infections (2% for Dupixent every four weeks, 3% for Dupixent every two weeks and 5% for placebo).

Detailed results from this trial will be presented at a future medical meeting and data will be submitted to regulatory authorities, starting with the U.S. Food and Drug Administration (FDA) in 4Q 2019. In 2016, the 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 efficacy and safety of Dupixent in children below the age of 12 has not been reviewed by any regulatory authority.

About the Dupixent Pediatric Trial

The Phase 3, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent combined with TCS in children with severe atopic dermatitis. The trial enrolled 367 patients aged 6 to 11 years with severe atopic dermatitis whose disease could not be adequately controlled with topical medications. In total, 92% of these patients suffered from at least one concurrent condition such as allergic rhinitis, asthma and food allergy.

All patients received TCS throughout the trial. Patients were randomized into one of three treatment groups for the 16-week treatment period: Dupixent subcutaneous injection 300 mg every four weeks (with an initial dose of 600 mg); Dupixent 100 mg or 200 mg every two weeks, based on weight (100 mg for <30 kg, 200 mg for ≥30 kg), with an initial dose of 200 mg or 400 mg, respectively; and placebo every two or four weeks.

Dupilumab Development Program

In addition to the currently approved indications, Sanofi and Regeneron are also studying dupilumab in a broad range of clinical development programs for diseases driven by allergic and other type 2 inflammation, including pediatric asthma and atopic dermatitis (6 to 11 years of age, Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 2/3), eosinophilic esophagitis (Phase 2/3), chronic obstructive pulmonary disease (Phase 3) and food and environmental allergies (Phase 2). Dupilumab is also being studied in combination with REGN3500 (SAR440340), which targets IL-33. 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 global collaboration agreement.

About Regeneron

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 seven 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, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, infectious diseases, pain 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.

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

Sanofi Media Relations Contact
Ashleigh Koss
Tel.: +1 (908) 981-8745
Ashleigh.Koss@sanofi.com

Sanofi Investor Relations Contact
George Grofik
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

Regeneron Media Relations Contact
Sharon Chen
Tel.: +1 (914) 847-5018
Sharon.Chen@regeneron.com

Regeneron Investor Relations Contact
Justin Holko
Tel.: +1 (914) 847-7786
Justin.Holko@regeneron.com

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, 2018. 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 press 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 pediatric asthma and pediatric atopic dermatitis, eosinophilic esophagitis, chronic obstructive pulmonary disease, food and environmental allergies, and other potential indications (as well as in combination with REGN3500); unforeseen safety issues resulting from the administration of products and product candidates (such as dupilumab) in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Dupixent), research and clinical programs, and business, including those relating to patient privacy; 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, including without limitation dupilumab; the availability and extent of reimbursement of the Company's products (such as Dupixent) from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates (such as Dupixent) and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of any such products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its 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 and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent, and Praluent® (alirocumab) Injection, the ultimate outcome of any such 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 U.S. Securities and Exchange Commission. 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).