SANOFI

Press Release

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

Dupixent® (dupilumab) eosinophilic esophagitis trial meets both co-primary endpoints

- Dupixent demonstrated significant clinical and anatomic improvements, including the ability to swallow, in Part A of pivotal trial
- 69% reduction in disease symptoms with Dupixent, compared to 32% for placebo (p=0.0002)
- There are currently no FDA-approved treatments for eosinophilic esophagitis, a condition that impacts patients' ability to eat

PARIS and TARRYTOWN, N.Y. - May 22, 2020 – Sanofi and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced positive results from Part A of the pivotal Phase 3 trial evaluating Dupixent® (dupilumab) in patients 12 years and older with eosinophilic esophagitis (EoE). The trial met both of its co-primary endpoints, as well as all key secondary endpoints. Dupixent is the first and only biologic to show positive and clinically-meaningful results in this population as part of a Phase 3 trial. An ongoing Part B portion of the Phase 3 trial evaluates an additional Dupixent dosing regimen.

EoE is a chronic and progressive type 2 inflammatory disease that damages the esophagus and prevents it from working properly, leading to difficulties swallowing. If untreated, symptoms and inflammation can progress, causing functional damage and scarring of the esophagus. EoE can lead to esophageal food impaction, requiring immediate emergency room visits. Almost half of the patients in this trial had prior procedures such as dilation of their esophagus, and almost three-quarters had previously been treated with corticosteroids. In the U.S., there are approximately 160,000 patients with EoE who are currently treated, of which an estimated 50,000 have failed multiple treatments.There are currently no therapies approved by the U.S. Food and Drug Administration (FDA).

> *"Eosinophilic esophagitis can be debilitating, and there are no approved treatment options. It impacts patients' ability to eat, causes severe pain and often results in repeated emergency room visits and medical procedures,"* said George D. Yancopoulos, M.D., Ph.D., Co-Founder, President and Chief Scientific Officer of Regeneron. *"These data are particularly impressive as Dupixent not only dramatically reduced eosinophils in the esophagus, but also improved all clinical, anatomic and histologic measures of the disease. In the past, EoE was thought to be a disease caused by eosinophils, but other biologics that decrease the eosinophils in the esophagus did not demonstrate consistent clinical or anatomical improvements. These Dupixent results demonstrate EoE is caused by multiple aspects of type 2 inflammation, driven by interleukin-4 and interleukin-13. EoE is*

the fourth atopic or type 2 inflammatory disease in which Dupixent has pivotal data demonstrating significant efficacy."

"These data demonstrate Dupixent's potential to continue to address treatment gaps across the spectrum of type 2 inflammatory diseases as common as asthma and as rare as eosinophilic esophagitis," said John Reed, M.D, Ph.D, Global Head of Research and Development at Sanofi. *"For the first time in a Phase 3 trial, patients reported an improvement in their ability to swallow food. For patients with eosinophilic esophagitis who are living with restricted diets and, in some cases, repeated hospital interventions, these findings are encouraging."*

Part A of the trial enrolled 81 patients (42 with Dupixent, 39 with placebo) aged 12 years and older with EoE, as determined by histological and patient-reported measures. The co-primary endpoints assessed the change from baseline in the Dysphagia Symptom Questionnaire (DSQ), a patient-reported measure of difficulty swallowing, and the proportion of patients achieving peak esophageal intraepithelial eosinophil count of ≤6 eos/hpf, a measure of an esophageal inflammation, at 24 weeks.

Patients treated with Dupixent 300 mg weekly experienced the following changes by week 24 from baseline:

- 69% reduction in disease symptoms compared to 32% for placebo (p=0.0002). Disease symptoms were measured by the DSQ scale, where patients experienced a 21.92 point improvement with Dupixent compared to a 9.60 point improvement for placebo, on a 0-84 scale (p=0.0004), the co-primary endpoint; baseline DSQ scores were approximately 34 points.
- 60% reduction in their esophageal eosinophilic count to a normal range compared to 5% for placebo (p<0.0001), the co-primary endpoint. This was measured by the proportion of patients who achieved a peak esophageal intraepithelial eosinophil count of ≤6 eos/hpf (a normal range); mean baseline peak levels were 89 eos/hpf.
- 39% reduction in abnormal endoscopic findings, compared to 0.6% worsening for placebo. This was measured by the EoE Endoscopic Reference Score (EoE-EREFS), where patients experienced a 3.2 point reduction with Dupixent compared to a 0.3 point reduction for placebo (p<0.0001).

The trial demonstrated similar safety results to the known safety profile of Dupixent in its approved indications. For the 24-week treatment period, overall rates of adverse events were 86% for Dupixent and 82% for placebo. Adverse events that were more commonly observed with Dupixent included injection site reactions (n=15 for Dupixent and n=12 for placebo) and upper respiratory-tract infections (n=11 for Dupixent and n=6 for placebo). There was one treatment discontinuation in the Dupixent group due to arthralgia.

Detailed results from this trial will be presented at an upcoming medical meeting. Dupixent received Orphan Drug Designation from the FDA in 2017 for the potential treatment of EoE. This status is given to investigational medicines intended for the safe and effective treatment of rare diseases that affect fewer than 200,000 people in the U.S. The potential use of Dupixent in eosinophilic esophagitis is currently under clinical development, and the safety and efficacy have not been evaluated by any regulatory authority.

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, chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis.

About the Dupixent Eosinophilic Esophagitis Trial

The Phase 3, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in adolescents and adults with eosinophilic esophagitis. Part A of the trial enrolled 81 patients aged 12 years and older with eosinophilic esophagitis, as determined by histological and patient-reported measures. In total, 85% of these patients suffered from at least one concurrent atopic condition such as allergic rhinitis, food allergy and asthma. Patients received weekly subcutaneous injections of Dupixent 300 mg or placebo for the 24-week treatment period.

The trial is ongoing, with additional patients enrolling in Part B as well as patients continuing in a 28-week extended active treatment period (Part C).

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 (6 to 11 years of age, Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 2/3), chronic obstructive pulmonary disease (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), and food and environmental allergies (Phase 2). 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.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 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 diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through 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

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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 fact that product may not 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 and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties 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, 2019. 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, suppliers, and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) in patients 12 years and older with eosinophilic esophagitis; 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 likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates and new indications for Regeneron's Products, such as dupilumab for the treatment of eosinophilic esophagitis, pediatric asthma, pediatric atopic dermatitis, chronic obstructive pulmonary disease, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications; unforeseen safety issues resulting from the administration of Regeneron's Products (such as Dupixent) and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; 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; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron'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; 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 and/or its collaborators may lead to advancement of product candidates to clinical trials or 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 Dupixent and Praluent® (alirocumab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, 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, including its Form 10-K for the year ended December 31, 2019 and its Form 10-Q for the quarterly period ended March 31, 2020. 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.