SANOFI

Press Release

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

Dupixent® (dupilumab) long-term data show sustained improvement in lung function and reduction in severe exacerbations in adults and adolescents with moderate-to-severe asthma

- With more than 2,200 patients enrolled, Phase 3 open-label extension trial is the largest of a biologic medicine ever conducted in asthma
- Data up to three years show a safety profile consistent with pivotal asthma trials
- Dupixent is the only biologic to demonstrate sustained improvements in lung function and asthma exacerbations across a broad patient population with type 2 inflammation
- Data to be presented at the 2020 ERS International Congress

PARIS and TARRYTOWN, NY – September 8, 2020 – New results from a Dupixent® (dupilumab) Phase 3 open-label extension trial showed that the safety and efficacy profile observed in previous Dupixent trials were maintained for up to three years in adults and adolescents with moderate-to-severe asthma. Data from the trial will be presented during a live session at the virtual 2020 European Respiratory Society (ERS) International Congress.

> *"These data suggest Dupixent may slow the progressive decline in lung function that many patients with moderate-to-severe asthma experience, as shown by the sustained improvement in lung function for up to three years. Further, patients on Dupixent maintained asthma control and reduced rates of severe asthma attacks that may result in hospitalizations,"* said Michael Wechsler, M.D., M.M.Sc., Director of the National Jewish Cohen Family Asthma Institute in Denver, Colorado, and principal investigator of the trial. *"This reinforces the importance of Dupixent as a continuous, long-term treatment option to improve patients' ability to breathe and maintain control of their asthma, particularly in those with higher markers of underlying type 2 inflammation."*

The analyses to be presented at ERS include more than 2,200 patients who previously participated in Dupixent asthma trials, including three pivotal trials that lasted between 24 and 52 weeks. Patients entered the extension trial after finishing active treatment or placebo in the initial trials and were treated for up to an additional two years, providing up to three years of treatment data in total. The safety analyses included patients from all three pivotal asthma trials and the efficacy and biomarker analyses included patients who are not dependent on oral corticosteroids (OCS) from the pivotal Phase 2b and Phase 3 QUEST trials. Additional long-term efficacy data in OCS-dependent patients will be presented at a later congress. Results showed:

Efficacy:

- Lung function: Patients continued to experience improvement in lung function by 13-22% at 96 weeks, as measured by the average change in forced expiratory volume over one second (FEV1) compared to baseline for the initial asthma trials.
- Asthma attacks: Patients maintained a low rate of severe asthma attacks (unadjusted annualized severe exacerbation rate) with an average of 0.31-0.35 events per year. In the year prior to commencing Dupixent trials, the rate of severe asthma attacks was 2.09-2.17 events per year.
- Type 2 inflammation: Improvements in lung function and asthma attacks were greater in those with elevated baseline blood eosinophils or fractional exhaled nitric oxide (FeNO), which are markers of type 2 inflammation. In these long-term results, patients showed reductions in blood eosinophils (23-35%) and in blood IgE for patients from the pivotal Phase 2b trial (82%) compared to baseline for the initial asthma trials.

Safety:

- The proportion of patients with adverse events (AEs) in the open-label extension trial was similar to that seen in prior pivotal trials of Dupixent in asthma. Over the 96-week treatment period, overall AE rates were 76-88% and the most common AEs were nasopharyngitis (18-26%) and injection-site erythema (2-23%). Overall serious AEs were experienced by 9-13% of patients.

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 asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP) and atopic dermatitis. Across all approved indications globally, more than 170,000 patients have been treated with Dupixent.

About the LIBERTY ASTHMA TRAVERSE OLE Trial

The Phase 3, multicenter, open-label extension trial evaluated long-term safety and efficacy of Dupixent treatment in 2,282 adults and adolescents with moderate-to-severe asthma who had previously participated in a controlled Dupixent clinical trial, including the pivotal Phase 2b DRI (24 weeks) and Phase 3 QUEST (52 weeks) trials in patients with moderate-to-severe asthma and the Phase 3 VENTURE (24 weeks) trial in patients with severe oral corticosteroid (OCS)-dependent asthma. Patients in the open-label extension trial received 300 mg Dupixent every other week for up to 96 weeks in addition to standard-of-care maintenance therapies. The primary endpoints were the number and proportion of patients experiencing any AEs up to 96 weeks. Secondary endpoints included mean change in FEV_1 and annualized severe exacerbation rate. Type 2 inflammation was defined as raised FeNO (≥ 25 ppb) or blood eosinophils (≥150 cells/µL) at initial trial baseline. Data at ERS are presented as a range of mean values for those treated with placebo and Dupixent in each of the initial pivotal trials.

About Dupixent

Dupixent is approved in the EU for adults and adolescents 12 years and older as an add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose inhaled corticosteroid (ICS) plus another medicinal product for maintenance treatment. In the U.S., Dupixent is approved for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma

medicines. Dupixent is also approved for use in certain patients with asthma in Japan and other countries around the world.

Dupixent is approved for additional uses in certain patients with atopic dermatitis and CRSwNP in the EU, U.S., and Japan, as well as other countries around the world. In adolescents 12 years of age or older, it is recommended that Dupixent be administered by or under the supervision of an adult. In children younger than 12 years of age, Dupixent should be administered by a caregiver.

Dupilumab Development Program

To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven in part by type 2 inflammation. 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 3), eosinophilic esophagitis (Phase 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, and 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); 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), including the study discussed in this press release, on the commercial success of Regeneron's Products (such as Dupixent) 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 pediatric asthma, pediatric atopic dermatitis, eosinophilic esophagitis, chronic obstructive pulmonary disease, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications; 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 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, or more cost effective than, 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 be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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)), 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 June 30, 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.

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).