SANOFI

Press Release

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

FDA expands approval of Dupixent® (dupilumab) to include children aged 6 to 11 years with moderate-to-severe asthma

- Dupixent is the only biologic medicine to improve lung function in children aged 6 to 11 years in a randomized Phase 3 trial, supporting potential as a best-in-class option
- Only biologic medicine approved for children with oral corticosteroid-dependent asthma
- Data reinforce well-established safety profile of Dupixent

PARIS and TARRYTOWN, N.Y. – October 20, 2021 - The U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) as an add-on maintenance treatment of patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma.

> *"This FDA approval brings new hope for children who may be suffering from life-threatening asthma attacks and poor lung function, affecting their ability to breathe, potentially into adulthood,"* says Naimish Patel, M.D. Head of Global Development in Immunology and Inflammation at Sanofi. *"Dupixent has helped to make a difference to the lives of many patients and families across three diseases with underlying type 2 inflammation, with more than 300,000 patients treated globally. We now have the opportunity to offer a safe and effective option to children as young as 6 years of age living with certain types of moderate-to-severe asthma."*

Asthma is one of the most common chronic diseases in children. Approximately 75,000 children aged 6 to 11 years live with the uncontrolled moderate-to-severe form of the disease in the U.S., with many more worldwide. Despite treatment with current standard-of-care inhaled corticosteroids and bronchodilators, these children may continue to experience serious symptoms such as coughing, wheezing and difficulty breathing. They also may require the use of multiple courses of systemic corticosteroids that carry significant risks.

> *"Despite available treatments, moderate-to-severe asthma can severely impact children's developing airways, causing sleepless nights, persistent coughing and wheezing, and potentially life-threatening exacerbations that require the use of systemic steroids that can negatively affect growth,"* says George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. *"This approval means that Dupixent, a first-of-its-kind treatment with a well-established efficacy and safety profile, can now be used by younger children with certain types of moderate-to-severe asthma in the U.S. In our pivotal trial, Dupixent helped children aged 6 to 11 years breathe better, suffer fewer asthma attacks and improve health-*

related quality of life. We also continue to study Dupixent in patients with other dermatologic, respiratory and gastrointestinal conditions, where type 2 inflammation may play a role."

The FDA approval is based on data from a Phase 3 randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of Dupixent combined with standard-of-care asthma therapy in children with uncontrolled moderate-to-severe asthma. More than 90% of children in the trial had at least one concurrent type 2 inflammatory condition.

Among patients who entered the trial with high levels of a certain type of white blood cell (eosinophils [EOS] ≥300 cells/µl; n=259), those who added Dupixent (100 mg or 200 mg every two weeks, based on weight) to standard-of-care experienced:

- Substantially reduced rate of severe asthma attacks, with a 65% average reduction over one year compared to placebo (0.24 events per year for Dupixent vs. 0.67 for placebo).
- Improved lung function observed as early as two weeks and sustained for up to 52 weeks, measured by percent predicted pre-bronchodilator FEV_1 (FEV_1pp).
    - At 12 weeks, patients taking Dupixent improved their lung function by 5.32 percentage points compared to placebo.
- Improved asthma control at 24 weeks, with 81% of patients reporting a clinically meaningful improvement based on disease symptoms and impact compared to 64% of placebo patients, as measured by a ≥0.5 improvement on a 7-point scale.

Children with elevated fractional exhaled nitric oxide (FeNO ≥20 ppb), an airway biomarker of inflammation that plays a major role in asthma, were also evaluated. In this subgroup, children who added Dupixent to standard-of-care experienced a reduction in the rate of severe asthma attacks.

The safety results from the trial were generally consistent with the known safety profile of Dupixent in patients aged 12 years and older with uncontrolled moderate-to-severe asthma, with the addition of helminth infections which were reported in 2.2% of Dupixent patients and 0.7% of placebo patients. The overall rates of adverse events were 83% for Dupixent and 80% for placebo. The most common adverse events that were more commonly observed with Dupixent compared to placebo were injection site reactions (18% Dupixent, 13% placebo), viral upper respiratory tract infections (12% Dupixent, 10% placebo) and eosinophilia (6% Dupixent, 1% placebo).

Dupixent is currently under regulatory review for children aged 6 to 11 years with moderate-to-severe asthma in the European Union and other health authorities worldwide.

About the LIBERTY ASTHMA VOYAGE Trial

The Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent combined with standard-of-care asthma therapy in 408 children aged 6

to 11 years with uncontrolled moderate-to-severe asthma. In this trial, 86% of children had markers of type 2 inflammation underlying their asthma.

The primary endpoint was the annualized rate of severe asthma exacerbations over one year, and the key secondary endpoint was the change from baseline in FEV_1pp at week 12. The FEV_1pp seeks to evaluate a patient's change in lung function compared to their predicted lung function based on age, height, sex and ethnicity to account for children's growing lung capacity at different stages of development. Additional secondary endpoints included mean change from baseline in responder rates as measured by a ≥0.5 improvement on the Asthma Control Questionnaire 7-Interviewer Administered.

About Dupixent

Dupixent is an injection under the skin (subcutaneous injection) at different injection sites. For pediatric patients aged 6 to 11 years, Dupixent dosing is based on weight (100 mg every two weeks or 300 mg every four weeks for children ≥15 to <30 kg, and 200 mg every two weeks for children ≥30 kg) and is supplied as a pre-filled syringe. It is also available as a pre-filled pen for adolescents (12 to 17 years) and adults at 200 mg and 300 mg doses. Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home by self-administration after training by a healthcare professional. In children younger than 12 years of age, Dupixent should be administered by a caregiver if given at home.

In the U.S., Dupixent is approved as an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral-steroid dependent asthma; in patients aged 6 years and older with uncontrolled moderate-to-severe atopic dermatitis; and for use with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled.

Sanofi and Regeneron are committed to helping patients in the U.S. who are prescribed Dupixent gain access to the medicine and receive the support they may need with the DUPIXENT *MyWay*® program. For more information, please call 1-844-DUPIXENT (1-844-387-4936) or visit www.DUPIXENT.com.

Dupixent is also approved in Europe, Japan and other countries around the world for use in certain patients with asthma or CRSwNP in different age populations, as well as specific patients with moderate-to-severe atopic dermatitis. Dupixent is approved in one or more of these indications in more than 60 countries around the world, and more than 300,000 patients have been treated globally.

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma, and CRSwNP.

Dupilumab Development Program

To date, dupilumab has been studied across 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation.

Sanofi and Regeneron are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes, including chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), eosinophilic esophagitis (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), chronic inducible urticaria-cold (Phase 3), chronic rhinosinusitis without nasal polyposis (Phase 3), allergic fungal rhinosinusitis (Phase 3), allergic bronchopulmonary aspergillosis (Phase 3) and peanut allergy (Phase 2). These potential uses of dupilumab are currently under clinical investigation, and the safety and efficacy in these conditions have not been fully 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 nine FDA-approved treatments and numerous product candidates in development, almost 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, hematologic conditions, 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.

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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, 2020. 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 or otherwise commercialized 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 product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Dupixent) and Regeneron's 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 any of the foregoing; 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 Dupixent for the treatment of chronic obstructive pulmonary disease with evidence of type 2 inflammation, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, peanut allergy, and other potential indications, as well as the possible regulatory approval of Dupixent for children aged 6 to 11 years with moderate-to-severe asthma in the European Union; 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 Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's 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 Regeneron's Product Candidates, including without limitation Dupixent; 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 Regeneron's 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; 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, collaboration, or supply 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; 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, Praluent® (alirocumab), and REGEN-COV™ (casirivimab and imdevimab)), 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, 2020 and its Form 10-Q for the quarterly period ended June 30, 2021. 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 or otherwise) 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).