SANOFI

Press Release

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

Dupixent® (dupilumab) approved by European Commission for adolescents with moderate-to-severe atopic dermatitis

- Only biologic approved in the European Union for patients aged 12 and above with moderate-to-severe atopic dermatitis
- Approval is based on Phase 3 trial results showing Dupixent significantly improved disease extent and severity, skin clearance, and itch intensity, as well as sleep and health-related quality of life

PARIS and TARRYTOWN, NY – August 6, 2019 - The European Commission (EC) today extended the marketing authorization for Dupixent® (dupilumab) in the European Union (EU) to include adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. Dupixent is now the first biologic medicine approved in the EU to treat these patients.

> *"Moderate-to-severe atopic dermatitis can affect many aspects of an adolescent's life, including their physical and emotional well-being,"* said Christine Janus, Chief Executive Officer of the International Alliance of Dermatology Patient Organizations. *"This disease places an immense burden not only on the young people living with it but also the family members who care for them. We welcome the addition of new treatment options to help adolescents control and manage an often debilitating disease."*

Atopic dermatitis, the most common form of eczema, is a chronic inflammatory disease. In its moderate-to-severe form, it is characterized by rashes that can potentially cover much of the body, and can include intense, persistent itching, skin lesions and skin dryness, cracking, redness, crusting and oozing. Inadequately controlled atopic dermatitis can have a physical, emotional and psychosocial impact, causing sleep disturbance, symptoms of anxiety and depression, and feelings of isolation. Despite standard-of-care therapy, there continues to be an unmet need for many adolescents with moderate-to-severe atopic dermatitis who often have uncontrolled, persistent symptoms.

> *"Adolescents with moderate-to-severe atopic dermatitis in the EU now have an approved biologic medicine that can significantly control persistent, debilitating symptoms like itch and skin lesions, as well as improve sleep, which is particularly critical during these formative years,"* said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. *"Today's approval also provides these young patients with a treatment option that addresses the type 2 inflammation that underlies atopic dermatitis. In addition to its approved uses in atopic dermatitis and asthma in the EU, we continue to investigate Dupixent in a broad range of patients with other type 2 inflammatory diseases."*

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, as well as asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP is currently under review in the EU).

> *"Adolescents with inadequately controlled moderate-to-severe atopic dermatitis face a certain set of challenges that can have a lasting impact on their lives. The physical and psychological symptoms of moderate-to-severe atopic dermatitis can prevent adolescents from fully participating in activities with their peers, including school, sports and hobbies, and can often place a serious burden on family members,"* said John Reed, M.D., Ph.D., Head of Research and Development at Sanofi. *"From our Phase 3 trials, we know Dupixent significantly reduced itch, helped clear the skin, and improved health-related quality of life outcomes for adolescents at this critical period of their lives."*

Efficacy and Safety from Clinical Trials

The EC approval is based on clinical data from the LIBERTY AD program, including a pivotal Phase 3 trial and an open-label extension trial evaluating the efficacy and safety of Dupixent in adolescents with uncontrolled moderate-to-severe atopic dermatitis. Key data points from the pivotal trials at 16 weeks include:

- More than five times as many Dupixent patients experienced at least 75% improvement in disease extent and severity compared to placebo: 42% of patients who received Dupixent achieved 75% or greater skin improvement compared to 8% with placebo, as measured by the Eczema Area and Severity Index (EASI-75), the co-primary endpoint of the trial.
- More than 10 times as many Dupixent patients had clear or almost clear skin compared to placebo: 24% of patients who received Dupixent achieved clear or almost clear skin compared to 2% with placebo, as measured by an Investigator's Global Assessment (IGA) score of 0 or 1, the co-primary endpoint of the trial.
- Dupixent patients experienced a 66% average improvement in the EASI score of skin inflammation from baseline compared to 24% for placebo.
- More than seven times as many Dupixent patients experienced significantly less itch compared to placebo: 37% of patients who received Dupixent achieved a clinically meaningful improvement in itch of at least four points on the Peak Pruritus Numerical Rating Scale (NRS) compared to 5% with placebo.
- More than three times as many Dupixent patients experienced significant improvements in health-related quality of life compared to placebo: 61% of patients who received Dupixent achieved a clinically meaningful improvement in quality of life of at least six points on the Children's Dermatology Life Quality Index (CDLQI) compared to 20% with placebo.
- More than six times as many Dupixent patients reported significant improvements in disease severity compared to placebo: 63% of patients who received Dupixent reported a clinically meaningful improvement in disease severity of at least six

points on the Patient Oriented Eczema Measure (POEM), which is a composite measure that includes sleep, compared to 10% with placebo.

Data from the open-label extension trial showed that the clinical benefit of Dupixent at week 16 was sustained through week 52. The safety profile of Dupixent in adolescent trials was similar to the safety profile from trials in adults with atopic dermatitis, and consistent through 52 weeks as observed in the open-label extension trial. The most common adverse events were injection site reactions, eye and eyelid inflammation including redness, swelling and itching, and cold sores.

There is no requirement for initial laboratory testing or ongoing laboratory monitoring for patients taking Dupixent.

About Dupixent

Dupixent comes in two doses (200 mg and 300 mg), each as a pre-filled syringe, and the dose is weight-based (<60 kilograms [kgs] or ≥60 kgs) in adolescents with atopic dermatitis. Dupixent is intended for injection under the skin (subcutaneous injection) and is given every other week following an initial dose (400 mg and 600 mg, respectively). Dupixent can be given in a clinic or at home by self-administration after training by a healthcare professional.

This approval in the EU expands the indication for Dupixent, which is approved for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. It is also 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 fractional exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroid (ICS) plus another medicinal product for maintenance treatment.

Outside of the EU, Dupixent is approved for use in specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including the U.S. and Japan. Dupixent is also approved in the U.S. for use with other medicines to treat CRSwNP in adults whose disease is not controlled and is currently under regulatory review for patients with CRSwNP in the EU.

Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

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.

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

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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, 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).