SANOFI

Press Release

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

CHMP recommends approval of Dupixent® (dupilumab) for moderate-to-severe atopic dermatitis in adolescents

PARIS AND TARRYTOWN, NY – June 27, 2019 - The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Dupixent® (dupilumab) recommending extending its approval in the European Union (EU) to also include adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

If approved, Dupixent would be the first biologic medicine approved in the EU to treat these patients. The positive CHMP opinion 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. A final decision on the Dupixent application by the European Commission (EC) is expected in the coming months.

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

About Moderate-to-Severe Atopic Dermatitis

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. Itch is one of the most burdensome symptoms for patients and can be debilitating. 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.

About Dupixent

Dupixent is being developed jointly by Sanofi and Regeneron as part of a global collaboration agreement. Dupixent is currently approved in the EU 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.

About the Dupilumab Development Program

In addition to the currently approved indications, Regeneron and Sanofi 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 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, neuromuscular diseases, infectious diseases 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 impact of the opinion adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use discussed in this press release on the European Commission's decision regarding the Marketing Authorization Application for Dupixent for the treatment of adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy; 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, including possible regulatory approval of Dupixent in the European Union discussed in this press release and possible regulatory approval of Dupixent in other jurisdictions and indications (such as for the treatment of pediatric asthma and 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 Dupixent) 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 Dupixent; 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, including its Form 10-K for the fiscal year ended December 31, 2018 and its Form 10-Q for the quarterly period ended March 31, 2019. 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).