

## **CHMP recommends approval of Dupixent® (dupilumab) for asthma indication**

**PARIS and TARRYTOWN, NY – March 1, 2019** - The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Dupixent® (dupilumab), recommending its approval in the European Union for use in adults and adolescents 12 years and older as 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 plus another medicinal product for maintenance treatment.

The positive CHMP opinion is based on clinical data from 2,888 adults and adolescents who participated in three pivotal trials from the global LIBERTY ASTHMA program, including the Phase 3 QUEST and VENTURE trials. QUEST compared Dupixent vs. placebo in asthma patients inadequately controlled on a medium or high dose inhaled corticosteroid and a second controller medication. VENTURE compared Dupixent vs. placebo in oral corticosteroid dependent asthma patients. The European Commission is expected to make a final decision on the application for Dupixent in the coming months.

Dupixent is a human monoclonal antibody that inhibits the signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that play a central role in type 2 inflammation that underlies specific types of asthma as well as several other allergic diseases. This effect is associated with the reduction of type 2 inflammatory biomarkers including fractional exhaled nitric oxide (FeNO), immunoglobulin E (IgE) and eotaxin-3 (CCL26).

Patients with severe asthma often have uncontrolled, persistent symptoms despite standard-of-care therapy that may make them suitable for treatment with a biologic therapy. Symptoms of uncontrolled disease include coughing, wheezing and difficulty breathing, and these patients are at risk of severe asthma attacks that may require emergency room visits or hospitalizations. Oral corticosteroids can provide relief for severe, short-term symptoms; however, current asthma guidelines suggest limiting their chronic use to the most severe patients due to the potential for serious side effects.

Dupixent is being developed jointly by Sanofi and Regeneron as part of a global collaboration agreement. In October 2018, Dupixent was approved in the U.S. as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. Dupixent is not used to treat sudden breathing problems. Dupixent is currently under regulatory review for specific types of asthma in Japan.

Dupixent is currently approved in the European Union for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. Dupixent is also approved for use in specific patients with moderate-to-severe atopic dermatitis in a number of other countries around the world.

### Dupilumab development program

Sanofi and Regeneron are also studying dupilumab in a broad range of clinical development programs for diseases driven by type 2 inflammation, including chronic rhinosinusitis with nasal polyps (Phase 3 completed), pediatric (6 to 11 years of age) atopic dermatitis (Phase 3), pediatric (6 months to 5 years of age) atopic dermatitis (Phase 2/3), adolescent (12 to 17 years of age) atopic dermatitis (Phase 3 completed), pediatric (6 to 11 years of age) asthma (Phase 3), eosinophilic esophagitis (Phase 2/3) and food and environmental allergies (Phase 2). A future trial is planned for chronic obstructive pulmonary disease. Dupilumab is also being studied in combination with REGN3500, 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](http://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, 2017. 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**

*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 Medicine Agency’s Committee for Medicinal Products for Human Use discussed in this news release on the European Commission’s decision regarding the Marketing Authorization Application for Dupixent for use as an add-on maintenance treatment for adults and adolescents (12 years and older) who have severe asthma with type 2 inflammation and who are inadequately controlled with medium-to-high dose inhaled corticosteroid plus another medicinal product for maintenance treatment, and for the treatment of oral corticosteroid-dependent asthma regardless of type 2 inflammatory biomarkers; 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 news release and possible regulatory approval of Dupixent in other jurisdictions and indications (such as for the treatment of pediatric and adolescent atopic dermatitis, pediatric asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, grass allergy, food allergy (including peanut), chronic obstructive pulmonary disease, 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 to perform 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 proceedings relating to EYLEA® (afibercept) Injection, Dupixent, and Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation 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-Q for the quarterly period ended September 30, 2018. 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.

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