FDA accepts Dupixent® (dupilumab) for review in children with moderate-to-severe asthma

- Submission supported by data demonstrating Dupixent significantly reduced severe asthma attacks and is the only biologic to improve lung function in children aged 6 to 11 years with asthma in a randomized Phase 3 trial, while also further adding to the well-established safety profile of Dupixent
- Dupixent has the potential to be a best-in-class treatment option in this younger population of children aged 6 to 11
- Acceptance represents another milestone in the development of Dupixent in addressing diseases driven by type 2 inflammation

PARIS and TARRYTOWN, N.Y. – March 4, 2021 - The U.S. Food and Drug Administration (FDA) has accepted for review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) as an add-on treatment for children aged 6 to 11 years with uncontrolled moderate-to-severe asthma. Dupixent is currently approved as an add-on treatment for patients with uncontrolled moderate-to-severe asthma aged 12 and older with elevated eosinophils or oral corticosteroid dependent asthma. The target action date for the FDA decision is October 21, 2021 and the EU regulatory submission for children aged 6 to 11 years with asthma is planned for Q1 2021.

In the U.S., approximately 75,000 children aged 6 to 11 years are living with uncontrolled moderate-to-severe asthma, which can carry a significant burden for children and their families. Despite treatment with current standard-of-care inhaled corticosteroids and bronchodilators, these children can still experience coughing, wheezing, and difficulty breathing. They are also at risk for life-threatening severe asthma attacks that can lead to hospitalization and emergency room visits, and may require the use of systemic corticosteroids which carry significant risks when used long term. Uncontrolled moderate-to-severe asthma can impair lung function, and can interfere with day-to-day activities, such as sleeping, attending school and playing sports.

The sBLA is supported by data that include pivotal Phase 3 results evaluating the efficacy and safety of Dupixent in addition to standard-of-care maintenance therapy in children with moderate-to-severe asthma with type 2 inflammation, characterized by elevated blood eosinophil levels and/or raised fractional exhaled nitric oxide (FeNO) levels. In the trial, Dupixent significantly reduced severe asthma attacks and rapidly improved lung function within two weeks in children aged 6 to 11 years. Safety results were generally consistent with the well-established safety profile of Dupixent in the approved indication for patients aged 12 and older with moderate-to-severe asthma. Adverse events in the Phase 3 trial that were more commonly observed with Dupixent included injection site reactions, viral
upper respiratory tract infections and eosinophilia. Detailed results from this Phase 3 trial will be published later this year.

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 asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), atopic dermatitis and eosinophilic esophagitis.

**About Dupixent**

Dupixent is approved in the U.S. to treat patients aged 6 years and older with moderate-to-severe atopic dermatitis that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies; 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; and for use with other medicines for the maintenance treatment of CRSwNP in adults whose disease is not controlled.

Outside of the U.S., Dupixent is approved for specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including the EU and Japan. Dupixent is also approved in the EU and Japan to treat certain adults with severe CRSwNP. Across all approved indications globally, more than 200,000 patients have been treated with Dupixent.

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.

**Dupilumab development program**

To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven by type 2 inflammation.

In addition to the currently approved indications, Sanofi and Regeneron are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes, including pediatric asthma (6 to 11 years of age, Phase 3), 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) and food allergies (Phase 2). These potential uses are under clinical investigation, and the safety and efficacy of dupilumab 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, 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, selling and other potential future revenues from 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 governmental regulation of 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, 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) as an add-on treatment for children aged 6 to 11 years with uncontrolled moderate-to-severe asthma characterized by raised blood eosinophil levels and/or raised fractional exhaled nitric oxide (FeNO) levels (“Pediatric Asthma”); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron’s Products and new indications and new indications for Regeneron’s Products, such as dupilumab for the treatment of allergic rhinitis, nodular conjunctivitis, nodular conjunctivitis, chronic obstructive pulmonary disease, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications; uncertainty of market acceptance and commercial success of Regeneron’s Products and Regeneron’s Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on the commercial success of Regeneron’s Products and Regeneron’s Product Candidates; safety issues resulting from the administration of Regeneron’s Products and Regeneron’s Product Candidates in patients, including serious complications related to 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; 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 products of other companies, and the uncertainties, many of which are difficult to predict and generally beyond the control of Regeneron, 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 governmental regulation of 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.
any of the foregoing may have on Regeneron’s business, prospects, operating results, and financial condition. A more complete
description of those 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. 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
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statement, including without limitation any financial projection or guidance, whether as a result of new information, future
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