Press Release

Dupixent® (dupilumab) approved by European Commission for children aged 6 to 11 years with severe asthma with type 2 inflammation

- Dupixent is the only biologic indicated in the European Union for severe asthma with type 2 inflammation, characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide
- Approval based on Phase 3 data showing Dupixent significantly reduced severe asthma attacks and also improved lung function and health-related quality of life for children
- Data reinforce well-established safety profile of Dupixent

Paris and Tarrytown, N.Y. April 7, 2022. The European Commission (EC) has expanded the marketing authorization for Dupixent® (dupilumab) in the European Union. Dupixent is now also approved in children aged 6 to 11 years 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 medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

> ***Naimish Patel, M.D.***
> Head of Global Development, Immunology and Inflammation, Sanofi
> *"We are excited to bring the well-established safety and efficacy of Dupixent to even younger patients living with uncontrolled severe asthma in Europe. In addition to greatly reducing severe asthma attacks and improving lung function, patients in our clinical trial also reduced their oral corticosteroid use. This is particularly meaningful as these are medicines that can carry significant safety risks if used long term. This approval underscores our continued commitment to bringing Dupixent to as many patients as possible suffering from the negative effects of severe asthma with the hope of improving their quality of life."*

Asthma is one of the most common chronic diseases in children. Up to 85% of children with asthma may have type 2 inflammation and are more likely to have higher disease burden. Despite treatment with current standard-of-care ICS and bronchodilators, these children may continue to experience serious symptoms such as coughing, wheezing and difficulty breathing. Severe asthma may impact children's developing airways and cause potentially life-threatening exacerbations. Children with severe asthma also may require the use of multiple courses of systemic corticosteroids that carry significant risks. Uncontrolled severe asthma can interfere with day-to-day activities, like sleeping, attending school and playing sports.

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. The Dupixent Phase 3 clinical program, which has shown significant clinical benefit and a decrease in type 2 inflammation, has established that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in in multiple related and often co-morbid diseases.

> ***George D. Yancopoulos, M.D., Ph.D.***
> President and Chief Scientific Officer, Regeneron
> *"Today's approval in Europe recognizes the benefits of Dupixent in helping children living with the profound effects of severe asthma, including unpredictable asthma attacks, routine disruption to daily activities and the use of systemic steroids that can impede children's growth. Dupixent is the only treatment available that specifically blocks two key drivers of type 2 inflammation, IL-4 and IL-13, which our trials show plays a major role in childhood asthma, as well as in related conditions such as chronic rhinosinusitis with nasal polyposis and the often co-morbid condition,*

atopic dermatitis. In clinical trials, Dupixent significantly reduced asthma attacks, helped children breathe better and improved their health-related quality of life. We also remain committed to investigating Dupixent in other conditions where type 2 inflammation may significantly impact patients' lives, including eosinophilic esophagitis, prurigo nodularis and chronic spontaneous urticaria."

The EC decision is based on pivotal data from the Phase 3 VOYAGE trial evaluating the efficacy and safety of Dupixent combined with standard-of-care asthma therapy in 408 children with uncontrolled moderate-to-severe asthma.

Two pre-specified populations with evidence of type 2 inflammation were evaluated for the primary analysis: 1) patients with baseline blood eosinophils (EOS) ≥300 cells/µl (n=259) and 2) patients with either baseline FeNO ≥20 parts per billion (ppb) or baseline blood EOS ≥150 cells/µl (n=350). Patients who added Dupixent to standard-of-care in these two groups, respectively, experienced:

- Substantially reduced rates of severe asthma attacks, with a 65% and 59% average reduction over one year compared to placebo (0.24 and 0.31 events per year for Dupixent vs. 0.67 and 0.75 for placebo, respectively).
- Improved lung function observed as early as two weeks and sustained for up to 52 weeks, measured by percent predicted FEV_1 (FEV_1pp).
    - At 12 weeks, patients taking Dupixent improved their lung function by 5.32 and 5.21 percentage points compared to placebo, respectively.
- Improved asthma control, with 81% and 79% of patients reporting a clinically meaningful improvement at 24 weeks, based on disease symptoms and impact compared to 64% and 69% of placebo patients, respectively.
- Improved health-related quality of life, with 73% and 73% of patients reporting a clinically meaningful improvement at 24 weeks, compared to 63% and 65% of placebo patients, respectively.
- Reduced systemic corticosteroid use by an average of 66% and 59% over one year compared to placebo (0.27 and 0.35 courses per year for Dupixent vs. 0.81 and 0.86 for placebo, respectively).

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. The overall rates of adverse events were 83% for Dupixent and 80% for placebo. Adverse events that were more commonly observed with Dupixent compared to placebo included injection site reactions (18% Dupixent, 13% placebo), viral upper respiratory tract infections (12% Dupixent, 10% placebo) and eosinophilia (7% Dupixent, 1% placebo). Helminth infections were also more commonly observed with Dupixent in patients aged 6 to 11 years and were reported in 2% of Dupixent patients and 0% of placebo patients.

About the LIBERTY ASTHMA VOYAGE Trial

The Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent (100 mg or 200 mg every two weeks, based on weight tier) combined with standard-of-care asthma therapy in 408 children aged 6 to 11 years with uncontrolled moderate-to-severe asthma. More than 90% of children in the trial had at least one concurrent atopic medical condition such as allergic rhinitis and atopic dermatitis.

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 percentage of predicted pre-bronchodilator FEV_1 (FEV_1pp) at week 12. The FEV1pp 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 responder rates for asthma control as measured by a ≥0.5 improvement on the Asthma Control Questionnaire-7 Interviewer Administered (ACQ-7-IA; 7-point scale) and health-related quality of life as measured by a ≥0.5 improvement on the Pediatric Asthma Quality of Life Questionnaire with Standardized Activities-Interviewer Administered (PAQLQ(S)-IA; 7-point scale).

About Dupixent

Dupixent is also approved in Europe, U.S., Japan and other countries around the world for use in certain patients with asthma, specific patients with moderate-to-severe atopic dermatitis as well as CRSwNP in different age populations. Dupixent is also approved in one or more of these indications in more than 60 countries around the world, and more than 400,000 patients have been treated globally.

Dupixent is an injection under the skin (subcutaneous injection) at different injection sites. In the EU for pediatric patients aged 6 to 11 years, Dupixent dosing is based on weight tier (100 mg every two weeks or 300 mg every four weeks for children ≥15 to <30 kg, 200 mg every two weeks or 300 mg every four weeks for children ≥30 to <60 kg and 200 mg every two weeks for children ≥60 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 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.

Dupilumab Development Program

Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. To date, dupilumab has been studied across more than 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part 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 atopic dermatitis (6 months to 5 years of age, Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (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.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 35 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

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We

provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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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, 2021. 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 or licensees (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 or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) as an add-on maintenance treatment for children aged 6 to 11 years with severe asthma with type 2 inflammation; 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 studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates; 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 pediatric atopic dermatitis, chronic obstructive pulmonary disease with evidence of type 2 inflammation, 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; the ability of Regeneron's collaborators, licensees, 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 or licensees 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, 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).