Press Release

FDA approves Dupixent® (dupilumab) as first treatment for adults and children aged 12 and older with eosinophilic esophagitis

- Dupixent is the first and only medicine indicated to treat eosinophilic esophagitis in the United States; approval granted more than two months ahead of FDA's Priority Review action date
- Dupixent 300 mg weekly significantly improved signs and symptoms of eosinophilic esophagitis compared to placebo in a Phase 3 trial, underscoring the role of type 2 inflammation in this complex disease
- Eosinophilic esophagitis is a chronic, progressive inflammatory disease driven by type 2 inflammation that damages the esophagus and prevents it from working properly
- Approval represents first indication for Dupixent in a gastrointestinal disease and fourth disease indicated overall

Paris and Tarrytown, N.Y. May 20, 2022. The U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) 300 mg weekly to treat patients with eosinophilic esophagitis (EoE) aged 12 years and older, weighing at least 40 kg. With this approval, Dupixent becomes the first and only medicine specifically indicated to treat EoE in the United States. A regulatory filing for EoE is under review by the European Medicines Agency, and submissions to regulatory authorities in additional countries are planned by the end of 2022.

Mary Jo Strobel
Executive Director, American Partnership for Eosinophilic Disorders (APFED)
"We have waited a long time for an FDA-approved treatment option for eosinophilic esophagitis - an underdiagnosed and misunderstood disease of the esophagus that can make it extremely challenging and uncomfortable to eat and swallow. Before today, there were no approved treatments specifically for eosinophilic esophagitis, resulting in many people needing to maintain a strict diet and live in constant fear of food getting stuck in their throat. We welcome therapeutic options that can provide much-needed relief for these patients."

EoE is a chronic inflammatory disease driven by type 2 inflammation that damages the esophagus and prevents it from working properly. For people with EoE, swallowing even small amounts of food can be a painful and worrisome choking experience. They are often left to contend with the frustration and anxiety of a constantly evolving list of foods to avoid, a poor quality of life and a higher risk of depression. In cases where EoE causes the esophagus to narrow, forced and potentially painful dilation (physical expansion) of the esophagus may be needed. In severe cases, a feeding tube may be the only option to ensure proper caloric intake and adequate nutrition. About 160,000 patients are living with EoE in the U.S. These individuals are currently treated with therapies not specifically approved for the disease, of whom approximately 48,000 continue to experience symptoms despite multiple treatments.

John Reed, M.D., Ph.D.
Global Head of Research and Development, Sanofi
"Eating regularly throughout the day is essential, yet significant difficulty swallowing food is a common symptom for people living with eosinophilic esophagitis. This can be incredibly upsetting and often leads to fear of pain or choking with every meal, every day. A large unmet need exists for treatment options that can provide meaningful symptom relief. Our Phase 3 clinical program showed that Dupixent weekly improved the ability to swallow and reduced inflammation in the esophagus, underscoring the

role of type 2 inflammation in this complex disease. This is a landmark FDA approval for patients and their caregivers who now have a new option for treating this devastating disease."

George D. Yancopoulos, M.D., Ph.D.
President and Chief Scientific Officer, Regeneron
"It is gratifying that Dupixent, a medicine that we invented in our laboratories, is now approved in yet another disease marked by allergic or type 2 inflammation, namely eosinophilic esophagitis. Eosinophilic esophagitis can be debilitating for patients, by inflaming and damaging the esophagus and limiting the ability to eat normally. Dupixent is the first and only medicine specifically indicated to treat eosinophilic esophagitis in the United States, and today's approval marks the fourth disease for which Dupixent is now indicated, reinforcing the promise of targeting IL-4 and IL-13 to effectively treat diseases with underlying type 2 inflammation."

The FDA approval is based on data from a Phase 3 trial with two parts (Part A and Part B) evaluating the efficacy and safety of Dupixent 300 mg weekly, compared to placebo, in patients aged 12 years and older with EoE, weighing at least 40 kg. After 24 weeks, patients treated with Dupixent 300 mg weekly experienced the following changes in Part A and Part B, respectively:

- 69% and 64% reduction in disease symptoms from baseline compared to 32% and 41% for placebo. Disease symptoms were measured by the Dysphagia Symptom Questionnaire (DSQ), where patients receiving Dupixent experienced a 21.9- and 23.8-point clinically meaningful improvement compared to 9.6- and 13.9-point improvement for placebo.
- Approximately 10 times as many patients achieved histological disease remission (peak esophageal intraepithelial eosinophil count of ≤6 eos/high power field [hpf]) compared to placebo: 60% and 59% compared to 5% and 6% of patients receiving placebo.

The safety results were generally consistent with the known safety profile of Dupixent in its approved indications. Pooled adverse events from Parts A and B that were more commonly (≥2%) observed with Dupixent than placebo were injection site reactions (38% Dupixent, 33% placebo), upper respiratory tract infections (18% Dupixent, 10% placebo), arthralgia (2% Dupixent, 1% placebo) and herpes viral infections (2% Dupixent, 1% placebo).

The FDA evaluated the Dupixent application under Priority Review, which is granted to therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions.

About the Dupixent Eosinophilic Esophagitis Trial

The Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in patients aged 12 years and older with EoE. Part A enrolled 81 patients and evaluated Dupixent 300 mg weekly (42 treated with Dupixent and 39 with placebo). Part B enrolled 159 patients and evaluated Dupixent 300 mg weekly (80 with Dupixent and 79 with placebo).

At 24 weeks, the co-primary endpoints in Parts A and B assessed patient-reported measures of difficulty swallowing (change from baseline in the DSQ on a 0-84 scale) and esophageal inflammation (proportion of patients achieving histological disease remission, defined as peak esophageal intraepithelial eosinophil count of ≤6 eos/hpf).

About Dupixent

Dupixent is administered as an injection under the skin (subcutaneous injection) at different injection sites. In patients aged 12 years and older, weighing at least 40 kg, with EoE, Dupixent is administered as a 300 mg dose with a pre-filled syringe or pen every week. 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 aged 12 to 17 years, Dupixent should be administered under the supervision of an adult.

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 development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent such as asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis (CRSwNP) and eosinophilic esophagitis, as well as investigational diseases such as prurigo nodularis.

Regeneron and Sanofi are committed to helping patients in the U.S. who are prescribed Dupixent gain access to the medicine and receive the support they may need with the DUPIXENT MyWay® program. For more information, please call 1-844-DUPIXENT (1-844-387-4936) or visit www.DUPIXENT.com.

Dupixent is also approved for use in certain patients with atopic dermatitis, asthma or CRSwNP in different age populations in a number of countries around the world, including the U.S., European Union and Japan. Dupixent is currently approved for one or more of these indications in more than 60 countries, and more than 400,000 patients have been treated globally.

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), hand and foot atopic dermatitis (Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), pediatric eosinophilic esophagitis (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), chronic pruritis of unknown origin (Phase 3), chronic inducible urticaria-cold (Phase 3), chronic rhinosinusitis without nasal polyposis (Phase 3), allergic fungal rhinosinusitis (Phase 3) and allergic bronchopulmonary aspergillosis (Phase 3). 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.

Sanofi Media Relations
Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com

Sanofi Investor Relations
Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com
Arnaud Delépine | + 33 06 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 06 40 56 92 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Priya Nanduri |+617 764 6418 | priya.nanduri@sanofi.com
Nathalie Pham | + 33 07 85 93 30 17 | nathalie.pham@sanofi.com

Regeneron Media Relations
Ashleigh Dixon | + 1 914 374 2422 | ashleigh.dixon@regeneron.com

Regeneron Investor Relations
Vesna Tosic | + 914 847 5443 | vesna.tosic@regeneron.com

Sanofi Disclaimers or 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) for the treatment of eosinophilic esophagitis; 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, pediatric 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 and its Form 10-Q for the quarterly period ended March 31, 2022. 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).