Press Release

Dupixent® (dupilumab) approved by European Commission as the first and only targeted medicine indicated for eosinophilic esophagitis

- Approximately 60% of patients aged 12 years and older treated with Dupixent 300 mg weekly in the pivotal trial experienced histological disease remission; patients also significantly improved their ability to swallow compared to placebo
- Dupixent is now an option for the approximately 50,000 adults and adolescents living with severe uncontrolled eosinophilic esophagitis in the European Union (EU)
- Dupixent now approved to treat five diseases with underlying type 2 inflammation in the EU

Paris and Tarrytown, N.Y. Jan 30, 2023. The European Commission (EC) has expanded the marketing authorization for Dupixent® (dupilumab) in the European Union (EU) to treat eosinophilic esophagitis (EoE) in adults and adolescents 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy. EoE is a chronic, progressive inflammatory disease that damages the esophagus and prevents it from working properly. With this approval, Dupixent is the first and only targeted medicine specifically indicated to treat EoE in Europe and the U.S.

Naimish Patel, M.D.
Head of Global Development, Immunology and Inflammation at Sanofi
"The impact of EoE on a patient's daily life cannot be overstated – the narrowing and scarring of the esophagus can make something as simple as eating a painful and distressing experience, and may lead to choking and food impaction. With this latest approval for Dupixent, adults and adolescents in the EU suffering from the chronic and often debilitating symptoms of EoE now have the first and only targeted treatment option clinically proven to reduce both esophageal inflammation and damage, as well as improve swallowing ability, pain and health-related quality of life."

George D. Yancopoulos, M.D., Ph.D.
President and Chief Scientific Officer at Regeneron
"This latest approval establishes Dupixent as the only targeted medicine specifically indicated for eosinophilic esophagitis in the European Union. Dupixent is also the only biologic shown in pivotal trials to help patients achieve histological remission, reduce difficulty swallowing and improve health-related quality of life – all of which are crucial to reducing the burden of this debilitating disease. Since its first approval, Dupixent has redefined the treatment of certain chronic diseases with underlying type 2 inflammation and is now indicated for five conditions in the European Union. We remain committed to investigating Dupixent's potential in additional diseases in which IL-4 and IL-13 may play a key role."

The EC decision is supported by 52-week data from a Phase 3 trial consisting of three parts (Part A, B and C). Part A and Part B investigated Dupixent 300 mg weekly (Part A n=42; Part B n=80) compared to placebo (Part A n=39; Part B n=79) for 24 weeks. Part C (n=188) observed patients who had continued on or switched to Dupixent from Parts A and B for an additional 28 weeks.

Dupixent patients in Parts A and B, respectively, experienced:

- An approximately 10 times higher rate of histological disease remission (60% and 59%), a co-primary endpoint, compared to placebo (5% and 6%).
- A 69% and 64% reduction in disease symptoms compared to 32% and 41% with placebo. Disease symptoms were measured using the Dysphagia Symptom Questionnaire (DSQ),

on which Dupixent patients experienced a 21.9- and 23.8-point clinically meaningful improvement compared to a 9.6- and 13.9-point improvement for placebo, a co-primary endpoint. Swallowing improvement was observed as early as four weeks.
- A greater than seven-fold reduction in abnormal endoscopic findings from baseline (-3.2 and -4.5 points) compared to placebo (-0.3 and -0.6 points).
- Nominally significant improvements in swallowing-related pain and health-related quality of life, as well as less frequent non-swallowing symptoms.

Histological disease remission, swallowing improvement and reduction in abnormal endoscopic findings were consistent with the overall population in patients who were uncontrolled, or not responsive to or not eligible for swallowed topical corticosteroids. Longer term efficacy in Part C was similar to results observed in Parts A and B.

The safety results of the trial were generally consistent with the known safety profile of Dupixent in its approved indications. The most common side effects across indications include injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes and eosinophilia. Adverse events more commonly observed in EoE patients treated with Dupixent (n=122) compared to placebo (n=117) included infections (32% vs. 25%). An additional adverse reaction of injection site bruising was reported in the EoE trial. The safety profile through 52 weeks was generally consistent with the safety profile observed at 24 weeks.

About Eosinophilic Esophagitis

EoE is a chronic, progressive inflammatory disease that damages the esophagus and prevents it from working properly. The results seen with Dupixent in adults and adolescents with EoE demonstrate that interleukin-4 (IL-4) and interleukin-13 (IL-13) are key and central drivers of the type 2 inflammation underlying this disease. 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. In the EU, about 50,000 adults and adolescents live with severe uncontrolled EoE.

About the Dupixent Eosinophilic Esophagitis Trial

The three-part Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in patients aged 12 years and older with EoE. All patients had previously not responded to proton pump inhibitors, and, across Parts A and B, 74% of patients were previously treated with swallowed topical corticosteroids.

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).

Additional endpoints included abnormal endoscopic findings (EoE Endoscopic Reference Score [EoE-EREFS] on a 0-18 scale), swallowing-related pain (DSQ pain score), health-related quality of life (EoE Impact Questionnaire [EoE-IQ]) and frequency of other non-dysphagia symptoms (EoE Symptom Questionnaire [EoE-SQ]).

About Dupixent

Dupixent is an injection administered under the skin (subcutaneous injection) at different injection sites. In the EU for adolescents and adults with EoE, Dupixent is administered at 300 mg every week. It is available as both a pre-filled pen and pre-filled syringe at the 300 mg dose. 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.

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 atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), prurigo nodularis and EoE.

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, CRSwNP, EoE or prurigo nodularis in different age populations. Dupixent is currently approved for one or more of these indications in more than 60 countries, including in Europe, the U.S. and Japan. More than 500,000 patients have been treated with Dupixent 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 in Phase 3 trials, including pediatric EoE, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis and bullous pemphigoid. 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, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for 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 more information, 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 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Priya Nanduri |+ 1 617 764 6418 | priya.nanduri@sanofi.com
Nathalie Pham | + 33 07 85 93 30 17 | nathalie.pham@sanofi.com

Regeneron Media Relations
Ilana Yellen | + 1 914 330 9618 |ilana.yellen@regeneron.com

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

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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 adults and adolescents with eosinophilic esophagitis ("EoE"); uncertainty of the utilization, 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 any of the foregoing; 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 EoE, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, bullous pemphigoid, 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 and Bayer (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, 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 September 30, 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).