Press Release

Dupixent® FDA approved as first and only treatment indicated for children aged 1 year and older with eosinophilic esophagitis (EoE)

- Approval based on Phase 3 EoE KIDS trial showing a greater proportion of children taking Dupixent achieved histological remission compared to placebo
- Expanded indication marks second disease for which Dupixent is approved in children this young, underscoring the commitment to bringing therapies to young patients with significant unmet needs
- EoE is one of five FDA-approved indications for Dupixent in the U.S. for which type 2 inflammation is an underlying driver

Paris and Tarrytown, N.Y. January 25, 2024. The U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) for the treatment of pediatric patients aged 1 to 11 years, weighing at least 15 kg, with eosinophilic esophagitis (EoE). Dupixent is now the first and only medicine approved in the U.S. specifically indicated to treat these patients. This approval expands the initial FDA approval for EoE in May 2022 for patients aged 12 years and older, weighing at least 40 kg. The FDA evaluated Dupixent for this expanded indication under Priority Review, which is reserved for medicines that represent potentially significant improvements in efficacy or safety in treating serious conditions.

EoE is a chronic, progressive disease driven in part by type 2 inflammation that damages the esophagus and impairs its function. EoE can severely impact a child's ability to eat, and they may experience heartburn, vomiting, abdominal discomfort, trouble swallowing, food refusal and failure to thrive. These symptoms can adversely impact their growth and development. Continuous treatment of EoE may be needed to reduce the risk of complications and disease progression. Approximately 21,000 children under the age of 12 in the U.S. are currently being treated for EoE with unapproved therapies. However, the actual prevalence of children with the disease is likely higher, given symptoms can be mistaken for other conditions and there are delays in diagnosis.

> ***Naimish Patel, M.D.***
> Head of Global Development, Immunology and Inflammation at Sanofi
> *"Young children with eosinophilic esophagitis have significant unmet medical needs; despite existing treatment options, 40% of these children in the U.S. under the age of 12 continue to experience symptoms of this disease. Today's approval underscores our commitment to bringing therapies to young patients with unmet needs and also brings hope to these patients who are at a critical age where struggling to eat and maintain weight directly impacts their overall nutritional intake and development."*

The FDA approval is based on data from the Phase 3 EoE KIDS trial with two parts (Part A and Part B) evaluating the efficacy and safety of Dupixent in children aged 1 to 11 years with EoE. At 16 weeks, 66% of children who received higher dose Dupixent at tiered dosing regimens based on weight (n=32) achieved histological disease remission (≤6 eosinophils/high power field), the primary endpoint, compared to 3% for placebo (n=29).

Histological remission was sustained at week 52, with 17 of 32 (53%) children treated with Dupixent in Parts A and B. Histological remission was also achieved at week 52 in 8 of 15 (53%) children who switched to Dupixent from placebo in Part B. In addition, a greater decrease in the proportion of days with one or more signs of EoE based on Pediatric EoE Sign/Symptom Questionnaire-caregiver version (PESQ-C) was observed in children treated with Dupixent at 16 weeks compared to placebo.

> ***George D. Yancopoulos, M.D., Ph.D.***
> Board co-chair, President and Chief Scientific Officer at Regeneron
> *"Young children are some of the most vulnerable patients with eosinophilic esophagitis, or EoE, as this debilitating and progressive disease threatens their basic ability to eat. Until today, these children had no approved treatment options specifically for EoE, leaving many with unapproved medicines that failed to target the root cause of their disease. With this approval, Dupixent becomes the first and only treatment option for EoE patients aged 1 year and older, weighing at least 15 kg. By targeting the underlying type 2 inflammation that contributes to this disease, Dupixent has the potential to transform the standard of care for these children as it has for adults and adolescents with EoE."*

The safety profile of Dupixent observed through 16 weeks in children aged 1 to 11 years weighing at least 15 kg was generally similar to the safety profile of Dupixent observed through 24 weeks in adult and pediatric patients aged 12 years and older with EoE. The most common adverse events (≥2%) more frequently observed with Dupixent than placebo were injection site reactions, upper respiratory tract infections, arthralgia (joint pain) and herpes viral infections. In EoE KIDS Part B, one case of helminth infection was reported in the Dupixent arm.

About the Dupixent Pediatric Eosinophilic Esophagitis Trial
The Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in children aged 1 to 11 years, weighing at least 15 kg, with EoE, as determined by histological, endoscopic and patient- or caregiver-reported measures. At baseline, 97% of these patients had at least one co-existing type 2 inflammatory disease, such as food allergy, allergic rhinitis, asthma and atopic dermatitis.

Part A, a 16-week, double-blind, placebo-controlled treatment period, enrolled 61 patients and evaluated the safety and efficacy of Dupixent in a tiered, weight-based dosing schema. The primary endpoint was histological disease remission, which was defined as peak esophageal intraepithelial eosinophil count of ≤6 eosinophils (eos)/high power field (hpf). Changes in caregiver-reported symptoms (proportion of days with 1 or more EoE signs [e.g., stomach pain, vomiting, food refusal]) were evaluated using PESQ-C.

Part B was a 36-week extended active treatment period (n=47) in which eligible children from Part A in the Dupixent group continued to receive their dose level and those in the placebo group in Part A switched to Dupixent.

About Dupixent
Dupixent, which was invented using Regeneron's proprietary *VelocImmune*® technology, 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, and 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 800,000 patients are being treated with Dupixent globally.

Dupilumab Development Program
Dupilumab is being jointly developed by Regeneron and Sanofi 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, Regeneron and Sanofi are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in Phase 3 trials, including chronic pruritus of unknown origin, chronic obstructive pulmonary disease (COPD) with evidence of type 2 inflammation, 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 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.

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 over 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and 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, 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 about Regeneron, please visit www.Regeneron.com or follow Regeneron on LinkedIn.

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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 pandemics or other global crises may 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. 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, 2022. 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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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 children aged 1 to 11 years with eosinophilic esophagitis ("pediatric EoE"); 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 chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, bullous pemphigoid, and other potential indications; 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 or any potential regulatory approval of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates; 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; 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; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; 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 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, 2022 and its Form 10-Q for the quarterly period ended June 30, 2023. 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.

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