Press Release

Dupixent positive phase 3 data in children one to 11 years of age with eosinophilic esophagitis published in NEJM

- *Majority of patients in this age group with eosinophilic esophagitis receiving Dupixent achieved histologic remission, with improvements sustained up to one year*
- *Dupixent is the first-and-only medicine indicated for eosinophilic esophagitis in the US for this age group*

Paris and Tarrytown, NY, June 26, 2024. *The New England Journal of Medicine* has published results from a positive phase 3 study of Dupixent (dupilumab) in children aged one to 11 years with eosinophilic esophagitis (EoE). The study showed a greater proportion of those receiving weight-tiered higher dose Dupixent experienced significant improvements in many key disease measures of EoE, compared to placebo at week 16. Data from the study were the basis for the US Food and Drug Administration Priority Review and approval of Dupixent in children aged one to 11 years with EoE weighing at least 15 kg, as well as for the regulatory submission that is currently under review by the European Medicines Agency for this age group.

EoE is a chronic, progressive disease associated with type-2 inflammation that is thought to be responsible for damaging the esophagus and impairing its function. Diagnosis is difficult, as symptoms can be mistaken for other conditions, and there are delays in diagnosis. EoE can severely impact a child's ability to eat and may also cause abdominal pain, trouble swallowing, heartburn, vomiting and failure to thrive. Continuous management of EoE may be needed to reduce the risk of complications and disease progression.

> ***Mirna Chehade, M.D., MPH***
> Mount Sinai Center for Eosinophilic Disorders, Icahn School of Medicine at Mount Sinai, New York, NY, and principal investigator of the study
> *"The NEJM publication of these phase 3 dupilumab results is a testament to the importance of these data and potential for dupilumab to change the standard of care for many young children living with eosinophilic esophagitis. These children commonly experience feeding difficulties, food refusal and failure to thrive during a critical time of their growth and development. These data showed weight-tiered higher dose dupilumab significantly improved key eosinophilic esophagitis histologic, endoscopic, and cellular measures in children as young as 1 year old with sustained results for up to one year. These results reinforce the positive results seen in older patients with eosinophilic esophagitis and strengthen our understanding of IL4 and IL13 as key drivers of the type 2 inflammation underlying this disease."*

As published, a significantly greater proportion of children receiving either a weight-tiered higher or lower dose regimen of Dupixent achieved histologic remission at week 16 in part A of the study, compared with placebo. Additionally, those treated with higher dose Dupixent experienced significant improvements in disease severity assessed by endoscopic measures, with improvements sustained for up to one year. Those receiving lower dose Dupixent experienced improvements that were either comparable or numerically lower than the higher dose group. Dupixent also led to numerical improvement in body weight for age percentile by

week 16 and sustained to one year, which was evaluated as an exploratory endpoint in part A and a secondary endpoint in part B.

Safety results were generally consistent with the known safety profile of Dupixent in adolescents and adults with EoE. Adverse events more commonly observed with Dupixent (≥10%) in either weight-based dosing regimen versus placebo in the study were COVID-19, nausea, injection site pain and headache during part A. The long-term safety profile of Dupixent in children aged one to 11 years through part B was similar to that observed during part A. In part B, one case of helminth infection was reported with Dupixent.

For patients in the US with EoE weighing at least 15 kg, the FDA-approved dosage for Dupixent is 200mg or 300mg every other week, or 300mg weekly, based on weight.

Dr. Mirna Chehade has served as a paid consultant for Sanofi and Regeneron and has received research grant funding from Regeneron.

About the Dupixent pediatric eosinophilic esophagitis study
The phase 3 randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of Dupixent in children aged one to 11 years with EoE. Part A enrolled 102 patients and evaluated Dupixent at a weight-tiered higher dose or lower dose regimen, compared to placebo for 16 weeks. Part B was a 36-week extended active treatment period in which eligible children from part A in the Dupixent group maintained their weight-tiered higher or lower dose level, while those in the placebo group switched to weight-tiered higher or lower dose Dupixent.

The primary endpoint was histologic remission at 16 weeks and secondary endpoints included assessments of endoscopic and histopathologic measures of the severity of disease along with clinical signs and symptoms of EoE. Change in body weight for age percentile was evaluated as an exploratory endpoint in part A and as a secondary endpoint in part B. The study is ongoing with a 108-week open-label extension period (part C) to evaluate longer-term outcomes.

About Dupixent
Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL4) and interleukin-13 (IL13) 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 studies, establishing that IL4 and IL13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, prurigo nodularis and chronic spontaneous urticaria in different age populations. More than 850,000 patients are being 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 studies 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 studies, including chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease 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 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 by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

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 the world, 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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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; 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 chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, 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; 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), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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, 2023 and its Form 10-Q for the quarterly period ended March 31, 2024. Any forward-looking

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