Press Release

Dupixent approved in the EU as the first and only medicine for young children with eosinophilic esophagitis

- Approval based on phase 3 data showing significantly more children aged one to 11 years on Dupixent achieved histological disease remission at 16 weeks compared to placebo, which was sustained up to one year
- Dupixent is the first-ever medicine in the EU indicated to treat these young patients, who persistently struggle to eat at a critical stage in life where growth is crucial

Paris and Tarrytown, NY, November 6, 2024. The European Medicines Agency has approved Dupixent (dupilumab) to treat eosinophilic esophagitis (EoE) in children as young as one year of age. Specifically, the approval covers children aged one to 11 years who weigh at least 15 kg and who are inadequately controlled by, intolerant to, or who are not candidates for conventional medicinal therapy. This expands the initial approval in the European Union (EU) for EoE in adults and adolescents and makes Dupixent the first and only medicine indicated to treat these young patients. Dupixent is also approved in this young age group in the US and Canada.

Roberta Giodice
President, ESEO Italia
"Young children with eosinophilic esophagitis are at the beginning of their life-long journey with a disease that challenges their ability to eat. Parents of these children have often relied on restrictive diets that do not specifically address the disease and can stunt their growth at a critical time in development that could impact them for years to come. We are pleased that research continues and offers new treatment options to improve the quality of their care."

Houman Ashrafian, MD, PhD
Executive Vice President, Head of Research and Development, Sanofi
"Up to half of all children in the EU with eosinophilic esophagitis remain uncontrolled despite existing standard of care treatment options, and, as a result, many of these young patients struggle to maintain weight due to serious symptoms such as difficulty swallowing and vomiting. This milestone provides an important new treatment for pediatric patients who were previously without options specifically approved for their disease. With this novel approach to addressing an underlying cause of eosinophilic esophagitis, Dupixent has the potential to give these young children a better chance to thrive."

The approval is based on the two-part (Part A and B) EoE KIDS phase 3 study in children aged one to 11 years, which established a bridge showing the response to Dupixent in children with EoE is similar to that of the approved adult and adolescent populations. In Part A, children who received a higher dose of Dupixent (n=37) based on a weight-based dosing regimen experienced the following outcomes, compared to placebo (n=34) at 16 weeks:

- 68% achieved histological disease remission (≤6 eosinophils/high power field) compared to 3%, the primary endpoint. These results were sustained for up to one year in Part B of the study.
- 86% reduction in peak esophageal intraepithelial eosinophil count from baseline compared to a 21% increase.

- Reductions in abnormal endoscopic findings and disease severity and extent (as measured at the microscopic level).
- Nominally significant improvement in the frequency and severity of EoE signs, and numerical reduction in days with at least one sign of EoE, based on caregiver-reported outcomes.

The safety results in the EoE KIDS study were generally consistent with the known safety profile of Dupixent in adolescents and adults with EoE. The most common adverse reactions for Dupixent overall are injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes and eosinophilia. In addition, the adverse reaction of injection site bruising was reported in EoE. In patients aged one to 11 years, adverse events more commonly observed with Dupixent (≥10%) in either weight-based dosing regimen compared to placebo during Part A were COVID-19, nausea, injection site pain, and headache. The long-term safety profile of Dupixent evaluated in Part B was similar to that observed during Part A.

> ***George D. Yancopoulos, M.D., Ph.D.***
> Board co-Chair, President, and Chief Scientific Officer at Regeneron
> *"Eosinophilic esophagitis presents a unique challenge in young children, who struggle with their basic ability to eat during a time in their lives where proper nutrition is essential for growth and development. This approval will bring the proven efficacy and demonstrated safety profile of Dupixent to this vulnerable, young population that has already been established in older EoE patients and has the potential to transform the standard of care for children with EoE who previously had no therapies specifically approved for them."*

About EoE
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 leading to delays in diagnosis. EoE can severely impact a child's ability to eat and may also cause vomiting, abdominal pain, difficulty swallowing, decreased appetite, and challenges thriving. Continuous management of EoE may be needed to reduce the risk of complications and disease progression.

About the Dupixent pediatric EoE study
The EoE KIDS phase 3 study was a randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of Dupixent in children aged one to 11 years with EoE. Part A enrolled 71 patients and evaluated Dupixent at a weight-based 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 continued treatment, while those in the placebo group switched to Dupixent. Patients included in this trial were previously treated and did not respond to conventional medicinal therapies, including proton pump inhibitors and/or swallowed topical corticosteroids.

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 caregiver-reported clinical signs and symptoms of EoE. The 108-week open-label extension period (Part C) to evaluate longer-term outcomes was recently completed.

Results from the study were published in *The New England Journal of Medicine*.

About Dupixent
Dupixent (dupilumab) is an injection administered under the skin (subcutaneous injection) at different injection sites. In patients aged one to 11 years with EoE, Dupixent is

administered every other week (200 mg for children ≥15 to <30 kg, 300 mg for children ≥30 to <40 kg) or every week (300 mg for children ≥40 kg), based on weight. Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home administered by a caregiver after training by a healthcare professional.

Dupixent 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 two of the 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 polyps, EoE, prurigo nodularis, chronic spontaneous urticaria, and chronic obstructive pulmonary disease in different age populations. More than 1,000,000 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 pruritus of unknown origin 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 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, 2023. 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; 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 pruritus of unknown origin, 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 September 30, 2024. 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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