Press Release

Sanofi and Regeneron's Dupixent approved in the US as the first biologic medicine for young children with uncontrolled chronic spontaneous urticaria

- Approval for children aged two to 11 years with CSU who remain symptomatic despite H1 antihistamine treatment based primarily on data from the LIBERTY-CUPID clinical study program
- CSU is a chronic skin disease that causes itch and hives that can be debilitating for young children, especially for those whose disease remains uncontrolled
- CSU marks the fifth disease driven in part by type 2 inflammation for which Dupixent is approved in children younger than 12 years of age

Paris and Tarrytown, NY, April 22, 2026. The US Food and Drug Administration has approved Dupixent (dupilumab) for the treatment of children aged two to 11 years with chronic spontaneous urticaria (CSU) who remain symptomatic despite histamine-1 antihistamine (H1AH) treatment. This expands the previous approval for Dupixent in adults and adolescents aged 12 years and older with CSU.

> *"Children with uncontrolled chronic spontaneous urticaria continue to experience the unpredictable appearance of debilitating itch and hives,"* said **Alyssa Johnsen,** MD, PhD, Global Therapeutic Area Head, Immunology Development at Sanofi. *"Until now, these patients had to rely on limited treatment options that didn't address potential critical mediators of chronic spontaneous urticaria. Dupixent is the first biologic approved for patients as young as two years of age, offering a targeted approach that inhibits IL4 and IL13 signaling, two key and central drivers of the type 2 inflammation that contributes to this disease. Today's approval underscores our ongoing commitment to advancing therapies for young patients with significant unmet needs."*

The approval is based primarily on data from the LIBERTY-CUPID clinical study program. This includes extrapolation of efficacy and safety data from two phase 3 studies (Study A and Study C; clinical study identifier: NCT04180488) in certain adults and adolescents aged 12 years and older with CSU complemented with pharmacokinetics data from the single-arm, CUPIDKids (clinical study identifier: NCT05526521) phase 3 study in children aged 2 to 11 years with CSU. In Study A and Study C, Dupixent significantly reduced itch severity and urticaria activity (a composite of itch and hives) compared to placebo at Week 24. In adults and adolescents, Dupixent also increased the likelihood of well-controlled disease or complete response compared to placebo at Week 24. Study B (clinical study identifier: NCT04180488) provided additional safety data and evaluated Dupixent in patients aged 12 years and older who were inadequate responders or intolerant to anti-IgE therapy and symptomatic despite antihistamine use. Safety in children aged 2 to 11 years with CSU was supported by data from pediatric patients in other indications.

The safety results from all four CSU studies were generally consistent with the known safety profile of Dupixent in its approved dermatological indications. In Study A, Study B, and Study

C, the most common adverse reaction (≥2%) in the US Prescribing Information more frequently observed in patients on Dupixent compared to placebo was injection site reactions. No new adverse reactions were identified in children aged 2 to 11 years with CSU treated with Dupixent.

> "With this approval, Dupixent has become the first biologic medicine in the US for young children suffering from uncontrolled chronic spontaneous urticaria, an unpredictable skin disease that impacts quality of life during these children's most formative years," said **George D. Yancopoulos**, MD, PhD, Board co-Chair, President and Chief Scientific Officer at Regeneron. "Dupixent is now approved for nine different allergy-related conditions, from asthma to atopic dermatitis, and this is the fifth of these indications now extended to young children. The FDA's authorization reinforces our medicine's well-established safety profile and potential to transform outcomes for chronic diseases driven in part by type 2 inflammation impacting some of the most vulnerable populations. As the most widely used innovative branded antibody medicine, Dupixent, has the potential to change yet another treatment paradigm."

In addition to the US, Dupixent is approved for CSU in certain children aged two to 11 years in the EU and other countries around the world.

About CSU

CSU is a chronic inflammatory skin disease driven in part by type 2 inflammation, which causes sudden and debilitating hives and recurring itch. CSU is typically treated with H1AH, medicines that target H1 receptors on cells to control symptoms of itch and urticaria. However, the disease remains uncontrolled despite H1AH treatment in more than 14,000 children in the US aged two to 11 years living with CSU, some of whom are left with limited alternative treatment options. These individuals continue to experience symptoms that can be debilitating and significantly impact their quality of life.

About the Dupixent CSU phase 3 study program

The LIBERTY-CUPID phase 3 program evaluating Dupixent for CSU in children aged two to 11 years consists of CUPIDKids, Study A, Study B and Study C. CUPIDKids was a single arm clinical study that assessed the safety, efficacy, and pharmacokinetics of Dupixent in children aged two to 11 years with CSU who remained symptomatic despite the use of antihistamines. During the 24-week treatment period, Dupixent was administered at 200 mg every two (Q2W) or four (Q4W) weeks or 300 mg Q4W, with or without an initial loading dose, based on age and weight. The primary endpoint measured the serum concentration of Dupixent over time, including C_{trough} (lowest concentration before the next dose) at Week 12 and Week 24.

Study A and Study C were replicate, double-blind, placebo-controlled clinical studies that assessed Dupixent as an add-on therapy to standard-of-care antihistamines compared to antihistamines alone in patients aged six years and older who remained symptomatic despite the use of antihistamines and were naïve to anti-Immunoglobulin E therapy. Study B was conducted in patients aged 12 years and older who were symptomatic despite use of antihistamines and were inadequate responders or intolerant to anti-IgE therapy. During the 24-week treatment period in all three studies, all patients received an initial loading dose followed by either 300 mg Dupixent Q2W or, for pediatric patients weighing 30 kg to <60 kg, 200 mg Q2W. In both studies, endpoints assessed at Week 24 included:

- Change from baseline in itch (measured by the weekly itch severity score, 0-21 scale), the primary endpoint
- Change from baseline in itch and hives (weekly urticaria activity score [UAS7], 0-42

scale), the key secondary endpoint
- Proportion of patients achieving well-controlled disease status (UAS7 ≤6)
- Proportion of patients with complete response (UAS7=0)

About Dupixent
Dupixent (dupilumab) is an injection administered under the skin (subcutaneous injection) at different injection sites. In children aged two to 11 years with CSU who remain symptomatic despite H1AH treatment, Dupixent is administered based on age and weight. In children aged two to five years, Dupixent is administered at 200 mg Q4W for patients weighing ≥5 kg to <15 kg and 300 mg Q4W for ≥15 kg to <30 kg, without an initial loading dose. In children aged six to 17 years, Dupixent is administered at 300 mg Q4W for ≥15 kg to <30 kg, 200 mg Q2W for ≥30 kg to <60 kg, and 300mg Q2W for ≥60 kg, after an initial loading dose. Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home after training by a healthcare professional. In children aged two to 11 years, Dupixent should be administered by a caregiver if given at home.

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.

Sanofi and Regeneron are committed to helping patients in the US 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 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, eosinophilic esophagitis, prurigo nodularis, CSU, chronic obstructive pulmonary disease, bullous pemphigoid, and allergic fungal rhinosinusitis in different age populations. More than 1.4 million 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 12,000 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 lichen simplex chronicus. 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

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY.

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Sanofi forward-looking statements

This press release contains forward-looking statements within the meaning of applicable securities laws, including 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 and their underlying assumptions regarding the marketing and other potential of the product; regarding potential future events and revenues from the product. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these and similar expressions are intended to identify forward-looking statements. 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, uncertainties and assumptions 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; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; 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 pending or future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that 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 French Markets Authority (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, 2025 or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.

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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 2 to 11 years with chronic spontaneous urticaria; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including Dupixent for the treatment of chronic pruritus of unknown origin, lichen simplex chronicus, and other potential indications; 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; 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 and risks associated with tariffs and other trade restrictions; 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's pricing strategy; other changes in laws, regulations, and policies affecting the healthcare industry; competing products and product candidates (including biosimilar products) 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 on Regeneron's business; and risks associated with 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), 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), 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, 2025. 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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