Press Release

Sanofi and Regeneron's Dupixent approved as the first targeted medicine in the EU in over a decade for chronic spontaneous urticaria

- Approval based on phase 3 studies showing Dupixent significantly reduced itch and hives at 24 weeks compared to placebo
- In the EU, there are approximately 270,000 adults and adolescents aged 12 years and older living with CSU who remain symptomatic despite standard-of-care antihistamine treatment
- Dupixent, which inhibits IL4 and IL13, two key and central drivers of type 2 inflammation, is now approved for patients across seven chronic, inflammatory diseases in the EU

Paris and Tarrytown, NY, November 25, 2025. The European Commission has approved Dupixent (dupilumab) for the treatment of moderate-to-severe chronic spontaneous urticaria (CSU) in adult and adolescent patients 12 years and above with inadequate response to histamine-1 antihistamines (H1AH) and who are naive to anti- immunoglobulin-E (IgE) therapy for CSU. Eligible patients can use Dupixent as a first-line targeted treatment option.

> *"The unpredictable nature of chronic spontaneous urticaria leaves patients guessing when they'll have their next outbreak of disruptive, debilitating hives and itch, which can make life challenging,"* said **Tonya Winders**, President & CEO, Global Allergy & Airways Patient Platform. *"Dupixent is proven to reduce these intense symptoms and has the potential to make a positive impact on people struggling to control this disease."*
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> *"Standard-of-care, first-line treatment options like antihistamines offer limited relief for many people living with uncontrolled chronic spontaneous urticaria, leaving them to face unrelenting cycles of itch and hives,"* said **Alyssa Johnsen**, MD, PhD, Global Therapeutic Area Head, Immunology Development at Sanofi. *"Dupixent significantly reduced these symptoms of CSU and led to more patients experiencing well-controlled disease or a complete response compared to placebo in two phase 3 studies. Now, eligible patients with CSU in the EU have a new option that is proven to reduce itch and hives."*

The approval is based on data from two phase 3 clinical studies in the LIBERTY-CUPID program (NCT04180488). Study A and Study C included 284 patients aged 12 years and older who were symptomatic despite the use of antihistamines and who were naïve to anti-IgE therapy. Both studies assessed Dupixent as an add-on therapy to standard-of-care antihistamines compared to antihistamines alone and demonstrated Dupixent significantly reduced urticaria activity (a composite of itch and hives), and individual measures of itch and hive severity compared to placebo at 24 weeks. Dupixent also increased the percentage of patients with well-controlled disease and complete response at 24 weeks compared to placebo. Study B (n=108) 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 results from Study A, Study B and Study C were generally consistent with the known safety profile of Dupixent in its approved indications. The most common adverse reactions for Dupixent overall are injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes, and eosinophilia. Additional adverse reactions of injection site induration, injection site dermatitis, and injection site hematoma were reported in the CSU adult and adolescent studies. Adverse events more commonly observed with Dupixent (≥5%) than placebo in patients with CSU were injection site reaction, COVID-19, hypertension, CSU, and accidental overdose.

> *"The approval of Dupixent for certain adults and adolescents with chronic spontaneous urticaria in the European Union represents the first innovation for patients with this disease in over a decade,"* said **George D. Yancopoulos,** MD, PhD, Board co-Chair, President and Chief Scientific Officer at Regeneron. *"Physicians now have a new approach for CSU with Dupixent, as the only treatment that inhibits IL4 and IL13, two key drivers of type 2 inflammation, and can offer patients significant improvement in debilitating itch and hives. This approval further demonstrates the ability of Dupixent to advance the treatment landscape for yet another chronic type 2 inflammatory disease, with a well-established safety profile across its indications."*

Beyond the EU, Dupixent is also approved for CSU in certain adults and adolescents in several countries including the US and Japan.

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 many patients, 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. More than 270,000 people in the EU aged 12 years and older suffer from CSU that is inadequately controlled by antihistamines.

About the Dupixent CSU phase 3 study program
The LIBERTY-CUPID phase 3 program evaluating Dupixent for CSU consists of Study A, Study B, and Study C. These studies were randomized, double-blind, placebo-controlled clinical studies that evaluated the efficacy and safety of Dupixent as an add-on therapy to standard-of-care antihistamines compared to antihistamines alone. Studies A and C were replicate studies that assessed patients aged 6 years and older who remained symptomatic despite the use of antihistamines and were naïve to anti-IgE 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 every two weeks, or 200 mg every two weeks for adolescents weighing <60 kg.

The primary endpoint in all three studies assessed the change from baseline in itch and hives (weekly urticaria activity score [UAS7], 0-42 scale). The key secondary endpoint (also assessed at 24 weeks) was change from baseline in itch (measured by the weekly itch severity score, 0-21 scale). Additional secondary endpoints assessed at 24 weeks evaluated:

- Change from baseline in hives (measured by the weekly hive severity score, 0-21 scale)
- Proportion of patients achieving well-controlled disease status (UAS7 ≤6)
- Proportion of patients with complete response (UAS7=0).

The results from Studies A and B were published in *The Journal of Allergy and Clinical Immunology*.

About Dupixent
Dupixent (dupilumab) is an injection administered under the skin (subcutaneous injection) at different injection sites. In adults with CSU who remain symptomatic despite H1AH treatment, Dupixent 300 mg is administered every two weeks after an initial loading dose. In patients aged 12 to 17 years with CSU who remain symptomatic despite H1AH treatment, Dupixent is administered every two weeks based on weight (200 mg for adolescents ≥30 to <60 kg, 300 mg for adolescents ≥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 adolescents aged 12 to 17 years, Dupixent should be administered under the supervision of an adult.

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, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, chronic obstructive pulmonary disease, and bullous pemphigoid in different age populations. More than 1.3 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 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, lichen simplex chronicus, and allergic fungal rhinosinusitis. 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 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 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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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 moderate-to-severe chronic spontaneous urticaria in adults and adolescent patients 12 years and above; 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, allergic fungal rhinosinusitis, 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 drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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, 2024 and its Form 10-Q for the quarterly period ended September 30, 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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