Press Release

Dupixent approved in the US as the first new targeted therapy in over a decade for chronic spontaneous urticaria

- Approval based on phase 3 studies demonstrating Dupixent significantly reduced itch and hives compared to placebo
- In the US, there are more than 300,000 adults and adolescents aged 12 years and older living with CSU who remain symptomatic despite antihistamine treatment
- CSU is the seventh disease with underlying type 2 inflammation in which Dupixent is approved

Paris and Tarrytown, NY, April 18, 2025. The US Food and Drug Administration (FDA) has approved Dupixent (dupilumab) for the treatment of adults and adolescents aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite histamine-1 (H1) antihistamine treatment.

> ***Kenneth Mendez***
> President and Chief Executive Officer at the Asthma and Allergy Foundation of America
> *"People with chronic spontaneous urticaria experience sudden, unpredictable hives and severe itch that cause a significant, and often overwhelming, burden on their everyday lives. The approval of this treatment offers patients more options and the chance to control their disease."*

> ***Alyssa Johnsen, M.D., Ph.D.***
> Global Therapeutic Area Head, Immunology and Oncology Development at Sanofi
> *"CSU patients with uncontrolled disease experience highly burdensome itch and hives that can significantly disrupt daily living. This FDA approval provides a new treatment option to help address the underlying drivers of these severe and recurring signs and symptoms. Dupixent has the potential to improve outcomes for CSU patients who previously had limited treatment options."*

The US approval is based on data from two phase 3 clinical studies, Study A (n=136) and Study C (n=148), which included biologic-naïve patients aged 12 years and older who were symptomatic despite the use of antihistamines and assessed Dupixent as an add-on therapy to standard-of-care antihistamines, compared to antihistamines alone. Both studies met their primary and key secondary endpoints with Dupixent demonstrating reductions in itch severity and urticaria activity (a composite of itch and hives) compared to placebo at 24 weeks. Dupixent also increased the likelihood of well-controlled disease or complete response compared to placebo at 24 weeks. 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. In pooled data from all three studies, the most common adverse event (≥2%) more frequently observed in patients on Dupixent compared to placebo was injection site reactions.

George D. Yancopoulus, M.D., Ph.D.
Board co-Chair, President and Chief Scientific Officer at Regeneron
"Dupixent is the first new targeted treatment for chronic spontaneous urticaria, or CSU, in over ten years, with pivotal trials demonstrating its ability to help patients significantly reduce the hallmark symptoms of intense itch and unpredictable hives associated with this disease. With this FDA decision, Dupixent is now approved for seven chronic, debilitating atopic conditions driven in part by underlying type 2 inflammation, several of which have been shown to co-morbidly occur with CSU, such as atopic dermatitis and asthma – providing patients with one treatment that might help multiple atopy conditions. We look forward to bringing Dupixent to the more than 300,000 CSU patients in the US with inadequately controlled disease on standard-of-care treatment who, until now, had limited treatment options."

Dupixent is already approved for CSU in Japan, the United Arab Emirates, and Brazil. Submissions are currently under review with other regulatory authorities around the world including in the EU.

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 H1 antihistamines, medicines that target H1 receptors on cells to control symptoms of itch and urticaria. However, the disease remains uncontrolled despite antihistamine 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 300,000 people in the US 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 six years and older who remained symptomatic despite the use of antihistamines. 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, patients received an initial loading dose followed by 300 mg Dupixent every two weeks, except for pediatric patients weighing <60 kg who received 200 mg every two weeks.

In all three studies, the primary endpoint assessed the change from baseline in itch at 24 weeks (measured by the weekly itch severity score, 0-21 scale). The key secondary endpoints (also assessed at 24 weeks) included change from baseline in itch and hives (weekly urticaria activity score [UAS7], 0-42 scale). Additional secondary endpoints assessed at 24 weeks evaluated the proportion of patients achieving well-controlled disease status (UAS7 ≤6) and the 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*. Study B did not meet the primary endpoint in the US of reduction in ISS7 compared to placebo at 24 weeks.

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 H1 antihistamine 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 H1 antihistamine 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.

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, and chronic obstructive pulmonary disease in different age populations. More than one 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, bullous pemphigoid, 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

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.

Sanofi Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Nicolas Obrist | +33 6 77 21 27 55 | nicolas.obrist@sanofi.com
Léo Le Bourhis | +33 6 75 06 43 81 | leo.lebourhis@sanofi.com
Victor Rouault | +33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | +1 516 521 2929 | timothy.gilbert@sanofi.com

Sanofi Investor Relations

Thomas Kudsk Larsen |+44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | +33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com
Tarik Elgoutni | +1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | +33 6 80 80 89 90 | thibaud.chatelet@sanofi.com
Yun Li | +33 6 84 00 90 72 | yun.li3@sanofi.com

Regeneron Media Relations

Ilana Yellen | +1 914-330-9618| ilana.yellen@regeneron.com

Regeneron Investor Relations

Mark Hudson | +1 914-847-3482 | mark.hudson@regeneron.com

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.

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 chronic spontaneous urticaria ("CSU"); 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 CSU in the European Union as well as for the treatment of chronic pruritus of unknown origin, bullous pemphigoid, lichen simplex chronicus, 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; 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. 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).