Press Release

Sanofi and Regeneron's Dupixent approved in the US as the first and only medicine for allergic fungal rhinosinusitis

- Approval in adults and children aged 6 years and older supported by phase 3 study demonstrating Dupixent significantly reduced nasal signs and symptoms and systemic corticosteroid use or surgery compared to placebo
- AFRS is a chronic type 2 inflammatory disease of the sinuses characterized by an allergic hypersensitivity to fungi, often requiring surgery with high rates of post-operative recurrence
- Dupixent is now approved in the US to treat nine distinct diseases driven in part by type 2 inflammation, including sino-nasal, skin, gut and respiratory system diseases that affect a broad range of patients, from infants to elderly adults

Paris and Tarrytown, NY, February 24, 2026. The US Food and Drug Administration (FDA) has approved Dupixent (dupilumab) for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery. The FDA evaluated Dupixent under priority review for the treatment of AFRS, which is reserved for medicines that have the potential to provide significant improvements in the treatment, diagnosis, or prevention of serious conditions. This approval expands our approved indications in sino-nasal diseases to now include AFRS, alongside chronic rhinosinusitis with nasal polyps.

> *"Allergic fungal rhinosinusitis (AFRS) is a disease that can leave both children and adults with inflamed nasal passages, nasal polyps, and thick mucus causing constant nasal congestion. Some patients can also experience more serious complications like deterioration of bone around the sinuses and facial deformities,"* said **Kenneth Mendez**, President and CEO, Asthma and Allergy Foundation of America (AAFA). *"As the first treatment specifically approved for AFRS, Dupixent offers the potential for relief to adults and children six years and older struggling with potentially debilitating symptoms."*

AFRS is a chronic type 2 inflammatory disease. It is a specific subtype of chronic rhinosinusitis distinctly caused by an intense allergic hypersensitivity to fungi. It primarily affects people living in warm, humid climates where fungal spores are common in the environment. It can lead to nasal polyps, nasal congestion, loss of smell, thick mucus discharge, poor health-related quality of life, and patients can also experience bone loss around the sinus cavities and facial deformities. AFRS can be a severe and hard-to-treat form of chronic rhinosinusitis because it may not respond well to available options. Current standard-of-care treatment is surgery and prolonged courses of systemic steroids; however, disease recurrence is not uncommon.

> *"Before Dupixent, people living with allergic fungal rhinosinusitis had to rely on treatments that left them potentially vulnerable to regrowth of nasal polyps and thick mucus that could rob them of their sense of smell,"* said **Alyssa Johnsen**, MD, PhD, Global Therapeutic Area Head, Immunology Development at Sanofi. *"As*

the first medicine approved specifically for AFRS, Dupixent has been proven to lessen multiple signs and symptoms of disease, help break the cycle of recurrence, and reduce the risk for subsequent surgeries and corticosteroids by 92%. We look forward to working with regulators in other countries to bring this innovative option to more patients in need."

The FDA approval is supported by the LIBERTY-AFRS-AIMS phase 3 study (clinical study identifier: NCT04684524), in which 62 adults and children aged 6 years and older with AFRS were randomized to receive an age- and weight-based dose of Dupixent (200 mg or 300 mg) every two (Q2W) or four weeks (Q4W) (n=33) or placebo (n=29). The differences for Dupixent compared to placebo were as follows:

Primary endpoint: Sinus opacification scores (a measure of extent of sinus involvement by the disease as assessed by computed tomography [CT] scans) improved by 50% versus 10% at Week 52 (7.36-point placebo-corrected reduction; p<0.0001); a significant reduction in sinus opacification scores was also observed at Week 24 (p<0.0001).

Secondary endpoints:

- *Select nasal signs and symptoms*
  - Patient-reported nasal congestion/obstruction improved by 67% versus 25% at Week 24 (0.87-point placebo-corrected reduction; p<0.0001), with continued improvement at Week 52 to 81% compared to 11% (1.40-point placebo-corrected reduction; p<0.0001)
  - Nasal polyp size (as assessed by endoscopy) reduced by 61% versus 15% at Week 24 (2.36-point placebo-corrected reduction; p<0.0001), with continued reduction of 63% compared to 4% up to Week 52 (2.77-point placebo-corrected reduction; p<0.0001)
- *Sense of smell*
  - Patient-reported loss of smell reduced by 67% versus 19% at Week 24 (0.89-point placebo-corrected reduction; p<0.0001)
- *Treatment burden*
  - 92% reduction in the risk of systemic corticosteroid use and/or need of surgery (29% fewer proportion of patients; p=0.0010) over 52 weeks. 3% or 0% of patients on Dupixent received systemic corticosteroids or had surgery, respectively, compared to 31% or 7% of patients on placebo

The safety results in the LIBERTY-AFRS-AIMS study were similar to the known safety profile of Dupixent in CRSwNP. In pooled data from two pivotal CRSwNP studies in adults, the most common adverse reactions (≥1%) in the US Prescribing Information more frequently observed in patients on Dupixent compared to placebo were injection site reactions, conjunctivitis, arthralgia, gastritis, insomnia, eosinophilia, and toothache.

"With this approval, Dupixent once again demonstrates its value in advancing the treatment landscape for a chronic type 2 inflammatory disease with high unmet need," said **George D. Yancopoulos,** MD, PhD, Board co-Chair, President and Chief Scientific Officer at Regeneron. *"Beyond reducing nasal signs and symptoms, Dupixent reduced the need for surgery or systemic corticosteroids with fewer patients having bone erosion in the sinuses. These results underscore its potential to establish a new standard of care for people living with AFRS. This ninth FDA approval for Dupixent, the most widely used innovative branded antibody medicine, strengthens the established efficacy and body of evidence that IL4 and IL13 are major drivers of type 2 inflammation across many chronic diseases."*

Additional submissions are planned to other regulatory authorities around the world.

About LIBERTY-AFRS-AIMS
The LIBERTY-AFRS-AIMS phase 3 study was a randomized, double-blind, placebo-controlled study assessing the safety and efficacy of Dupixent in adults and children aged 6 years and older with AFRS. The 52-week study included an age- and weight-based dose of Dupixent (300 mg Q2W for adults and children weighing ≥60 kg, 200 mg Q2W for children weighing ≥30 kg to <60 kg, or 300 mg Q4W for children weighing ≥15 kg to <30 kg) or placebo. More than 80% of patients had a history of type 2 comorbidities.

The primary endpoint assessed change from baseline in sinus opacification assessed by CT scans using the Lund-Mackay score (LMK; scale: 0-24) at Week 52. Secondary endpoints assessed at Week 24 included:

- Change from baseline in patient-reported nasal congestion (scale: 0-3)
- Change from baseline in nasal polyp score (scale: 0-8) as measured by endoscopy
- LMK score
- Change from baseline in patient-reported loss of smell (scale: 0-3)

Some secondary endpoints were also assessed at Week 52 in addition to proportion of patients requiring surgery or systemic corticosteroids during the treatment period. Proportion of patients with bone erosion in the sinuses as evaluated by CT scans was a tertiary endpoint assessed at Week 52.

About Dupixent
Dupixent (dupilumab) is an injection administered under the skin (subcutaneous injection) at different injection sites. In adults with AFRS, Dupixent 300 mg is administered every two weeks. In children with AFRS, Dupixent is administered based on weight: 300 mg every two weeks for ≥60 kg, 200 mg every two weeks for ≥30 kg to <60 kg, or 300 mg every four weeks for ≥15 kg to <30 kg. 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 12 to 17 years, Dupixent should be administered under the supervision of an adult. In children younger than 12 years of age, 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, chronic spontaneous urticaria, chronic obstructive pulmonary disease, bullous pemphigoid, and AFRS 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.

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 adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis; 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.

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).