Press Release

EAACI: Dupixent demonstrated superiority over Xolair (omalizumab) in chronic rhinosinusitis with nasal polyps in patients with coexisting asthma in first-ever presented phase 4 head-to-head respiratory study

- New late-breaking data at EAACI showed Dupixent outperformed Xolair across all primary and secondary efficacy endpoints of CRSwNP and in all asthma-related endpoints
- Dupixent also outperformed Xolair in improving such key signs and symptoms as nasal polyp size and sense of smell in CRSwNP, and lung function and disease control in asthma, with rapid improvements seen as early as 4 weeks
- Results reinforce the efficacy of Dupixent in treating both upper and lower respiratory diseases by targeting IL-4 and IL-13, two key drivers of type 2 inflammation

Paris and Tarrytown, NY, June 15, 2025. Sanofi and Regeneron Pharmaceuticals, Inc. today presented positive results from the EVEREST phase 4 study of adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) and coexisting asthma. In the study, Dupixent (dupilumab) outperformed Xolair (omalizumab) on all primary and secondary efficacy endpoints of CRSwNP, and in all asthma-related endpoints. The data are from the first-ever presented head-to-head respiratory study with biologic medicines and were shared today in a late-breaking oral presentation at the 2025 European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress, Glasgow, UK.

> ***Eugenio De Corso, MD, PhD***
> ENT Specialist, Otolaryngology, Head and Neck Surgery, Rhinology, A. Gemelli University Hospital Foundation, IRCSS, Rome, Italy, and lead investigator of the study
> *"Patients suffering from chronic rhinosinusitis with nasal polyps often live with the constant obstruction of their nasal passages that can lead to burdensome nasal congestion and loss of smell. What's more, a majority of these individuals also have asthma that can substantially impact their quality of life. EVEREST is the first-ever trial to demonstrate the superiority of Dupixent over Xolair on CRSwNP endpoints in patients with coexisting asthma, along with generally similar safety profiles. Together, these Dupixent outcomes provide important insights that will help guide patients and physicians through the treatment decision-making process."*

In the EVEREST study, 360 adults with severe, uncontrolled CRSwNP and coexisting asthma were randomized to receive Dupixent 300 mg (n=181) every two weeks or a weight- and immunoglobulin E (IgE) level-based dosing regimen of omalizumab (n=179) every two or four weeks. Both Dupixent and omalizumab were added to background mometasone furoate nasal spray (MFNS).

Primary and secondary endpoint results in CRSwNP for patients treated with Dupixent compared to omalizumab at 24 weeks were as follows with differences were seen as early as four weeks:

- 1.60-point superior **reduction in nasal polyp size**, a primary endpoint ($p<0.0001$[1])
- 8.0-point superior **improvement in ability to identify different smells**, a primary endpoint ($p<0.0001$[1]). More patients on Dupixent improved above the anosmia threshold compared to omalizumab
- 0.58-point superior reduction in **nasal congestion/obstruction**, a key secondary endpoint ($p<0.0001$[1])
- 0.81-point superior **improvement in loss of smell**, a key secondary endpoint ($p<0.0001$[1])
- 1.74-point superior **reduction in symptom severity** ($p<0.0001$[1])
- 12.7-point difference **in health-related quality of life** ($p<0.0001$[2])
- 31.27-point difference in **peak nasal inspiratory flow** ($p<0.0001$[2])
- 1.87 difference in **overall severity of rhinosinusitis** ($p<0.0001$[2])

Asthma endpoint results for patients treated with Dupixent compared to omalizumab at 24 weeks were as follows, with differences seen as early as four weeks:

- 150 mL difference **in lung function** (pre-bronchodilator $FEV_{1;}$ $p=0.003$[2])
- 0.48-point difference **in asthma control** ($p<0.0001$[2])

The safety results in the EVEREST study were generally consistent with the known safety profile of Dupixent in its approved respiratory indications, with similar overall rates of adverse events (AEs) observed between Dupixent (64%) and omalizumab (67%). Serious AEs were reported in 2% and 4% of patients treated with Dupixent and omalizumab, respectively. Additionally, AEs leading to study discontinuation were reported in 3% of Dupixent patients and 1% of omalizumab patients.

About the Dupixent phase 4 study

EVEREST is a randomized, double-blind phase 4 study comparing the efficacy and safety of Dupixent to omalizumab in adults with severe, uncontrolled CRSwNP and coexisting mild, moderate, or severe asthma. During the 24-week study, patients received Dupixent 300 mg every two weeks or omalizumab 75 to 600 mg every two or four weeks, which was added to background MFNS. Omalizumab dosing was determined based on body weight and serum total IgE levels as per the approved label. All endpoints were assessed at 24 weeks.

The primary endpoints assessed change from baseline in nasal polyp score (scale: 0-8) and the University of Pennsylvania Smell Identification Test (scale: 0-40). Secondary endpoints included change from baseline in nasal congestion (scale: 0-3), loss of smell (scale: 0-3), total symptom score (scale: 0-9), SNOT-22 (scale: 0-110), peak nasal inspiratory flow, and rhinosinusitis disease severity (visual analogue scale: 0-10 cm). Other endpoints assessed pre-bronchodilator forced expiratory volume over one second and the 7-item Asthma Control Questionnaire (scale: 0-6).

About Dupixent

Dupixent (dupilumab) 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.

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[1] Statistically significant.

[2] Nominally significant as the endpoint was not included in the multiplicity adjustment hierarchy.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, CRSwNP, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, 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
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.

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 rhinosinusitis with nasal polyps as discussed in this press release; 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, 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 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 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 March 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).

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