Press Release

Dupixent approved in the US as the first-ever biologic medicine for patients with COPD

- Dupixent is indicated for the approximately 300,000 adults in the US with inadequately controlled COPD and an eosinophilic phenotype
- Following recent approvals in the EU and China, the US approval is based on two landmark phase 3 studies that showed Dupixent achieved significant reduction in exacerbations, and also showed improvements in lung function and health-related quality of life compared to placebo
- Dupixent is the leading biologic medicine for all of its FDA-approved indications in new-to-brand prescriptions, and the most prescribed biologic by pulmonologists in the US

Paris and Tarrytown, NY, September 27, 2024. The US Food and Drug Administration (FDA) has approved Dupixent (dupilumab) as an add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. Dupixent is the first biologic medicine approved in the US to treat these patients.

> ***Jean Wright, M.D.***
> Chief Executive Officer at The COPD Foundation
> *"People living with inadequately controlled COPD have long awaited new medicines to help manage the daily suffering they experience from breathlessness, coughing, wheezing, exhaustion and unpredictable hospitalization. These patients often struggle with everyday activities many people take for granted such as taking a walk or running errands outside the home. We welcome the approval of this new therapeutic option to offer patients a new way to help gain better control of their disease."*

> ***Paul Hudson***
> Chief Executive Officer at Sanofi
> *"Dupixent has already shown it can revolutionize the treatment paradigm of many diseases driven in part by type 2 inflammation with high unmet medical needs, with one million patients being treated globally across all currently approved indications. With today's approval, Dupixent once again paves the way and becomes the first and only approved add-on biologic medicine for inadequately controlled COPD, giving patients living with this devastating disease the chance to look forward to the potential of improved breathing and a life with fewer exacerbations."*

The FDA approval is based on data from two landmark pivotal phase 3 studies (BOREAS and NOTUS) that evaluated the efficacy and safety of Dupixent compared to placebo in adults currently on maximal standard-of-care inhaled therapy (nearly all on triple therapy) with inadequately controlled COPD and blood eosinophils ≥300 cells per µL. Patients who received Dupixent in BOREAS (n=468) and NOTUS (n=470) experienced the following outcomes, respectively, compared to placebo (BOREAS n=471; NOTUS n=465):

- 30% and 34% reduction in the annualized rate of moderate or severe COPD exacerbations over 52 weeks, the primary endpoint.
- 74mL and 68mL numerically greater improvements in post-bronchodilator FEV_1 from baseline at week 12 compared to placebo, sustained at 52 weeks. Statistically significant improvements of similar magnitude were observed in pre-bronchodilator FEV_1 from baseline at 12 and 52 weeks, a key secondary endpoint.
- 51% response in a health-related quality of life measure in both trials compared to 43% and 47% with placebo at 52 weeks, as assessed by a 4-point improvement on the St. George's Respiratory Questionnaire (SGRQ).

Safety results in both studies were generally consistent with the known safety profile of Dupixent in its approved indications. In pooled BOREAS and NOTUS data, the most common adverse events (≥2%) more frequently observed in patients on Dupixent compared to placebo were viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration reaction, rhinitis, eosinophilia, toothache, and gastritis. While less common, cholecystitis was reported in 0.6% of patients on Dupixent compared to 0.1% of patients on placebo.

> ***George D. Yancopoulos, M.D., Ph.D.***
> Board Co-Chair, President and Chief Scientific Officer at Regeneron
> *"This latest FDA approval for Dupixent represents new hope for the hundreds of thousands of COPD patients in the US who can sometimes struggle just to breathe during their everyday lives. Dupixent has a proven track record as a first-in-class medicine, providing benefit to the many patients suffering from type 2 inflammatory related diseases such as asthma and atopic dermatitis. This latest approval represents an important next chapter for Dupixent, giving those with COPD a novel option that has demonstrated the unprecedented ability to help patients experience fewer exacerbations, while also helping them breathe better and improve quality of life in phase 3 studies."*

The FDA evaluated Dupixent under Priority Review, which is reserved for medicines that represent potentially significant improvements in efficacy or safety in treating serious conditions. In July 2024, Sanofi and Regeneron announced that the European Medicines Agency approved Dupixent as an add-on maintenance treatment for adults with uncontrolled COPD characterized by raised blood eosinophils. Submissions are currently under review with other regulatory authorities around the world, including in Japan.

About COPD
COPD is a respiratory disease that damages the lungs and causes progressive lung function decline and is the fourth leading cause of death worldwide. Symptoms include persistent cough, excessive mucus production and shortness of breath that may impair the ability to perform routine daily activities, which may lead to sleep disturbances, anxiety, and depression. COPD is also associated with a significant health and economic burden due to recurrent acute exacerbations that require systemic corticosteroid medicine and/or antibiotics. Smoking and exposure to noxious particles are key risk factors for COPD, but even individuals who quit smoking can still have progressive lung disease.

About half of COPD patients continue to experience exacerbations despite being on triple inhaled therapy. In the US, approximately 300,000 people live with inadequately controlled COPD and an eosinophilic phenotype. Patients with an eosinophilic phenotype contribute to an ~30% increase in exacerbations and an increased risk of COPD-related re-hospitalizations within a year.

About the Dupixent COPD phase 3 study program
BOREAS and NOTUS were replicate, randomized, phase 3, double-blind, placebo-controlled studies that evaluated the efficacy and safety of Dupixent in adults who were current or former smokers with moderate-to-severe COPD with an eosinophilic phenotype, as defined by blood eosinophils ≥300 cells per µL. The studies included adults with COPD across a broad range of clinical presentations, including those with chronic bronchitis and emphysema. The studies enrolled 1,874 patients who were aged 40 to 80 years in BOREAS and 40 to 85 years in NOTUS.

During the 52-week treatment period, patients in BOREAS and NOTUS received Dupixent or placebo every two weeks added to a maximal standard-of-care inhaled triple therapy of ICS, LABA and LAMA. Double maintenance therapy, which included LABA and LAMA, was allowed if ICS was not appropriate.

The primary endpoint for BOREAS and NOTUS evaluated the annualized rate of acute moderate or severe COPD exacerbations. Key secondary endpoints included change from baseline in lung function (assessed by pre-bronchodilator forced expiratory volume [FEV_1]) at 12 and 52 weeks, change from baseline at 52 weeks in SGRQ total score compared to placebo, and safety.

The results of both BOREAS and NOTUS were separately published in *The New England Journal of Medicine*.

About Sanofi and Regeneron's COPD Clinical Research Program
Sanofi and Regeneron are motivated to transform the treatment paradigm of COPD by examining the role different types of inflammation play in the disease progression through Dupixent, a first-in-class biologic, and the investigation of itepekimab.

Dupixent inhibits the signaling of the interleukin-4 (IL4) and interleukin-13 (IL13) pathways and the program focuses on a specific population of people with evidence of type 2 inflammation. Itepekimab is a fully human monoclonal antibody that binds to and inhibits interleukin-33 (IL33), an initiator and amplifier of broad inflammation in COPD.

Itepekimab is currently under clinical investigation for COPD in two phase 3 studies and its safety and efficacy have not been evaluated by any regulatory authority.

About Dupixent
Dupixent is a fully human monoclonal antibody that inhibits the signaling of the IL4 and 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 type 2 inflammation that play 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,

and COPD in different age populations. More than 1,000,000 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 in part by type 2 inflammation or other allergic processes in phase 3 studies, including chronic pruritus of unknown origin and bullous pemphigoid. 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

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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 pandemics or other 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, 2023. 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) as an add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease ("COPD") and an eosinophilic phenotype; 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 or any potential regulatory approval of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates (such as itepekimab); 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 COPD in Japan and other jurisdictions as well as Dupixent for the treatment of chronic pruritus of unknown origin, bullous pemphigoid, 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 (such as itepekimab) 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; competing drugs and product candidates 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 (such as the COVID-19 pandemic) on Regeneron's business; and 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), other 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), 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, 2023 and its Form 10-Q for the quarterly period ended June 30, 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).