Press Release

Dupixent approved in the EU as the first-ever targeted therapy for patients with COPD

- First-in-world approval of Dupixent for adults with uncontrolled COPD with raised blood eosinophils based on two landmark phase 3 studies showing Dupixent significantly reduced exacerbations, improved lung function and also improved health-related quality of life
- Dupixent is the first new treatment approach for COPD in more than a decade and a new option for approximately 220,000 adults in the EU
- Approval represents the sixth approved indication for Dupixent in the EU and seventh approved indication globally

Paris and Tarrytown, NY, July 3, 2024. The European Medicines Agency (EMA) has approved Dupixent (dupilumab) as an add-on maintenance treatment for adults with uncontrolled chronic obstructive pulmonary disease (COPD) characterized by raised blood eosinophils. Specifically, the approval covers patients already on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate. The EMA is the first regulatory authority in the world to approve Dupixent for COPD patients. Additional submissions are under review with other regulatory authorities around the world, including in the US, China, and Japan.

> ***Tonya Winders***
> President & CEO of Global Allergy & Airways Patient Platform
> *"As a progressive and devastating disease, COPD leads to suffering from breathlessness that limits a person's ability to conduct everyday activities such as walking up the stairs or to the mailbox. Many patients feel marginalized and isolated because of the physical and mental toll of the disease. After more than a decade of limited treatment advancements for those living with uncontrolled COPD, we are now in a new era of disease management for patients and caregivers, and we welcome the addition of innovative, new treatments such as Dupixent to help manage this progressive and irreversible disease."*
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> ***Paul Hudson***
> Chief Executive Officer at Sanofi
> *"Patients with uncontrolled COPD have been waiting for a new treatment approach for many years, so we are thrilled to bring to market the first biologic to target an underlying cause of this devastating disease to reduce COPD exacerbations and improve lung function. With today's approval of Dupixent, we can change the treatment landscape for the more than 200,000 patients throughout the EU living with uncontrolled COPD with raised blood eosinophils. We look forward to working with other regulators around the world as quickly as possible to bring this novel treatment approach to patients in more countries."*

The approval is based on results from the landmark phase 3 BOREAS and NOTUS studies, which were separately published in *The New England Journal of Medicine* and evaluated the efficacy and safety of Dupixent in adults with uncontrolled COPD with evidence of type 2

inflammation (i.e., blood eosinophils ≥300 cells per µL). All patients were on background maximal standard-of-care inhaled therapy (with nearly all on triple therapy). In terms of efficacy, Dupixent patients in BOREAS (n=468) and NOTUS (n=470) experienced the following, 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.
- Improvements in lung function (pre-bronchodilator FEV_1) from baseline by 160 mL and 139 mL at 12 weeks compared to 77 mL and 57 mL. These improvements were observed as early as week 2 and 4 and were sustained at 52 weeks in both studies.
- Improvements in health-related quality of life (statistically significant in BOREAS and nominally significant in NOTUS), as assessed by the St. George's Respiratory Questionnaire.

Reductions in exacerbations and improvements in lung function for Dupixent versus placebo were also observed in patients with higher baseline fractional exhaled nitric oxide (≥20ppb) - an airway biomarker of inflammation – and across all pre-defined subgroups including smoking status, baseline lung function, and history of exacerbations.

Safety results in both studies were generally consistent with the known safety profile of Dupixent in its approved indications. The most common side effects across indications include injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes, and eosinophilia. Adverse events more commonly observed with Dupixent (≥5%) compared to placebo in either COPD study were back pain, COVID-19, diarrhea, headache and nasopharyngitis. Additional adverse reactions of injection site bruising, injection site induration, injection site rash and injection site dermatitis were reported in the COPD studies.

> ***George D. Yancopoulos, M.D., Ph.D.***
> Board Co-Chair, President and Chief Scientific Officer at Regeneron
> *"The approval of Dupixent for COPD is a long-awaited turning point for those who struggle to breathe even through the simplest of tasks, while also facing the risk of hospitalization, irreversible health decline and feelings of hopelessness. With this approval, we are proud that Dupixent has the potential to redefine the treatment landscape in yet another disease, as a first-in-class therapy demonstrating unprecedented improvements on exacerbations and lung function, as well as improving health-related quality of life across two large phase 3 trials."*

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 treatment and/or lead to hospitalization. Smoking and exposure to noxious particles are key risk factors for COPD, but even individuals who quit smoking can still develop or continue having the disease. There have been no new treatment approaches approved for more than a decade.

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 evidence of type 2 inflammation, as measured by blood eosinophils ≥300 cells per µL. 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 moderate or severe COPD exacerbations. Moderate exacerbations were defined as those requiring systemic steroids and/or antibiotics. Severe exacerbations were defined as those requiring hospitalization; requiring more than a day of observation in an emergency department or urgent care facility; or resulting in death. 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.

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 the investigation of two potentially first-in-class biologics, Dupixent and 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 (IL-33), an initiator and amplifier of broad inflammation in COPD.

Itepekimab is currently under clinical investigation 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 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 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 polyposis, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and COPD in different age populations. More than 900,000 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 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.

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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 for adults with uncontrolled chronic obstructive pulmonary disease ("COPD") characterized by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate; 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 the United States, China, 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 March 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.
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