

## Press Release

### *Dupixent approved as the first-ever biologic medicine in Japan for patients with COPD*

- Following recent approvals in the EU, China, and the US, this approval was based on pivotal phase 3 results in adults with elevated eosinophils
- Approval marks the first new treatment approach for COPD in more than a decade in Japan and the sixth approved indication for chronic diseases with underlying type 2 inflammation

**Paris and Tarrytown, NY, March 28, 2025.** The Ministry of Health, Labour and Welfare in Japan has granted marketing and manufacturing authorization for Dupixent (dupilumab) for the treatment of chronic obstructive pulmonary disease (COPD) in adults whose disease is not adequately controlled with existing therapy.

The approval in Japan was based on data from the landmark [BOREAS](#) phase 3 study. The study evaluated Dupixent added to background maximal standard-of-care inhaled therapy (with nearly all patients on triple therapy or double therapy if inhaled corticosteroids were contraindicated) in adults with uncontrolled COPD and elevated blood eosinophils. In the study, Dupixent significantly reduced exacerbations and improved lung function compared to placebo. Safety results in the study were generally consistent with the known safety profile of Dupixent in its approved indications. The most commonly reported adverse event with Dupixent was injection site reaction. Results from BOREAS and the replicate [NOTUS](#) phase 3 study were published in *The New England Journal of Medicine*.

In addition to COPD, Dupixent is approved in Japan in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), prurigo nodularis, and chronic spontaneous urticaria (CSU). Dupixent for the treatment of COPD has been approved in more than 45 countries worldwide, including the 27 member countries of the EU.

#### **About COPD**

COPD is a chronic 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 inhaled particles are key risk factors for COPD, and even individuals who stop smoking can still have progressive lung disease. About half of COPD patients continue to experience exacerbations despite being on triple inhaled therapy. Patients with COPD and elevated eosinophils have an increased risk of exacerbations and COPD-related hospitalizations within a year.

### **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 clinical assessment of two biologics, Dupixent and itepekimab.

Dupixent is a first-in-class biologic that 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 (dupilumab) is available in Japan in a 300 mg dose as a pre-filled syringe or pre-filled pen and is now available for COPD. Dupixent is intended for injection under the skin (subcutaneous injection) and is given every other week. It can be given in a clinic or at home by self-administration after training by a healthcare professional.

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 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, CRSwNP, eosinophilic esophagitis, prurigo nodularis, CSU, and COPD 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 assessed 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*<sup>®</sup>, 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<sup>®</sup> 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](http://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 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.*

*All trademarks mentioned in this press release are the property of the Sanofi group except for VelociSuite and Regeneron Genetics Center.*

#### **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 obstructive pulmonary disease; 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 adults with 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® (afibercept) 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.

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