

## *Dupixent® sBLA accepted for FDA Priority Review for treatment of COPD with type 2 inflammation*

- \* *Priority Review granted based on positive results from two Phase 3 trials*
- \* *If approved, Dupixent would be the only biologic therapy for COPD and the first new treatment approach for the disease in more than a decade*
- \* *Regulatory submissions are also under review in China and Europe*

**Paris and Tarrytown, N.Y. February 23, 2024.** The U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) in a sixth potential indication as an add-on maintenance treatment in certain adult patients with uncontrolled chronic obstructive pulmonary disease (COPD). The target action date for the FDA decision is June 27, 2024. Regulatory submissions are also under review in China and the European Union.

The sBLA, as well as other submissions around the world, is supported by data from the Phase 3 COPD clinical research program evaluating the efficacy and safety of Dupixent in adults who were current or former smokers with uncontrolled COPD with evidence of type 2 inflammation (screening blood eosinophils  $\geq 300$  cells/microliter). All patients were on background maximal standard-of-care inhaled therapy (nearly all on triple therapy). The primary endpoint was met in both trials ([BOREAS](#), [NOTUS](#)), showing Dupixent significantly reduced moderate or severe acute COPD exacerbations by 30% and 34% respectively, compared to placebo. In both trials, Dupixent also rapidly and significantly improved lung function compared to placebo, with improvements sustained at 52 weeks.

Safety results in both trials were generally consistent with the known safety profile of Dupixent in its approved indications. Adverse events more commonly observed with Dupixent ( $\geq 5\%$ ) compared to placebo in either trial were back pain, COVID-19, diarrhea, headache and nasopharyngitis.

Priority Review is granted to regulatory applications seeking approval for therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions. The potential use of Dupixent in COPD is currently under clinical development, and its safety and efficacy for this indication have not been fully evaluated by any regulatory authority.

### **About COPD**

COPD is a respiratory disease that damages the lungs and causes progressive lung function decline. Symptoms include persistent cough, breathlessness and excessive mucus production that may not only impair the ability to perform routine daily activities, but can also lead to anxiety, depression and sleep disturbances. 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. In the U.S., approximately 300,000 people live with uncontrolled COPD with evidence of type 2 inflammation.

### **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 (IL-4) and interleukin-13 (IL-13) 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, with two Phase 3 trials currently enrolling, 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 (IL-4) and interleukin-13 (IL-13) 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 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent, such as atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis and chronic spontaneous urticaria (CSU).

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, CRSwNP, EoE, prurigo nodularis and CSU in different age populations. Dupixent is currently approved for one or more of these indications in more than 60 countries, including in Europe, the U.S. and Japan. More than 800,000 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 trials 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 trials, including chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation 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 for over 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all 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, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*<sup>®</sup> technologies, such as *VelocImmune*<sup>®</sup>, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For more information about Regeneron, please visit [www.Regeneron.com](http://www.Regeneron.com) or follow Regeneron on [LinkedIn](#).

### *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 some 100 countries, 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, 2022.*

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) and itepekimab for the treatment of chronic obstructive pulmonary disease ("COPD"); 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 and itepekimab for the treatment of COPD (including, in the case of Dupixent, based on the supplemental Biologics License Application discussed in this press release) as well as Dupixent for the treatment of chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, bullous pemphigoid, and other potential indications; 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 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, 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. 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>)*