

Press Release

Dupixent® demonstrates potential to become first biologic to treat COPD by showing significant reduction in exacerbations in pivotal trial

- First and only biologic to demonstrate clinically meaningful and statistically significant reduction (30%) in exacerbations compared to placebo
- First and only biologic to show rapid and significant improvement in lung function (160 mL in FEV₁) compared to placebo (77 mL in FEV₁)
- First and only biologic to demonstrate significant improvements in quality of life and respiratory symptoms
- COPD is the third leading cause of death worldwide with no new treatment approaches approved in more than a decade; trial enrolled patients with moderate to severe disease and evidence of type 2 inflammation (i.e., blood eosinophils ≥ 300 cells/ μ L)
- COPD is the seventh disease in which Dupixent has shown positive pivotal results, confirming the key role of IL-4 and IL-13 in these type 2 inflammatory diseases

Paris and Tarrytown, N.Y. March 23, 2023. The primary and all key secondary endpoints were met in a Phase 3 trial evaluating the investigational use of Dupixent® (dupilumab) compared to placebo in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled chronic obstructive pulmonary disease (COPD) and evidence of type 2 inflammation. Dupixent is the first and only biologic to demonstrate a clinically meaningful and highly significant reduction (30%) in moderate or severe acute exacerbations of COPD (rapid and acute worsening of respiratory symptoms), while also demonstrating significant improvements in lung function, quality of life and COPD respiratory symptoms.

Dietmar Berger, M.D., Ph.D.

Head of Global R&D ad interim and Chief Medical Officer at Sanofi

"Change cannot come quick enough for people living with uncontrolled COPD but, unfortunately, many investigational treatments have failed to demonstrate significant clinical outcomes leaving these vulnerable patients with limited treatment options. We took a bold approach with our direct to Phase 3 program, shaving years off standard clinical development timelines. We are excited to share these unprecedented and potentially paradigm-shifting clinical results, which may give new hope to patients, caregivers and physicians."

COPD is a life-threatening respiratory disease that damages the lungs and causes progressive lung function decline. Symptoms include persistent cough and breathlessness 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 or even death. Smoking is a key risk factor for COPD, but even individuals who quit smoking can still develop the disease. In the U.S. alone, approximately 300,000 people live with uncontrolled COPD with type 2 inflammation.

George D. Yancopoulos, M.D., Ph.D.

President and Chief Scientific Officer at Regeneron

"COPD is an urgent global health concern and a notoriously difficult-to-treat disease due to its heterogeneity, with no novel treatments approved in more than a decade. In this landmark Phase 3 trial, patients with uncontrolled COPD achieved clinical outcomes with Dupixent at a magnitude never before seen with a biologic. These results also validate the role type 2 inflammation plays in driving COPD in these patients, advancing the scientific community's

understanding of the underlying biology of this disease. We look forward to discussing these exciting results with regulatory authorities.”

In the BOREAS Phase 3 trial (the first of two Phase 3 trials), 939 adults who were current or former smokers aged 40 to 80 years were randomized to receive Dupixent (n=468) or placebo (n=471), added to maximal standard-of-care inhaled therapy. Patients receiving Dupixent experienced:

- 30% reduction in moderate or severe acute COPD exacerbations over 52 weeks (p=0.0005), the primary endpoint.
- Improved lung function from baseline by 160 mL at 12 weeks compared to 77 mL for placebo (p<0.0001), with the benefit versus placebo sustained through week 52 (p=0.0003), both of which were key secondary endpoints.

Dupixent met all endpoints tested in the hierarchy, including improvement in patient-reported health-related quality of life as measured by St. George’s Respiratory Questionnaire (SGRQ) and reduction in the severity of respiratory symptoms of COPD as measured by Evaluation Respiratory Symptoms: COPD (E-RS: COPD) Scale.

The safety results were generally consistent with the known safety profile of Dupixent in its approved indications. Overall rates of adverse events (AE) were 77% for Dupixent and 76% for placebo. AEs more commonly observed with Dupixent compared to placebo included headache (8.1% Dupixent, 6.8% placebo), diarrhea (5.3% Dupixent, 3.6% placebo) and back pain (5.1% Dupixent, 3.4% placebo). AEs more commonly observed with placebo compared to Dupixent included upper respiratory tract infection (9.8% placebo, 7.9% Dupixent), hypertension (6.0% placebo, 3.6% Dupixent) and COVID-19 (5.7% placebo, 4.1% Dupixent). AEs leading to deaths were balanced between the two arms (1.7% placebo, 1.5% Dupixent).

Detailed efficacy and safety results from this trial will be presented in a future scientific forum.

The broader Sanofi and Regeneron COPD clinical research program includes Phase 3 trials with itepekimab, a fully human monoclonal antibody that binds to and inhibits interleukin-33 (IL-33). Itepekimab received Fast Track Designation from the U.S. Food and Drug Administration in January 2023 for the treatment of COPD in patients who do not currently smoke. Data from this pivotal program is expected in 2025.

The safety and efficacy of Dupixent and itepekimab in COPD have not been fully evaluated by any regulatory authority.

About the Dupixent COPD Phase 3 Trial Program

BOREAS is one of two pivotal trials in the Dupixent COPD program. The randomized, Phase 3, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in 939 adults who were current or former smokers aged 40 to 80 years with moderate-to-severe COPD. All patients in the trial had evidence of type 2 inflammation, as measured by blood eosinophils ≥ 300 cells/ μ L. During the 52-week treatment period, patients received Dupixent or placebo every two weeks, added to triple therapy of inhaled corticosteroids (ICS), long-acting beta agonists, and long-acting muscarinic antagonists. Double maintenance therapy was allowed if ICS was contraindicated.

The primary endpoint evaluated the annualized rate of acute 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; 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 FEV₁) at 12 and 52 weeks; change from baseline at week 52 in SGRQ total score compared to placebo; proportion of patients with SGRQ improvement ≥ 4 points at week 52; and the change from baseline at 52 weeks in the ERS: COPD Scale symptom score. The second, replicate Phase 3 trial of Dupixent in COPD (NOTUS) is ongoing with data expected in 2024.

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. Across both programs, four Phase 3 trials are ongoing and designed to inform next-generation treatments for people with COPD whom might not have other options.

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), prurigo nodularis and eosinophilic esophagitis (EoE).

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, CRSwNP, EoE or prurigo nodularis 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 600,000 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 pediatric EoE, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, COPD with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis 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 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous 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, pain, hematologic conditions, infectious diseases and rare diseases. Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*[®] technologies, such as *VelocImmune*[®], 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, please visit www.Regeneron.com or follow @Regeneron on Twitter.

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.

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com

Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com

Kate Conway | + 1 508 364 4931 | kate.conway@sanofi.com

Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@sanofi.com

Victor Rouault | + 33 6 70 93 71 40 | victor.rouault@sanofi.com

Chrystel Baude | + 33 6 70 98 70 59 | chrystel.baude@sanofi.com

Investor Relations

Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com

Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com

Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com

Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@sanofi.com

Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com

Regeneron Media Relations

Sharon Chen | +1 914-847-1546 | sharon.chen@regeneron.com

Regeneron Investor Relations

Vesna Tasic | + 914 847 5443 | vesna.tasic@regeneron.com

Sanofi Disclaimers or 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 COVID-19 will 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of 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) in patients with uncontrolled chronic obstructive pulmonary disease ("COPD") and evidence of type 2 inflammation and itepekimab (a fully human monoclonal antibody that binds to and inhibits interleukin-33) in patients with COPD as discussed in this press release; 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 as discussed in this press release as well as for the treatment of pediatric eosinophilic esophagitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, 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 for the treatment of COPD) 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, including without limitation Dupixent; 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; 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® (afibercept) Injection, Praluent® (alirocumab), and REGEN-COV® (casirivimab and imdevimab)), 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, 2022. 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 (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).