Press Release

Positive Dupixent® (dupilumab) Phase 3 results in adults and adolescents with eosinophilic esophagitis published in the New England Journal of Medicine

- Dupixent 300 mg weekly showed significant histological disease remission and improvement in symptoms of the disease compared to placebo
- Improvements were sustained for up to one year in patients aged 12 years and older with eosinophilic esophagitis (EoE)
- Dupixent is the first and only targeted medicine indicated in the U.S. to treat EoE patients aged 12 and older weighing at least 40 kg

Paris and Tarrytown, N.Y. DECEMBER 21, 2022 The *New England Journal of Medicine* has published results from a positive Phase 3 trial showing adults and adolescents treated with Dupixent® (dupilumab) 300 mg weekly experienced significant improvements in signs and symptoms of eosinophilic esophagitis (EoE), which were sustained for up to one year.

EoE is a chronic, progressive inflammatory disease that damages the esophagus and prevents it from working properly. These data formed the basis for the U.S. Food and Drug Administration (FDA) approval of Dupixent in May 2022, making it the first and only medicine indicated to treat patients with EoE aged 12 years and older, weighing at least 40 kg. These Phase 3 data have been submitted to the European Medicines Agency (EMA) to support regulatory approval for adults and adolescents with EoE. The EMA's Committee for Medicinal Products for Human Use recently adopted a positive opinion recommending approval with a final decision expected in the coming months.

> ***Evan S. Dellon, M.D., M.P.H.***
> Professor of Gastroenterology and Hepatology at the University of North Carolina School of Medicine
> *"The publication of these Phase 3 results in the New England Journal of Medicine reinforces the impact of the clinical trial data. These data showed dupilumab 300 mg weekly substantially decreased patient symptoms of difficulty swallowing, and led to histological disease remission and improvements in the endoscopic appearance of the esophagus, as compared to placebo. These data also underscore the role of inhibiting the IL-4 and IL-13 pathways in eosinophilic esophagitis with dupilumab, adding to our growing knowledge of this poorly understood disease."*

As published, patients received Dupixent 300 mg either weekly or every two weeks in the Phase 3 trial. Patients receiving Dupixent weekly experienced improvement in the ability to swallow and achieved histological disease remission. Additionally, these patients experienced improved anatomic, cellular, molecular and health-related quality of life measures, with improvements in signs and symptoms of EoE sustained for up to one year. Patients treated with Dupixent every two weeks experienced histological disease remission but did not experience improvement in the ability to swallow. The current FDA-approved dosage for Dupixent as a treatment for children and adults aged 12 years and older with EoE, weighing at least 40 kg, is 300 mg weekly.

The safety results were generally consistent with the known safety profile of Dupixent in its approved indications. Adverse events (≥5%) that were more commonly observed with Dupixent included injection site reactions, nasopharyngitis and rash.

About Eosinophilic Esophagitis

EoE is a chronic, progressive inflammatory disease that damages the esophagus and prevents it from working properly. The results seen with Dupixent in adults and adolescents with EoE demonstrate that interleukin-4 (IL-4) and interleukin-13 (IL-13) are key and central drivers of the type 2 inflammation underlying this disease. For people with EoE, swallowing even small amounts of food can be a painful and worrisome choking experience. They are often left to contend with the frustration and anxiety of a constantly evolving list of foods to avoid, a poor quality of life and a higher risk of depression. In cases where EoE causes the esophagus to narrow, forced and potentially painful dilation (physical expansion) of the esophagus may be needed. In severe cases, a feeding tube may be the only option to ensure proper caloric intake and adequate nutrition. Of the approximately 209,000 patients aged 12 years and older living with EoE in the U.S. who are currently treated with therapies not specifically approved for the disease, about 42,000 continue to experience symptoms despite multiple treatments.

About the Dupixent Eosinophilic Esophagitis Trial

The Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in patients aged 12 years and older with EoE in three parts. Part A enrolled 81 patients and evaluated Dupixent 300 mg weekly for 24 weeks. Part B enrolled 240 patients and evaluated Dupixent 300 mg weekly and every two weeks for 24 weeks. Parts A and B were designed similarly and consisted of separate patient groups. All patients in Parts A and B had an option to participate in Part C for an additional 28 weeks, for up to 52 weeks of Dupixent treatment. Part C enrolled 77 patients from Part A.

At 24 weeks, the co-primary endpoints in Parts A and B assessed patient-reported measures of difficulty swallowing and esophageal inflammation. The secondary endpoints included assessments of histopathologic measures of the severity and extent of additional histological measures in the esophagus, and other measures. In Part C, all primary and secondary endpoints assessed in Parts A and B were assessed as secondary endpoints at 52 weeks.

About Dupixent

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the IL-4 and 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 asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis (CRSwNP), EoE and prurigo nodularis (PN).

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 PN in different age populations. Dupixent is currently approved across these indications in the U.S. and for one or more of these indications in more than 60 countries, including in the European Union and Japan. More than 500,000 patients have been 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 pruritis of unknown origin, chronic obstructive pulmonary disease 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 is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for nearly 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.

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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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. 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, 2021. 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) for the treatment of adults and adolescents with eosinophilic esophagitis ("EoE"); 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 and Regeneron's Product Candidates; 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 and adolescents with EoE based on the European Medicines Agency submission referenced in this press release, as well as for the treatment of pediatric EoE, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritis of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, bullous pemphigoidand, 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, 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® (aflibercept) 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, 2021 and its Form 10-Q for the quarterly period ended September 30, 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).