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# **Media Update**

Dupixent<sup>®</sup> continues scientific leadership with latebreaking results showing reduced airway inflammation and mucus plugging in adults with uncontrolled moderate-to-severe asthma

- \* Results provide new insights into ability of Dupixent to improve lung function by inhibiting IL-4 and IL-13, key drivers of type 2 inflammation
- \* Largest global-scale trial to use novel functional respiratory imaging (FRI) to assess the effect of a biologic on airway inflammation and mucus plugging in adults with uncontrolled moderate-to-severe asthma
- \* Data reinforces Sanofi's commitment to advancements in Immunology and Inflammation

**Paris, February 24, 2024.** Topline results from the VESTIGE Phase 4 clinical trial evaluating the effect of Dupixent<sup>®</sup> (dupilumab) on airway remodeling parameters through the use of functional respiratory imaging (FRI) in adults with uncontrolled moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma will be presented in collaboration with Regeneron in a late-breaking poster session at the 2024 American Academy of Allergy, Asthma, and Immunology (AAAAI) Annual Meeting. The study, the largest of its kind to utilize FRI to evaluate a biologic's impact on the lungs, found that patients taking Dupixent achieved a significant reduction in airway inflammation, and had numerically greater reductions in mucus plug (mucus buildup in the lungs) scores and numerically greater improvements in airway volume and flow, indicating improvements in their ability to breathe more normally.

Mucus plugs in patients with asthma and other respiratory conditions are associated with type 2 inflammation and play a role in airflow obstruction, sometimes leading to persistent symptoms. Further utilization of novel FRI technologies has the potential to more accurately measure a biologic's effect on mucus plugging in at-risk patients across multiple respiratory diseases.

## *Njira Lugogo, MD, MS, Division of Pulmonary & Critical Care Medicine's Asthma Program Director, University of Michigan*

"By using functional respiratory imaging to produce 3D visualizations, we were able to track asthma disease progression and the biologic's efficacy with much greater accuracy than with traditional methods like spirometry. These findings reinforce the efficacy of dupilumab in improving airflow in the lungs, and the importance of reducing mucus plugging when managing asthma. These data show the impact of dupilumab on the lungs of patients with moderate-to-severe asthma and further add to its ability to effectively treat respiratory diseases."

Data presented at the 2024 AAAAI Annual Meeting showed that patients treated with Dupixent experienced the following changes compared to placebo at Week 24:

- 56.9% of patients taking Dupixent achieved a significant reduction in airway inflammation as measured by fractional exhaled nitric oxide (FeNO) <25 parts per billion (ppb) compared to 10.8% of patients on placebo (P <0.001), a primary endpoint
- Numerically greater reductions in mucus plug scores compared to placebo in which Dupixent reduced mucus scores while an increase was observed in patients on placebo. The difference between Dupixent and placebo was -4.9 (nominal P<0.001)
- Dupixent also reduced mucus volume by Week 24 vs placebo: -0.107 mL (p<0.001). The reductions in mucus plug count and volume are also clearly visible in the computed tomography
- Numerically greater improvements in lung function from baseline compared to placebo as defined by in airway volumes ([s]iVaw) at total lung capacity (TLC), the other primary endpoint, and airway resistance ([s]iRaw) at TLC, were also achieved

The safety results were generally consistent with the known safety profile of Dupixent in moderate-to-severe asthma. The most common adverse events (AEs) observed with Dupixent ( $\geq$ 1%) compared to placebo included cardiac disorders (Dupixent n=1/72, placebo n=2/37), vascular disorders (Dupixent n=3/72, placebo n=0/37), infections and infestations (Dupixent n=13/72, placebo n=10/37), injection site reaction (Dupixent n=7/72, placebo 2/37) and COVID-19 (Dupixent n=7/72, placebo n=2/37).

## About the VESTIGE Clinical Trial

The Phase 4 randomized, double-blind, placebo-controlled trial evaluated the efficacy of Dupixent on lung inflammation and structural/functional changes in airway volume using novel imaging technology along with safety among 109 adult patients aged 21 to 70 years with uncontrolled moderate-to-severe asthma and raised type 2 biomarkers (blood eosinophils  $\geq$ 300 cells/µL and FeNO  $\geq$ 25 ppb). During the 24-week treatment period, patients were randomized 2:1 to receive 300 mg of Dupixent (n=72) or matched placebo (n=37) every two weeks.

The study's primary endpoints were the proportion of patients achieving FeNO <25 ppb and the percent change from baseline at 24 weeks in airway volumes ([s]iVaw) at total lung capacity (TLC). Main secondary endpoints included percent change from baseline at 24 weeks in untrimmed distal airway resistance corrected for lung volume ([s]iRaw) at TLC and change from baseline at 24 weeks in global lung mucus score (University of California, San Francisco [UCSF] mucus scoring).

## **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, EoE and chronic spontaneous urticaria (CSU) (in Japan).

In the U.S., Dupixent is indicated as an add-on maintenance treatment for adults and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

In the EU, Dupixent is approved in children aged 6 to 11 years as an add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. For adolescents and adults 12 years and older with severe asthma with type 2 inflammation, patients must be inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.

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 Regeneron and Sanofi 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, Regeneron and Sanofi are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in Phase 3 trials, including chronic pruritus of unknown origin, chronic obstructive pulmonary disease (COPD) 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 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.

### 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*®, 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 <u>www.Regeneron.com</u> or follow Regeneron on <u>LinkedIn</u>.

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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.

#### **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 research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) for the treatment of children aged 1 to 11 years with eosinophilic esophagitis ("pediatric EOE"); 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 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 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; 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; 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 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 and its Form 10-Q for the quarterly period ended June 30, 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 forwardlooking 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 (<u>https://investor.regeneron.com</u>) and its LinkedIn page (<u>https://www.linkedin.com/company/regeneron-pharmaceuticals</u>).