Dupixent® (dupilumab) Late-Breaking Data from NOTUS Confirmatory Phase 3 COPD Trial Presented at ATS and Published in The New England Journal of Medicine

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NOTUS results confirm landmark data from the Phase 3 BOREAS trial and show Dupixent significantly reduced exacerbations by 34% and improved lung function, compared to placebo, in uncontrolled chronic obstructive pulmonary disease (COPD) with evidence of type 2 inflammation

Data support the potential of Dupixent as the first new treatment approach in more than a decade and first-ever targeted therapy for COPD

TARRYTOWN, N.Y. and PARIS, May 20, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today presented late-breaking data from the NOTUS Phase 3 trial evaluating the investigational use of Dupixent® (dupilumab) as an add-on maintenance treatment in adults with uncontrolled COPD on maximal standard-of-care inhaled therapy (nearly all on triple therapy) and evidence of type 2 inflammation (i.e., blood eosinophils ≥300 cells per µL). The NOTUS trial confirmed the positive results demonstrated in the landmark Phase 3 BOREAS trial, with its data presented at a late-breaking session of the 2024 American Thoracic Society (ATS) International Conference and simultaneously published in the *New England Journal of Medicine (NEJM)*.

"In my more than 20 years of practice, there have been limited advancements for patients struggling with the debilitating effects of uncontrolled COPD, and too many patients experience a vicious cycle of exacerbations that can result in loss of lung function and greatly diminish their quality of life," said Surya Bhatt, M.D., MSPH, Professor at the University of Alabama at Birmingham, Division of Pulmonary, Allergy, and Critical Care Medicine and a co-principal investigator of the trial. "In NOTUS, dupilumab reduced exacerbations by a magnitude never seen before with an investigational biologic in a Phase 3 COPD clinical trial. These comprehensive results reinforce that, if approved, dupilumab could provide a first-of-its-kind medical advancement for the COPD community."

As presented and published, the NOTUS trial met its primary and key secondary endpoints. All patients were on background maximal standard-of-care inhaled therapy (nearly all on triple therapy). Patients receiving Dupixent (n=470) experienced the following, compared to placebo (n=465):

- **34% reduction in moderate or severe COPD exacerbations** over 52 weeks (p<0.001), the primary endpoint.
- **More than two times greater improvement in lung function** (pre-bronchodilator FEV_1) from baseline at 12 weeks (139 mL vs. 57 mL; p<0.001), with an improvement maintained at week 52 (115 mL vs. 54 mL; p=0.018), secondary endpoints.
- **Numerically greater improvements in health-related quality of life** from baseline at 52 weeks, a secondary endpoint**,** as defined by patient-reported outcomes (PRO) in the St. George's Respiratory Questionnaire (SGRQ).
- **Numerically greater reductions in respiratory symptom severity** from baseline to 52 weeks, a secondary endpoint, as defined by PROs in Evaluating Respiratory Symptoms in COPD (E-RS).

The safety results were generally consistent with the known safety profile of Dupixent in its approved indications. Overall rates of adverse events (AE) were 67% for Dupixent and 66% for placebo. AEs more commonly observed with Dupixent than placebo included COVID-19 (9.4% Dupixent, 8.2% placebo), nasopharyngitis (6.2% Dupixent, 5.2% placebo), and headache (7.5% Dupixent, 6.5% placebo). AEs more commonly observed with placebo than Dupixent included COPD (7.8% placebo, 4.9% Dupixent). AEs leading to deaths were 2.6% for Dupixent and 1.5% for placebo.

Dupixent is currently under Priority Review by the U.S. Food and Drug Administration as an add-on maintenance treatment in certain adult patients with uncontrolled COPD with evidence of type 2 inflammation. The target action date is June 27, 2024. Regulatory submissions are also under review in the European Union and China, and discussions with other regulatory authorities around the world are ongoing.

The potential use of Dupixent in COPD is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority in this setting.

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 impair the ability to perform routine daily activities, which may 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 the Dupixent COPD Phase 3 Trial Program
BOREAS and NOTUS are replicate, randomized, Phase 3, double-blind, placebo-controlled trials that evaluated the efficacy and safety of Dupixent in adults who were current or former smokers with moderate-to-severe COPD. Patients were aged 40 to 80 years in BOREAS and 40 to 85 years in NOTUS. All 1,874 patients enrolled in BOREAS and NOTUS had evidence of type 2 inflammation, as measured by blood eosinophils ≥300 cells per µL. Patients with a diagnosis or history of asthma were excluded from the trials.

During the 52-week treatment period, patients in BOREAS and NOTUS received Dupixent or placebo every two weeks added to a maximal standard-of-care inhaled triple therapy of inhaled corticosteroids (ICS), long-acting beta agonists (LABA), and long-acting muscarinic antagonists (LAMA). Double maintenance therapy, which included LABA and LAMA, was allowed if ICS was contraindicated.

The primary endpoint for BOREAS and NOTUS 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; requiring 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 forced expiratory volume [FEV1]) at 12 and 52 weeks, change from baseline at 52 weeks in SGRQ total score compared to placebo, and safety.

Data from BOREAS were previously published in the *New England Journal of Medicine*.

About Regeneron and Sanofi's COPD Clinical Research Program
Regeneron and Sanofi 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, which was invented using Regeneron's proprietary *VelocImmune*® technology, 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 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, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis, and chronic spontaneous urticaria (CSU) in different age populations. More than 850,000 patients are being treated with Dupixent globally.

About Regeneron's *VelocImmune*® Technology
Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's co-Founder, President and Chief Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985, they were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite*® *technologies*. Dr. Yancopoulos and his team have used *VelocImmune* technology to create a substantial portion of all original, FDA-approved or authorized fully human monoclonal antibodies. This includes REGEN-COV® (casirivimab and imdevimab), Dupixent, Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb) and Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn).

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 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.

U.S. INDICATIONS

DUPIXENT is a prescription medicine used:

- to treat adults and children 6 months of age and older with moderate-to-severe eczema (atopic dermatitis or AD) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 6 months of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in adults and children 6 years of age and older whose asthma is not controlled with their current asthma medicines. DUPIXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. DUPIXENT is not used to treat sudden breathing problems. It is not known if DUPIXENT is safe and effective in children with asthma under 6 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.
- to treat adults and children 1 year of age and older with eosinophilic esophagitis (EoE), who weigh at least 33 pounds (15 kg). It is not known if DUPIXENT is safe and effective in children with eosinophilic esophagitis under 1 year of age, or who weigh less than 33 pounds (15 kg).
- to treat adults with prurigo nodularis (PN). It is not known if DUPIXENT is safe and effective in children with prurigo nodularis under 18 years of age.

IMPORTANT SAFETY INFORMATION

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems.
- have a parasitic (helminth) infection.
- are scheduled to receive any vaccinations. You should not receive a “live vaccine” right before and during treatment with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
    - A pregnancy registry for women who take DUPIXENT during pregnancy collects information about the health of you and your baby. To enroll or get more information call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the- counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you are taking oral, topical, or inhaled corticosteroid medicines; have asthma and use an asthma medicine; or have atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, or prurigo nodularis and also have asthma. **Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions. DUPIXENT can cause allergic reactions that can sometimes be severe.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms: breathing problems or wheezing, swelling of the face, lips, mouth, tongue or throat, fainting, dizziness, feeling lightheaded, fast pulse, fever, hives, joint pain, general ill feeling, itching, skin rash, swollen lymph nodes, nausea or vomiting, or cramps in your stomach-area.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision. Your healthcare provider may send you to an ophthalmologist for an exam if needed.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have: rash, chest pain, worsening shortness of breath, a feeling of pins and needles or numbness of your arms or legs, or persistent fever.
- **Joint aches and pain.** Some people who use DUPIXENT have had trouble walking or moving due to their joint symptoms, and in some cases needed to be hospitalized. Tell your healthcare provider about any new or worsening joint symptoms. Your healthcare provider may stop DUPIXENT if you develop joint symptoms.

The most common side effects include:

- **Eczema:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, dry eye, cold sores in your mouth or on your lips, and high count of a certain white blood cell (eosinophilia).
- **Asthma:** injection site reactions, high count of a certain white blood cell (eosinophilia), pain in the throat (oropharyngeal pain), and parasitic (helminth) infections.
- **Chronic Rhinosinusitis with Nasal Polyposis: injection** site reactions, eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, high count of a certain white blood cell (eosinophilia), gastritis, joint pain (arthralgia), trouble sleeping (insomnia), and toothache.
- **Eosinophilic Esophagitis:** injection site reactions, upper respiratory tract infections, cold sores in your mouth or on your lips, and joint pain (arthralgia).
- **Prurigo Nodularis:** eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, herpes virus infections, common cold symptoms (nasopharyngitis), dizziness, muscle pain, and diarrhea.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed by your healthcare provider. It's an injection given under the skin (subcutaneous injection). Your healthcare provider will decide if you or your caregiver can inject DUPIXENT. **Do not** try to prepare and inject DUPIXENT until you or your caregiver have been trained by your healthcare provider. In children 12 years of age and older, it's recommended DUPIXENT be administered by or under supervision of an adult. In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.

Please see accompanying full Prescribing Information including Patient Information.

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*®, 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® 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 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

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; 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 uncontrolled chronic obstructive pulmonary disease with evidence of type 2 inflammation as discussed in this press release (including the impact of the previously disclosed request by the U.S. Food and Drug Administration to provide additional analyses regarding sub-populations from the BOREAS and NOTUS pivotal studies) as well as for the treatment of chronic spontaneous urticaria, chronic pruritus of unknown origin, 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 (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), 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 and its Form 10-Q for the quarterly period ended March 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.

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).

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 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.

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