Press Release

Dupixent approved in China as the first-ever biologic medicine for patients with COPD

- Approval follows EU approval of Dupixent for adults with COPD with raised blood eosinophils, and is based on two landmark phase 3 studies showing Dupixent significantly reduced exacerbations, improved lung function, and also improved health-related quality of life
- COPD is the most prevalent chronic respiratory disease in China, and is a priority within the government's Healthy China 2030 public health plan
- Dupixent is now approved in four indications across respiratory and dermatological diseases in China

Paris and Tarrytown, New York, Sept. 27, 2024. The National Medical Products Administration (NMPA) in China has approved Dupixent (dupilumab) as an add-on maintenance treatment for adults with uncontrolled chronic obstructive pulmonary disease (COPD) characterized by raised blood eosinophils. Specifically, the approval covers patients already on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate. Dupixent for the treatment of COPD has been approved in more than 30 countries worldwide, including the 27 countries in the EU.

Professor Kang Jian
Chair of COPD Branch, Chinese Association of Chest Physicians, CMDA, Respiratory Department of First Hospital of China Medical University
"The impact of COPD extends far beyond the patient. Debilitating breathlessness and irreversible lung damage make it difficult for patients to do simple daily tasks, placing a significant burden on family members, the central caregivers in Chinese families. The approval of Dupixent for COPD in China is critical, as it fills a gap in targeted therapy for the disease and provides clinicians with a new treatment approach. This offers new hope for COPD patients who remain inadequately controlled even after triple therapy, as well as those who care for them."

Houman Ashrafian, MD, PhD
Executive Vice President, Head of Research and Development at Sanofi
"China has the largest number of people living with COPD worldwide, and a significant proportion of patients are uncontrolled on current therapies and desperate for an effective treatment option. The Dupixent COPD clinical program has furthered our scientific understanding of COPD, and given us a new way to think about which patients could benefit most from such a treatment. With its well-established safety and efficacy profile, Dupixent is a long-awaited advancement for patients, caregivers, and physicians who are desperate for a new treatment option."

Despite the high prevalence and burden of COPD in China, public awareness is limited. The Healthy China 2030 public health initiative includes a focus on addressing chronic respiratory diseases like COPD and aims to improve the quality of life for patients with COPD.

The approval is based on results from the landmark BOREAS and NOTUS phase 3 studies, which evaluated the efficacy and safety of Dupixent in adults with uncontrolled COPD with raised blood eosinophils. All patients were on background maximal standard-of-care inhaled therapy (nearly all on triple therapy). Dupixent significantly reduced COPD exacerbations by 30% and 34% compared to placebo in the BOREAS and NOTUS studies respectively. Dupixent significantly and rapidly improved lung function compared to placebo, with improvements sustained at 52 weeks. Improvements in health-related quality of life (statistically significant in BOREAS and nominally significant in NOTUS) compared to placebo were also observed, as assessed by the St. George's Respiratory Questionnaire (SGRQ). Data from both studies were published in separate manuscripts in *The New England Journal of Medicine* (BOREAS and NOTUS).

Safety results in both studies were generally consistent with the known safety profile of Dupixent in its approved indications. The most common side effects across indications include injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes, and eosinophilia. Additional adverse reactions of injection site bruising, injection site induration, injection site rash, and injection site dermatitis were reported in the COPD studies. Adverse events more commonly observed with Dupixent (≥5%) compared to placebo in either COPD study were back pain, COVID-19, diarrhea, headache, and nasopharyngitis.

> ***George D. Yancopoulos, M.D., Ph.D.***
> Board co-Chair, President, and Chief Scientific Officer at Regeneron
> *"One in four people with COPD live in China, and many patients are unable to control their disease with standard of care treatments and experience repeated hospitalizations from exacerbations and debilitating limitations on their quality of life. With millions of people in industrialized areas worldwide facing increased risk for developing COPD, it is more important than ever to deliver innovative new options for this complex and notoriously difficult-to-treat disease. With this latest Dupixent approval, patients in China have a novel treatment approach that has shown groundbreaking results by reducing exacerbations while also improving lung function and supporting a better quality of life."*

Additional submissions for Dupixent in COPD are under review with regulatory authorities around the world, including in the US and Japan.

About COPD
COPD is a respiratory disease that damages the lungs and causes progressive lung function decline. Symptoms include persistent cough, excessive mucus production, and shortness of breath that may impair the ability to perform routine daily activities, which may lead to sleep disturbances, anxiety and depression. 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 have progressive lung disease.

About half of COPD patients continue to experience exacerbations despite being on triple inhaled therapy. Patients with an eosinophilic phenotype contribute to a ~30% increase in exacerbations and an increased risk of COPD-related re-hospitalizations within a year.

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 (IL4) and interleukin-13 (IL13) 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 (IL33), an initiator and amplifier of broad inflammation in COPD.

Itepekimab is currently under clinical investigation for COPD in two phase 3 studies and its safety and efficacy have not been evaluated by any regulatory authority.

About Dupixent
Dupixent is available in China in a 300 mg dose as a pre-filled syringe or pre-filled pen and is now available for COPD. Dupixent is intended for injection under the skin (subcutaneous injection) and is given every other week. It can be given in a clinic or at home by self-administration after training by a healthcare professional.

Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL4) and interleukin-13 (IL13) 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 studies, establishing that IL4 and IL13 are 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 polyps, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and COPD in different age populations. More than 1,000,000 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 studies 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 studies, including chronic pruritus of unknown origin 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 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

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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

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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) as an add-on maintenance treatment for adults with uncontrolled chronic obstructive pulmonary disease characterized by raised blood eosinophils ("COPD"); 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 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 in the United States, Japan, and other jurisdictions as well as Dupixent for the treatment of chronic pruritus of unknown origin, bullous pemphigoid, and 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 (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. 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