Press Release

Dupixent® (dupilumab) approved by FDA as the first and only treatment indicated for prurigo nodularis

- Dupixent significantly reduced itch and skin lesions compared to placebo in direct-to-Phase 3 program consisting of two pivotal trials
- About 75,000 adults in the U.S. living with prurigo nodularis are most in need of new treatment options
- Approval represents the second dermatology indication for Dupixent and fifth disease indication overall in the U.S.

Paris and Tarrytown, N.Y. September 28, 2022. The U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) for the treatment of adult patients with prurigo nodularis. With this approval, Dupixent becomes the first and only medicine specifically indicated to treat prurigo nodularis in the U.S. Prurigo nodularis is a chronic, debilitating skin disease with underlying type 2 inflammation and its impact on quality of life is one of the highest among inflammatory skin diseases. The FDA evaluated the Dupixent application for prurigo nodularis under Priority Review, which is granted to therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions.

Naimish Patel, M.D
Head of Global Development, Immunology and Inflammation, Sanofi
"Until today, there were limited treatment options to manage the relentless itch and associated sensations of burning and stinging skin that can negatively impact the lives of patients struggling with prurigo nodularis. Dupixent has the potential to transform the standard-of-care for prurigo nodularis patients by alleviating the key hallmarks of the disease, such as reducing itch and achieving clearer skin. With Dupixent now approved in two diseases in dermatology where type 2 inflammation is a central driver, we look forward to further evaluating the potential of inhibiting IL-4 and IL-13 in other chronic skin diseases."

George D. Yancopoulos, M.D., Ph.D.
President and Chief Scientific Officer, Regeneron
"Patients living with prurigo nodularis must often contend with dozens, if not hundreds, of itchy and painful nodules covering their body and have not had an approved treatment option for their disease. Dupixent has already transformed the treatment landscape of several diseases driven by type 2 inflammation – including atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis – and been prescribed to more than half a million patients around the world for its approved indications. With this approval, those suffering with prurigo nodularis finally have a medicine to address the debilitating signs and symptoms of the disease."

The FDA approval is based on data from two Phase 3 trials, PRIME and PRIME2, evaluating the efficacy and safety of Dupixent in adults with prurigo nodularis. Efficacy in these trials assessed the proportion of subjects with clinically meaningful reduction in itch, clearing of skin, or both:

- About three times as many Dupixent patients (60% and 58%) experienced a clinically meaningful reduction in itch from baseline at 24 weeks, compared to 18% and 20% for placebo, the primary endpoint in PRIME.
- 44% and 37% of Dupixent patients experienced a clinically meaningful reduction in itch from baseline at 12 weeks, compared to 16% and 22% for placebo, the primary endpoint in PRIME2.
- More than twice as many Dupixent patients (48% and 45%) achieved clear or almost clear skin at 24 weeks, compared to 18% and 16% for placebo.

- More than three times as many Dupixent patients (39% and 32%) experienced both a clinically meaningful reduction in itch and clear or almost clear skin, compared to 9% and 9% of placebo patients at 24 weeks.

The safety results of the trial were generally consistent with the known safety profile of Dupixent in its approved dermatology indication. The most common adverse events (≥2%) from pooled PRIME and PRIME2 data more frequently observed with Dupixent than placebo were nasopharyngitis (5% Dupixent, 2% placebo), conjunctivitis (4% Dupixent, 1% placebo), herpes infection (3% Dupixent, 0% placebo), dizziness (3% Dupixent, 1% placebo), muscle pain (3% Dupixent, 1% placebo), and diarrhea (3% Dupixent, 1% placebo).

A regulatory filing for prurigo nodularis is under review by the European Medicines Agency, and submissions to regulatory authorities in additional countries are also planned in 2022.

About Prurigo Nodularis
People with prurigo nodularis experience intense, persistent itch with thick skin lesions (called nodules) that can cover most of the body. The disease is often painful, with burning, stinging and tingling of the skin. The impact of prurigo nodularis on quality of life is one of the highest among inflammatory skin diseases due to the extreme itch and is comparable to other debilitating chronic diseases that can negatively affect mental health, activities of daily living and social interactions. High-potency topical steroids are commonly prescribed but are associated with safety risks if used long-term. There are about 75,000 adults in the U.S. living with prurigo nodularis and are most in need of new treatment options.

About the Dupixent Prurigo Nodularis Trials
The PRIME and PRIME2 Phase 3 double-blind, placebo-controlled trials evaluated the efficacy and safety of Dupixent in 311 adults with uncontrolled prurigo nodularis.

In PRIME and PRIME2, the primary endpoint evaluated the proportion of patients with clinically meaningful improvement in itch from baseline (measured by a ≥4-point reduction in Worst-Itch Numeric Rating Scale [WI-NRS] on a 0-10 scale) at 24 and 12 weeks, respectively. Additional endpoints included the proportion of patients with clear or almost clear skin of nodules at 24 weeks (measured by a score of 0 or 1 on the Investigator's Global Assessment PN-Stage [IGA PN-S] on a 0-4 scale), and the proportion of patients who achieved a clinically meaningful response in both WI-NRS and IGA PN-S.

About Dupixent
Dupixent is administered as an injection under the skin (subcutaneous injection) at different injection sites. In patients aged 18 years and older with prurigo nodularis, Dupixent 300 mg is administered with a pre-filled syringe or pre-filled pen every two weeks following an initial loading dose. Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home by self-administration after training by a healthcare professional.

Regeneron and Sanofi are committed to helping patients in the U.S. who are prescribed Dupixent gain access to the medicine and receive the support they may need with the DUPIXENT *MyWay*® program. For more information, please call 1-844-DUPIXENT (1-844-387-4936) or visit www.DUPIXENT.com.

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE) or prurigo nodularis 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.

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 prurigo nodularis, atopic dermatitis, asthma, CRSwNP and EoE.

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 eosinophilic esophagitis, 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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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. 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 prurigo nodularis; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Dupixent) 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; 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 pediatric eosinophilic esophagitis, 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 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 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, Bayer, and Teva Pharmaceutical Industries Ltd. (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, Dupixent, 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 June 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).