**Press Release**

# *Late-breaking Phase 3 data at AAD 2022 show Dupixent® (dupilumab) significantly improved signs and symptoms of prurigo nodularis*

- Dupixent significantly reduced itch at 12 weeks, and at 24 weeks nearly three times as many Dupixent patients experienced clinically meaningful reductions in itch and skin lesions
- There are currently no approved systemic treatments for prurigo nodularis; regulatory filings for prurigo nodularis planned in the first half of 2022

**Paris and Tarrytown, N.Y. March 26, 2022.** Detailed positive results from the Phase 3 PRIME2 trial evaluating the safety and efficacy of Dupixent® (dupilumab) was presented today in a late-breaking session at the American Academy of Dermatology (AAD) 2022 Annual Meeting. The companies previously announced topline results from PRIME2 and a second trial called PRIME investigating the use of Dupixent in adults with uncontrolled prurigo nodularis. In both trials, Dupixent significantly reduced itch and skin lesions compared to placebo. In total, 21 scientific abstracts evaluating the safety and efficacy of Dupixent in patients with atopic dermatitis in different age groups, as well as investigational indications – prurigo nodularis and chronic spontaneous urticaria – will be presented at the congress.

> ***Gil Yosipovitch, M.D.***
> Professor of Dermatology, Miller School of Medicine, University of Miami, and principal investigator of the PRIME2 trial
> *"Prurigo nodularis is a relentless and often misunderstood itchy skin disease that leaves many patients with uncontrolled symptoms such as unbearable itch and painful skin lesions, along with a significantly impaired quality of life that should not be underestimated. These positive results are the first time a Phase 3 trial has demonstrated that targeting key drivers of type 2 inflammation, IL-4 and IL-13, with dupilumab significantly improved itch and skin lesions in this highly burdensome disease."*

The randomized, placebo-controlled PRIME2 trial met primary and all key secondary endpointswith data presented at AAD 2022 showing:

- 37% of Dupixent patients experienced a clinically meaningful reduction in itch from baseline compared to 22% of placebo patients (p=0.0216) at week 12, the primary endpoint.
- Nearly three times as many Dupixent patients experienced a clinically meaningful reduction in itch from baseline at week 24: 58% of Dupixent patients compared to 20% of placebo patients (p<0.0001).
- Nearly three times as many Dupixent patients achieved clear or almost clear skin at week 24: 45% of Dupixent patients compared to 16% of placebo patients (p<0.0001).

The safety results of the trial were generally consistent with the known safety profile of Dupixent in its approved dermatology indications. For the 24-week treatment period, overall rates of adverse events were generally similar between Dupixent and placebo groups (57% Dupixent, 51% placebo). Adverse events that were more commonly (≥5%) observed with Dupixent were herpes viral infections (7% Dupixent, 0% placebo). A lower rate of skin infections were observed with Dupixent (5% Dupixent, 9% placebo). Additionally, 3% of Dupixent patients and 30% of placebo patients discontinued prior to week 24.

Results from the confirmatory PRIME trial will be presented at an upcoming medical congress. Data from both trials will form the basis of regulatory submissions around the world for Dupixent in prurigo nodularis, which are planned to begin in the first half of 2022.

The potential use of Dupixent in prurigo nodularis is currently under clinical development, and the safety and efficacy have not been fully evaluated by any regulatory authority.

**About Prurigo Nodularis**
People with prurigo nodularis experience intense, persistent itch, with thick skin lesions (called nodules) that can cover most of the body. Prurigo nodularis is often described as painful with burning, stinging and tingling of the skin. The impact of uncontrolled 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 approximately 75,000 people in the U.S. who are unable to control their disease with systemic therapy and are most in need of a treatment option.

**About the Trial**
PRIME2, part of the LIBERTY-PN PRIME clinical program, is a randomized, Phase 3, double-blind, placebo-controlled trial that evaluated the efficacy and safety of Dupixent in 160 adults with prurigo nodularis inadequately controlled with topical prescription therapies or with whom those therapies were not advisable. During the 24-week treatment period, patients received Dupixent or placebo every two weeks with or without topical treatments (low- or medium-dose topical corticosteroids or topical calcineurin inhibitors were continued if patients were using these treatments at randomization).

The primary endpoint evaluated the proportion of patients with clinically meaningful improvement in itch at week 12 (measured by a ≥4-point reduction in Worst-Itch Numeric Rating Scale [WI-NRS] of 0-10). Key secondary endpoints included the proportion of patients with clinically meaningful improvement in itch at week 24 and the proportion of patients with clear or almost clear skin at week 24 (measured by a score of 0 or 1 on the Investigator's Global Assessment PN-Stage [IGA PN-S] 0-4 scale).

**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. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP).

Dupixent is currently approved in the U.S., Europe, Japan and other countries around the world for use in specific patients with moderate-to-severe atopic dermatitis, as well as certain patients with asthma or CRSwNP in different age populations. Dupixent is also approved in one or more of these indications in more than 60 countries around the world and more than 400,000 patients have been treated globally.

**Dupilumab Development Program**
Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. To date, dupilumab has been studied in 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, including prurigo nodularis (Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), hand and foot atopic dermatitis (Phase 3), eosinophilic esophagitis (Phase 3), chronic spontaneous urticaria (Phase 3), bullous pemphigoid (Phase 3), chronic inducible urticaria-cold (Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), chronic rhinosinusitis without nasal polyposis (Phase 3), allergic fungal rhinosinusitis (Phase 3), allergic bronchopulmonary aspergillosis (Phase 3) and peanut allergy (Phase 2). 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 life-transforming medicines for people with serious diseases. Founded and led for over 30 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 additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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*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 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; 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 prurigo nodularis, chronic obstructive pulmonary disease with evidence of type 2 inflammation, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, chronic spontaneous urticaria, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, peanut allergy, and other potential indications; 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 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, 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. 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).