

Dupixent® (dupilumab) is the first biologic to significantly reduce itch and skin lesions in Phase 3 trial for prurigo nodularis, demonstrating the role of type 2 inflammation in this disease

- * Pivotal trial met primary and all key secondary endpoints
- * Dupixent significantly reduced itch at 12 weeks, and nearly three times as many Dupixent patients experienced reductions in both itch and skin lesions at 24 weeks
- * Data reinforce impact of targeting IL-4 and IL-13, key and central drivers of type 2 inflammation, to address itch and skin lesions
- * Sixth disease in a Phase 3 trial for Dupixent that reinforces well-established safety profile

PARIS and TARRYTOWN, N.Y. – October 22, 2021 - A pivotal Phase 3 trial evaluating Dupixent® (dupilumab) in adults with uncontrolled prurigo nodularis, a chronic type 2 inflammatory skin disease that causes extreme itch and skin lesions, met its primary and all key secondary endpoints, showing that Dupixent significantly reduced itch and skin lesions compared to placebo in this investigational setting. The impact of uncontrolled prurigo nodularis on quality of life is one of the highest among inflammatory skin diseases with intense, chronic itch.

“We are encouraged that patients in this trial experienced a significant reduction in itch and skin lesions, especially given that prior to enrollment nearly all patients had severe itch and nearly 40% had 100 or more nodules covering their body,” said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. *“These data are an important step forward in furthering our knowledge of the role that targeting IL-4 and IL-13 can play in the treatment of skin diseases that cause extreme itch. We are committed to continuing to leverage the robust Dupixent clinical program to transform the understanding of the science behind a number of type 2 inflammatory diseases and look forward to presenting the full results at a future medical congress.”*

People with prurigo nodularis experience intense, persistent itch, with thick skin lesions (called nodules) that can cover most of the body. It is often described as painful with burning, stinging and tingling of the skin. The debilitating signs and symptoms of prurigo nodularis can negatively impact health-related quality of life, including mental health, activities of daily living and social interactions. There are no approved systemic treatments

for prurigo nodularis. High-potency topical steroids are commonly used, which are associated with safety risks if used long-term.

“Prurigo nodularis is an underdiagnosed disease with immense physical and emotional burden for the 74,000 people in the U.S. who are unable to control their disease with topical steroids and otherwise do not have an approved treatment option,” said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. *“These patients are left to cope with severe itching and painful nodules that, in turn, significantly impair one’s quality of life with many resorting to immunosuppressants and some to antidepressants. These results show – for the first time in a Phase 3 prurigo nodularis trial – that a systemic medicine is able to address the most debilitating symptoms such as itch without broadly suppressing the immune system, building on the promise of Dupixent in a broad range of serious dermatologic, respiratory and gastrointestinal diseases.”*

In the Phase 3 PRIME2 trial, topline results comparing Dupixent (n=78) to placebo (n=82) showed:

- 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.
- At week 24, nearly three times as many Dupixent patients experienced a clinically meaningful reduction in itch from baseline: 58% of Dupixent patients compared to 20% of placebo patients (p<0.0001).
- At 24 weeks, Dupixent patients were nearly three times as likely to achieve clear or almost clear skin: 45% of Dupixent patients compared to 16% of placebo patients (p<0.0001).
- Dupixent patients experienced significantly greater improvements in measures of health-related quality of life, skin pain and symptoms of anxiety and depression.

The safety results of the trial were generally consistent with the known safety profile of Dupixent in its approved indications. The occurrences of treatment-emergent adverse events were generally similar between Dupixent and placebo groups (57% Dupixent, 51% placebo). The most common adverse events were conjunctivitis (6.5% Dupixent, 0% placebo), herpes viral infections (6.5% Dupixent, 0% placebo) and skin infections (5% Dupixent, 9% placebo). Additionally, 3% of Dupixent patients and 30% of placebo patients discontinued prior to week 24.

An additional trial in the LIBERTY-PN PRIME clinical program, PRIME, is fully enrolled. PRIME has a similar trial design and is expected to read out in the first half of 2022. Sanofi and Regeneron plan to begin regulatory submissions in 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 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 are 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 12 weeks (measured by a ≥ 4 -point reduction in worst-itch numeric rating scale [WI-NRS] of 0-10). Key secondary endpoints included the proportion of participants with clinically meaningful improvement in itch at 24 weeks and the proportion of participants with clear or almost clear skin at 24 weeks (measured by a score of 0 or 1 on the Investigator's Global Assessment PN-Stage [IGA PN-S] 0-4 scale). Additional secondary endpoints included health-related quality of life (measured by change in baseline according to the 0–30-point Dermatology Life Quality Index), skin pain (measured by change in baseline on a 0-10 scale), and symptoms of anxiety and depression (measured by change in baseline according to a 0-42 Hospital Anxiety and Depression scale).

The average age in the trial was 49 years and 64% were female. Approximately 33% of patients were Asian, 13% were Latino/Hispanic and 5% were Black/African American. In the trial, 46% of patients had at least one coexisting type 2 inflammatory disease. About 24% of patients enrolled had prior history with systemic (non-steroidal) immunosuppressants and 11% had been treated with antidepressants.

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 300,000 patients have been treated globally.

Dupilumab Development Program

To date, dupilumab has been studied across 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation.

Sanofi and Regeneron are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes, including chronic obstructive pulmonary

disease with evidence of type 2 inflammation (Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), eosinophilic esophagitis (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), chronic inducible urticaria-cold (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. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

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.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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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, 2020. 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 (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 (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab); 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, prurigo nodularis, 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 and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the study discussed 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, 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 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® (afibercept) 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, 2020 and its Form 10-Q for the quarterly period ended June 30, 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>).