SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Dupixent® (dupilumab) significantly improved itch and hives in patients with chronic spontaneous urticaria, a step forward in demonstrating the role of type 2 inflammation in these patients

- Fifth disease that Dupixent has demonstrated positive pivotal results
- Phase 3 trial met its primary endpoints and all key secondary endpoints at 24 weeks, showing Dupixent nearly doubled reduction in itch and urticaria activity scores
- CSU results further demonstrate the potential of targeting IL-4 and IL-13 via IL-4Ra blockade in improving diseases with components of type 2 inflammation
- Approximately 300,000 people in the U.S. have moderate to severe CSU that does not respond adequately to antihistamines alone
- Data continue to support well-established safety profile of Dupixent

PARIS and TARRYTOWN, N.Y. – July 29, 2021 - A pivotal Phase 3 trial evaluating Dupixent® (dupilumab) in patients with moderate-to-severe chronic spontaneous urticaria (CSU), an inflammatory skin disease, met its primary endpoints and all key secondary endpoints at 24 weeks. Adding Dupixent to standard-of-care antihistamines significantly reduced itch and hives for biologic-naïve patients, compared to those treated with antihistamines alone (placebo) in Study A (the first of two trials) of the LIBERTY CUPID clinical program.

"The chronic nature of CSU, coupled with intense itch, causes both a physical and emotional burden on people who have not found an effective treatment," said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. *"This is the fifth inflammatory disease in which Dupixent has demonstrated a significant improvement in symptoms and disease manifestations in Phase 3 pivotal studies. The success of this trial underscores the agility of our clinical operations team considering the pandemic conditions and underscores our ability to deliver on an aggressive timeline for addressing a significant unmet need for this patient population."*

"This is the first Phase 3 trial to show that by targeting IL-4 and IL-13, Dupixent can address the debilitating symptoms of chronic spontaneous urticaria like persistent itch and hives when standard-of-care antihistamines cannot sufficiently

control the disease," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. *"These data add to the increasing body of evidence that using Dupixent can reduce the disease burden of a diverse range of dermatologic, respiratory and gastrointestinal diseases. By early 2022 we look forward to reporting results from a second trial in patients who were unable to control their chronic spontaneous urticaria with another biologic medicine, as well other trial results in additional dermatologic diseases."*

CSU is a chronic inflammatory skin disease characterized by the sudden onset of hives on the skin and/or swelling deep under the skin. Despite standard-of-care treatment, people with CSU often experience symptoms including a persistent itch or burning sensation, which can be debilitating and significantly impact quality of life. Swelling often occurs on the face, hands and feet, but can also affect the throat and upper airways. CSU is typically treated with antihistamines but for up to 50% of people living with CSU their disease remains uncontrolled and available treatment options are few. CSU is the fifth inflammatory disease for which Dupixent has achieved positive Phase 3 data, including atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis (EoE, investigational).

In the trial (n=138), adding Dupixent to standard-of-care antihistamines nearly doubled the reduction in itch and urticaria activity compared to standard-of-care alone at 24 weeks:

- 63% reduction in itch severity with Dupixent vs 35% with standard-of-care (antihistamines) as measured by a 0-21-point itch severity scale (10.24-point reduction with Dupixent vs 6.01-point reduction with standard-of-care) ($p<0.001$), the primary endpoint in the US (secondary endpoint in the EU) with continuous improvement out to week 24.
- 65% reduction in urticaria activity (itch and hives) severity with Dupixent vs 37% with standard-of-care, as measured by a 0-42-point urticaria activity scale, (20.53-point reduction with Dupixent vs 12.00-point reduction with standard-of-care) ($p<0.001$), the primary endpoint in the EU (secondary endpoint in the US) with continuous improvement out to week 24.

The trial demonstrated safety results similar to the known safety profile of Dupixent in its approved indications. For the 24-week treatment period, the occurrence of treatment emergent adverse events were generally similar between the Dupixent and placebo groups (50% of Dupixent patients and 59% of placebo patients). The most common adverse events were injection site reactions (11% Dupixent, 13% placebo).

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

About the Dupixent CUPID trial

Study A of the Phase 3 randomized, double-blind, placebo-controlled clinical program evaluated the efficacy and safety of Dupixent as an add-on therapy to standard-of-care

H1 antihistamines compared to antihistamines in 138 patients aged 6 years and older with CSU who remained symptomatic despite antihistamine use and who were not previously treated with anti-IgE therapeutics.

The primary endpoints assessed the change from baseline in itch (measured by the weekly itch severity score [ISS7]) at 24 weeks and the change from baseline in itch and hives (measured by the weekly urticaria activity score [UAS7]) at 24 weeks.

Study B of the clinical trial will evaluate Dupixent in adults and adolescents who remain symptomatic despite standard-of-care treatment and are intolerant or incomplete responders to an anti-IgE therapeutic (omalizumab). That study is expected to read out in H1 2022. Sanofi and Regeneron plan to begin submissions in 2022. In addition to CSU, Sanofi and Regeneron are also studying Dupixent in chronic inducible urticaria triggered by cold (LIBERTY-CINDU CUrIADS program) in an ongoing Phase 3 trial.

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 asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), atopic dermatitis, eosinophilic esophagitis and may contribute to CSU.

In the United States and Europe, Dupixent is approved for patients 6 years and older with moderate-to-severe atopic dermatitis, patients 12 years and older with moderate-to-severe asthma, and in adults with uncontrolled CRSwNP. 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, Dupixent has been studied across 50 clinical trials involving 10,000 patients with various chronic diseases driven 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 pediatric asthma (6 to 11 years of age, Phase 3), 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) for the treatment of chronic spontaneous urticaria ("CSU"); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators (including the results from the Phase 3 trial evaluating Dupixent in patients with CSU discussed in this press release) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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 CSU, pediatric asthma, chronic obstructive pulmonary disease with evidence of type 2 inflammation, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, 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) on any of the foregoing or any potential regulatory approval of Regeneron's Products 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; 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, 2020 and its Form 10-Q for the quarterly period ended March 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).