

Update on ongoing Dupixent® (dupilumab) chronic spontaneous urticaria Phase 3 program

- * In a Phase 3 trial in patients refractory to omalizumab, Dupixent did not reach statistical significance in an interim analysis despite numeric improvements observed across key endpoints; trial will be stopped due to futility
- * Positive results from a previous Phase 3 trial in biologic-naïve patients showed Dupixent significantly reduced itch and hives compared to standard of care
- * Companies remain committed to advancing Dupixent for patients with chronic spontaneous urticaria uncontrolled on antihistamines and are evaluating next steps

PARIS and TARRYTOWN, N.Y., February 18, 2022. A Phase 3 trial (CUPID STUDY B) evaluating Dupixent® (dupilumab) in patients with chronic spontaneous urticaria (CSU), who were refractory to omalizumab, will stop due to futility based on a pre-specified interim analysis. Although positive numerical trends in reducing itch and hives were observed, the results from the interim analysis did not demonstrate statistical significance for the primary endpoints. The analysis was conducted by an independent interim analysis review committee. In the trial, patients who were refractory to omalizumab treatment and uncontrolled on antihistamines received Dupixent plus standard of care compared to standard of care alone for 24 weeks. The safety data were generally consistent with the known safety profile of Dupixent in its approved indications.

The LIBERTY-CUPID pivotal program was initiated in 2020 with an accelerated direct-to-Phase 3 strategy. The [previously reported](#) Phase 3 trial, which evaluated a different group of patients who were biologic-naïve, met its primary and all key secondary endpoints at 24 weeks showing that adding Dupixent to standard-of-care antihistamines significantly reduced itch and hives compared to antihistamines alone. The companies remain committed to advancing Dupixent for patients with CSU uncontrolled on antihistamines and are evaluating next steps.

John Reed, M.D., Ph.D.

Executive Vice President, Global Head of Research and Development at Sanofi
“Although we are disappointed in these latest results, this interim analysis contributes to furthering our understanding of the role of type 2 inflammation in this subset of CSU patients who are refractory to all other approved therapies. Based on the results seen in our first Phase 3 trial, and the numerical trends observed in this interim analysis, we remain committed to advancing Dupixent as an option for patients suffering from CSU who are uncontrolled on antihistamines. We look forward to discussing next steps with regulators.”

Detailed results from the first trial will be presented at the AAAAI Annual Meeting later this month and the companies expect to share results from the second trial in a scientific forum. Sanofi and Regeneron are rapidly advancing a broad clinical development program to evaluate Dupixent in diseases with significant unmet need and where type 2 inflammation may play a role. The companies also recently announced positive Phase 3 results in eosinophilic esophagitis (EoE) and prurigo nodularis (PN), and additional results are also expected later this year in pediatric EoE, chronic inducible urticaria-cold (CindU), and hand and foot atopic dermatitis.

The potential use of Dupixent in CSU, EoE, PN, CindU and hand and foot atopic dermatitis are currently under clinical development and the safety and efficacy have not been fully evaluated by any regulatory authority.

About Chronic Spontaneous Urticaria

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.

About the Dupixent Phase 3 Program in CSU (LIBERTY-CUPID)

Study B of the Phase 3 randomized, double-blind, placebo-controlled LIBERTY-CUPID clinical program evaluated the efficacy and safety of Dupixent in 83 patients with CSU aged 12 to 80 years who remained symptomatic despite standard-of-care treatment and were intolerant or incomplete responders to omalizumab. During the 24-week treatment period, patients received Dupixent, or placebo every two weeks added to standard-of-care antihistamines.

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

Study A of clinical program evaluated the efficacy and safety of Dupixent as an add-on therapy to standard-of-care antihistamines compared to antihistamines alone in 138 patients aged 6 years and older with CSU who remained symptomatic despite antihistamine use and were not previously treated with omalizumab.

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 polyps (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 350,000 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 across 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 chronic spontaneous urticaria (Phase 3), chronic inducible urticaria-cold (Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), prurigo nodularis (Phase 3), eosinophilic esophagitis (Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), bullous pemphigoid (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.

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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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 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 chronic spontaneous urticaria ("CSU"); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees, such as the LIBERTY-CUPID clinical program (including Study A of the program, results of which were previously reported), may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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 for the treatment of CSU) and Regeneron's Product Candidates; 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 atopic dermatitis, chronic obstructive pulmonary disease with evidence of type 2 inflammation, 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; 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; 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.

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