SANOFI

Press Release

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

Safety and efficacy of Dupixent® (dupilumab) in patients as young as 6 years with moderate-to-severe atopic dermatitis further reinforced by new data analyses presented at EADV

- Three-year efficacy and safety follow-up from Phase 3 trial in adults is the longest for any approved systemic therapy in atopic dermatitis
- Additional data evaluated effect of Dupixent on disease severity, itch, and sleep disturbance starting two weeks after first dose in adolescents and children as young as 6 years
- Dupixent has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven by type 2 inflammation

PARIS and TARRYTOWN, N.Y. – October 29, 2020 – New analyses of Phase 3 Dupixent® (dupilumab) data in adults, adolescents, and children with atopic dermatitis will be presented at the 2020 European Academy of Dermatology and Venereology (EADV) Virtual Congress from October 29-31.

Presentations include data from open-label extension trials evaluating laboratory assessments in adults treated with Dupixent for up to three years and adolescents (aged 12 to 17 years) treated up to one year. These data reinforce the well-established long-term safety profile of Dupixent in moderate-to-severe atopic dermatitis, which does not require initial blood testing or ongoing laboratory monitoring.

Additionally, data will be presented from trials that assessed the impact of Dupixent, measured as early as 2 weeks after the first dose, on signs and symptoms including itch, oozing/crusting, swelling and sleep disturbance, using SCOring Atopic Dermatitis (SCORAD) in adolescents with moderate-to-severe disease and children (aged 6 to 11 years) with severe disease.

> *"Our new data at EADV build on the existing wealth of evidence supporting the unique way Dupixent specifically targets the underlying type 2 inflammation that contributes to diseases like atopic dermatitis, thus significantly improving itch and skin lesions and other important measures that impact a patient's quality of life," said Paul Rowe, MD, ATSF, Vice President, Head of Global Medical, Immunology at* Sanofi *Genzyme. "We will also present data from the adult trial showing how the majority of patients reported high satisfaction with Dupixent after long-term treatment up to three years, which is very important when treating a life-long chronic disease like atopic dermatitis."*

Sanofi and Regeneron joint presentations at EADV will be available starting October 29 at 7 a.m. CET and include:

- **Laboratory safety**
  - P0234: Laboratory Safety of Dupilumab in Pediatric Patients aged ≥ 6 to < 12 years with Severe Atopic Dermatitis: Results from a Phase III Trial (LIBERTY AD PEDS), Andreas Wollenberg
  - P0229: Laboratory Safety of Dupilumab in Adolescent Patients with Atopic Dermatitis: 52-Week Laboratory Safety Findings From an Open-Label Study (LIBERTY AD PED-OLE), Michael J. Cork
  - P0262: Laboratory Safety of Long-Term Dupilumab Treatment for up to 3 Years in Adults with Moderate-to-Severe Atopic Dermatitis (LIBERTY AD OLE), Andreas Wollenberg
- **Long-term results and patient satisfaction**
  - P0250: High Incidence of Treatment Satisfaction with Long-Term Dupilumab Treatment in Adult Patients With Moderate-to-Severe Atopic Dermatitis (LIBERTY AD OLE), Diamant Thaçi
- **Disease signs and symptoms**
  - P0237: Dupilumab in Children Aged ≥ 6 to < 12 Years Significantly Improves Symptoms of Atopic Dermatitis Assessed by SCORAD (LIBERTY AD PEDS), Sebastien Barbarot
  - P0266: Dupilumab Improves Signs and Symptoms Assessed by SCORAD in Adolescents with Moderate-to-Severe Atopic Dermatitis, Ulrike Blume-Peytavi

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins, and is not an immunosuppressant. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP).

About Dupixent

Dupixent is approved for adolescents and adults with moderate-to-severe atopic dermatitis, asthma and/or in adults with CRSwNP in a number of countries around the world, including the EU and Japan, as well as the U.S. where Dupixent is also approved for children with moderate-to-severe atopic dermatitis. Dupixent is currently approved in more than 60 countries, and more than 190,000 patients have been treated globally.

Dupilumab development program

To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven by type 2 inflammation.

In addition to the currently approved indications, Sanofi and Regeneron are also studying dupilumab in a broad range of diseases driven by type 2 inflammation and other allergic processes, including pediatric atopic dermatitis (6 months to 5 years of age, Phase 3),

pediatric asthma (6 to 11 years of age, Phase 3), eosinophilic esophagitis (Phase 3), chronic obstructive pulmonary disease (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), and food and environmental allergies (Phase 2). These potential uses are investigational, and the safety and efficacy of dupilumab in these conditions have not been evaluated by any regulatory authority. Dupilumab is being jointly developed by Regeneron and Sanofi 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 eight FDA-approved treatments and numerous product candidates in development, 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, 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.

Sanofi, Empowering Life

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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, 2019. 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 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 Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) in patients 12 years and older with eosinophilic esophagitis; uncertainty of market acceptance and commercial success of Regeneron's Products and 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 the commercial success of Regeneron's Products (such as Dupixent) and 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 eosinophilic esophagitis, pediatric asthma, pediatric atopic dermatitis, chronic obstructive pulmonary disease, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications; safety issues resulting

from the administration of Regeneron's Products (such as Dupixent) and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 product candidates; 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 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; the ability of Regeneron to manufacture and manage supply chains for multiple products and 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 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 or collaboration 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, and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended June 30, 2020. 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 to (publicly or otherwise) any obligation 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).