SANOFI

Press Release

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

Dupixent® (dupilumab) Phase 3 data show significant improvement in severe atopic dermatitis for children aged 6 to 11 years

- Detailed data to be presented at the Revolutionizing Atopic Dermatitis Conference show adding Dupixent to topical corticosteroids improved skin clearance; average overall disease improved by approximately 80%
- Data further reinforce consistent safety and tolerability profile observed across adult and adolescent atopic dermatitis trials, including a numerically lower rate of skin infections compared to placebo
- Expanded Dupixent indication in children aged 6 to 11 years currently under Priority Review with the FDA; decision expected by May 26, 2020

Paris and Tarrytown, NY – April 3, 2020 – The pivotal Phase 3 clinical trial results announced today show Dupixent ® (dupilumab) combined with standard-of-care topical corticosteroids (TCS) in children aged 6-11 years with uncontrolled severe atopic dermatitis significantly improved disease signs, symptoms and health-related quality of life. Sanofi and Regeneron previously announced topline positive results of this trial in August 2019.

Detailed results will be presented during a session at the 2020 Revolutionizing Atopic Dermatitis (RAD) Virtual Conference on April 5.

> *"In my practice, I see children with severe atopic dermatitis struggling with intense, persistent itching and skin lesions covering much of their body, and caregivers who are desperate for additional treatment options that can help control this disease,"* said Amy S. Paller, M.D.,Walter J. Hamlin Professor and Chair of Dermatology and Professor of Pediatrics at Northwestern University Feinberg School of Medicine and principal investigator of the trial. "*Data from the Phase 3 trial in children aged 6 to 11 adds to the established efficacy and safety data in adults and adolescents and provides hope to physicians and families for a potential new treatment option for children with this chronic disease*."

Data to be presented at RAD show that at 16 weeks, nearly three times as many children achieved clear or almost clear skin when treated with Dupixent and TCS, and more than two-thirds experienced at least a 75% overall improvement of their disease compared to TCS alone. Additionally, more than three times as many children experienced a significant

reduction in itch with Dupixent compared to TCS alone. Itch is often described as the most burdensome symptom of atopic dermatitis. Improvements in itch and disease severity were observed with Dupixent as early as two weeks after the first dose and continued throughout active treatment.

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins. 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). Across all approved indications in the U.S., more than 100,000 patients have started treatment with Dupixent.

The results from the Phase 3 pediatric trial are currently being reviewed by regulatory authorities, including in the U.S., EU and Canada. In the U.S. the supplemental Biologics License Application for children aged 6 to 11 years, is currently under Priority Review with a target action date of May 26, 2020. There are currently no biologic medicines approved for children with severe atopic dermatitis. In 2016, the U.S. Food and Drug Administration granted Breakthrough Therapy designation to review Dupixent for the treatment of severe atopic dermatitis in children 6 months to 11 years of age not well controlled on topical prescription medications. Dupixent is also being studied in a Phase 3 trial for children with uncontrolled persistent asthma, with results expected later this year. The safety and efficacy of Dupixent in these pediatric populations have not been fully evaluated by any regulatory authority.

The virtual late-breaking presentation at RAD included the following data:

The Phase 3, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent combined with TCS in 367 children with severe atopic dermatitis that covered on average 60% of their skin. More than 90% of children in the trial had a history of at least one atopic comorbidity, including asthma (nearly 50%).

Results at 16 weeks showed:

- 33% of patients who received Dupixent every four weeks (300 mg, regardless of weight) and 30% of patients who received Dupixent every two weeks (100 mg or 200 mg, based on weight) achieved clear or almost clear skin (Investigator's Global Assessment or IGA), compared to 11% for TCS alone ($p<0.0001$ and $p=0.0004$, respectively), the primary endpoint in the U.S.
- 70% of patients who received Dupixent every four weeks and 67% of patients who received Dupixent every two weeks achieved EASI-75 (Eczema Area and Severity Index-75), compared to 27% for TCS alone ($p<0.0001$ for both), a co-primary endpoint outside of the U.S.
- The average EASI score improvement from baseline was 82% in patients who received Dupixent every four weeks and 78% in patients who received Dupixent every two weeks, compared to 49% for TCS alone ($p<0.0001$ for both).
- 60% of patients who received Dupixent every four weeks and 68% of patients who received Dupixent every two weeks experienced at least a 3-point reduction in itch intensity on an 11-point scale (weekly average of daily Peak Pruritus Numerical Rating Scale), compared to 21% for TCS alone ($p<0.0001$ for both).

Safety data over the 16-week treatment period showed:

- Overall rates of adverse events were 65% for Dupixent every four weeks, 67% for Dupixent every two weeks and 73% for TCS alone.
- Adverse events that were more commonly observed with Dupixent included conjunctivitis (7% for Dupixent every four weeks, 15% for Dupixent every two weeks and 4% for placebo), nasopharyngitis (13% for Dupixent every four weeks, 7% for Dupixent every two weeks and 7% placebo) and injection site reactions (10% for Dupixent every four weeks, 11% for Dupixent every two weeks and 6% for placebo).
- Additional prespecified adverse events included skin infections (6% for Dupixent every four weeks, 8% for Dupixent every two weeks and 13% for placebo) and herpes viral infections (2% for Dupixent every four weeks, 3% for Dupixent every two weeks and 5% for placebo).

Dupilumab Development Program

To date, Dupixent has been studied in more than 8,000 patients across 40 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 clinical development programs for diseases driven by allergic and other type 2 inflammation, including pediatric asthma (6 to 11 years of age, Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 2/3), 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). Dupilumab is also being studied in combination with REGN3500 (SAR440340), which targets IL-33. These potential uses are investigational, and the safety and efficacy have not been evaluated by any regulatory authority. Dupilumab and REGN3500 are being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

IMPORTANT SAFETY INFORMATION FOR U.S. PATIENTS

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems
- have a parasitic (helminth) infection
- are taking oral, topical, or inhaled corticosteroid medicines. **Do not** stop taking your corticosteroid medicines unless instructed by your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine to come back.
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with DUPIXENT.

- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. If you are taking asthma medicines, do not change or stop your asthma medicine without talking to your healthcare provider.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following symptoms: breathing problems, fever, general ill feeling, swollen lymph nodes, swelling of the face, mouth and tongue, hives, itching, fainting, dizziness, feeling lightheaded (low blood pressure), joint pain, or skin rash.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have: rash, shortness of breath, persistent fever, chest pain, or a feeling of pins and needles or numbness of your arms or legs.

The most common side effects include:

- **Atopic dermatitis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, and cold sores in your mouth or on your lips.
- **Asthma:** injection site reactions, pain in the throat (oropharyngeal pain), and high count of a certain white blood cell (eosinophilia).
- **Chronic rhinosinusitis with nasal polyposis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, high count of a certain white blood cell (eosinophilia), trouble sleeping (insomnia), toothache, gastritis, and joint pain (arthralgia).

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed. DUPIXENT is an injection given under the skin (subcutaneous injection). If your healthcare provider decides that you or a caregiver can give DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. Do not try to inject DUPIXENT until you have been

shown the right way by your healthcare provider. In children 12 years of age and older, it is recommended that DUPIXENT be administered by or under supervision of an adult.

Please see full Prescribing Information including Patient Information.

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 seven 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, infectious diseases, pain 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, the risk of global disruption, including pandemics, as well as those risks 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 nature, timing, and possible success and therapeutic applications of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products") and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) for the treatment of pediatric asthma; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates (such as Dupixent) and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and product candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for Regeneron's Products, such as dupilumab for the treatment of pediatric asthma, pediatric atopic dermatitis, eosinophilic esophagitis, chronic obstructive pulmonary disease, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications (as well as in combination with REGN3500); unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates (such as dupilumab) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; ongoing regulatory obligations and oversight impacting Regeneron's Products (such as Dupixent), research and clinical programs, and business, including those relating to patient privacy; 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, including without limitation dupilumab; 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 Regeneron's Products and product candidates; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; 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 without any further product success; 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 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. 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 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).