Dupixent® (dupilumab) Approved by European Commission as First and Only Biologic Medicine for Children Aged 6 to 11 Years with Severe Atopic Dermatitis

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Pivotal trial showed more than four times as many children achieved itch reduction and more than three times as many children achieved clear or almost clear skin with Dupixent plus topical corticosteroids (TCS) compared to TCS alone

Nearly three in four children achieved a 75% improvement in disease extent and severity, with an average improvement of approximately 80%

Approximately 80% of children experienced clinically meaningful improvements in a composite of health-related quality of life measures that include sleep, school, emotional well-being and relationships

Expanded approval of Dupixent for these children reinforces well-established, long-term safety profile

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that the European Commission (EC) has extended the marketing authorization for Dupixent® (dupilumab) in the European Union (EU) to include children 6 to 11 years of age with severe atopic dermatitis who are candidates for systemic therapy. Dupixent is the only systemic medicine approved in the EU to treat these patients.

"As the parent of a child with atopic dermatitis, and someone who works with families impacted by this condition daily, I've seen first-hand the enormous physical and mental health burden of this disease, and the toll it can take on the entire family," said Korey Capozza, MPH, Founder and Executive Director of Global Parents for Eczema Research (GPER). "Young children with severe atopic dermatitis currently have few treatment choices and significant unmet needs. We welcome the addition of new medicines for these underserved patients."

Atopic dermatitis is a chronic inflammatory disease of the skin that can be debilitating, and severe disease can significantly impact many aspects of life for both children and their families. The current standard of care for children with severe atopic dermatitis in Europe is limited to topical treatments, leaving those with poorly-controlled disease to cope with intense, unrelenting itch and skin lesions that can cover much of the body, resulting in skin cracking, redness or darkening, crusting and oozing. In addition, uncontrolled severe atopic dermatitis can have a substantial emotional and psychosocial impact, causing sleep disturbance, symptoms of anxiety and depression and feelings of isolation in children.

"This approval for Dupixent in the EU represents a major advancement for children with severe atopic dermatitis and their families, who spend countless days and nights tending to their child's disease with few treatment options to help alleviate the debilitating symptoms," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "Dupixent is a novel therapy that addresses a root cause of atopic dermatitis by specifically targeting the underlying type 2 inflammation of the disease. Dupixent has already been used by hundreds of thousands of patients around the world, including those with atopic dermatitis as well as other type 2 inflammatory diseases such as asthma and adults with chronic rhinosinusitis with nasal polyps. We are pleased to bring this paradigm-changing medicine to even younger patients in the EU who need new options beyond steroids or immunosuppressants."

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins, that was invented using Regeneron's proprietary *VelocImmune*® technology, 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).

"The approval of Dupixent for children in Europe marks another significant milestone for atopic dermatitis patients and their families, broadening the availability of a first-in-class medicine that offers a proven safe and effective treatment for this debilitating skin disease," said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. "Dupixent's ability to provide significantly clearer skin, and clinically meaningful reduction of persistent itch, addresses important unmet needs for these children. In addition to atopic dermatitis, we continue to investigate the potential of Dupixent in younger age groups and across a variety of type 2 inflammatory diseases."

In children aged 6 to 11 years weighing 15 to <60 kg, Dupixent 300 mg is administered as an injection under the skin (subcutaneous injection) every four weeks following the initial loading dose given as two injections 14 days apart. For those

weighing ≥60 kg, Dupixent 300 mg is administered every two weeks following the initial loading dose given the same day. The dose may be increased to 200 mg every two weeks in patients weighing 15 to <60 kg based on physician's assessment.

The EC decision is based primarily on data that includes pivotal Phase 3 efficacy and safety results of Dupixent combined with topical corticosteroids (TCS) compared to TCS alone (placebo) in children 6 to 11 years with severe atopic dermatitis. At 16 weeks, patients in treatment groups of Dupixent 300 mg every four weeks (N=122) or 200 mg every two weeks (N=59) with TCS experienced:

-- **Improved disease extent and severity**:

- 82% average improvement from baseline with Dupixent every four weeks compared to 49% for placebo.
- 80% average improvement from baseline with Dupixent every two weeks compared to 48% for placebo.
- 70% of patients in the every four week treatment group achieved at least a 75% improvement compared to 17% for placebo.
- 75% of patients in the every two week treatment group achieved at least a 75% improvement compared to 26% for placebo.

-- **Skin clearance:**

- 33% of patients achieved clear or almost clear skin with Dupixent every four weeks compared to 11% for placebo.
- 39% of patients achieved clear or almost clear skin with Dupixent every two weeks compared to 10% for placebo.

-- **Reduced itch**:

- 51% of patients achieved clinically significant reduction of itch with Dupixent every four weeks compared to 12% for placebo.
- 61% of patients achieved clinically significant reduction of itch with Dupixent every two weeks compared to 13% for placebo.
- A significantly greater proportion of Dupixent patients achieved improvement in itch as early as four weeks.

-- **Improved health-related quality of life (HR-QoL)**:

- 77% of patients experienced clinically meaningful improvement in patient-reported HR-QoL with Dupixent every four weeks compared to 39% for placebo.
- 81% of patients experienced clinically meaningful improvement in patient-reported HR-QoL with Dupixent every two weeks compared to 36% for placebo.
- Dupixent patients also experienced improvements in additional HR-QoL measures assessing disease severity and patient-reported measures such as itch and sleep.

The safety profile of Dupixent in children 6 to 11 years of age followed through week 52, based on an open-label extension trial, was similar to the safety profile observed at week 16 and consistent with the safety profile seen in adults and adolescents with atopic dermatitis. Overall rates of adverse events (AEs) were 65% and 61% for Dupixent every four and two weeks, respectively, and 73% and 75% for placebo. AEs that were more commonly observed with Dupixent included upper respiratory tract infections (11% and 9% for Dupixent every four and two weeks, 10% and 12% for placebo), injection site reactions (10% and 14% for Dupixent every four and two weeks, 6% and 5% for placebo), nasopharyngitis (13% and 3% for Dupixent every four and two weeks, 7% and 10% for placebo), conjunctivitis (7% and 9% for Dupixent every four and two weeks, 4% and 5% for placebo), and fever (3% for both Dupixent groups, 2% and 0% for placebo). Additional prespecified AEs included skin infections (6% and 9% for Dupixent every four and two weeks, 13% for both placebo groups), and herpes viral infections (2% for both Dupixent groups, 5% for both placebo groups).

About the Pediatric Trial
The co-primary endpoints in the pediatric trial were skin clearance, as measured by a score of 0 or 1 on the Investigator's Global Assessment (IGA), and disease extent and severity, as measured by Eczema Area and Severity Index score (EASI-75).

Secondary endpoints included the average change in EASI score from baseline, and itch as measured by at least a 4-point reduction in itch intensity on a 0 to 10-point scale (weekly average of daily Peak Pruritus Numerical Rating Scale). Additionally, HR-QoL was measured by the proportion of patients who achieved at least six points on the patient-reported Children's Dermatology Life Quality Index (CDLQI), as well as additional measures from Patient Oriented Eczema Measure (POEM) and SCORing Atopic Dermatitis (SCORAD).

About Dupixent
Dupixent is approved for specific patients with atopic dermatitis, asthma and/or in adults with CRSwNP in a number of countries around the world, including the European Union, U.S. and Japan. Dupixent is currently approved in more than 60 countries, and more than 200,000 patients have been treated globally.

Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home by self-administration after training by a healthcare professional. In children younger than 12 years of age, Dupixent should be administered by a caregiver. No initial lab testing or ongoing lab monitoring is required with Dupixent treatment in any approved indication or age group.

Dupilumab was invented using Regeneron's *VelocImmune*® technology that utilizes a proprietary genetically-engineered mouse platform endowed with a genetically-humanized immune system to produce optimized fully-human antibodies. VelocImmune technology has been used to create multiple antibodies including Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab) and Kevzara® (sarilumab), which are approved in multiple countries around the world. Regeneron previously used these technologies to rapidly develop a treatment for *Zaire ebolavirus* infection, which is approved by the FDA, and to create a potentially preventative and therapeutic investigational medicine for COVID-19 that was recently granted Emergency Use Authorization (EUA).

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, Regeneron and Sanofi are also studying dupilumab in a broad range of diseases driven by type 2 inflammation and other allergic pathways, 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.

U.S. Indications
DUPIXENT is a prescription medicine used:

- to treat people aged 6 years and older with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 6 years of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in people aged 12 years and older whose asthma is not controlled with their current asthma medicines. DUPIXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. DUPIXENT is not used to treat sudden breathing problems. It is not known if DUPIXENT is safe and effective in children with asthma under 12 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.

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 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.

- There is a pregnancy exposure registry for women who take DUPIXENT during pregnancy to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself. To get more information about the registry call 1–877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/.

-- 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.

Especially tell your healthcare provider if you are taking oral, topical, or inhaled corticosteroid medicines; have asthma and use an asthma medicine; or have atopic dermatitis or CRSwNP, and also have asthma. **Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

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 by indication are as follows:

- **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. Your healthcare provider will tell you how much DUPIXENT to inject and how often to inject it. 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. In children younger than 12 years of age, DUPIXENT should be given by a caregiver.

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 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

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 Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab); 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) 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 dupilumab for the treatment of pediatric atopic dermatitis, pediatric asthma, eosinophilic esophagitis, 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, 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, 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 September 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 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).

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 absence of guarantee that the product will 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 conditions, 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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