

FDA approves Dupixent® (dupilumab) as first biologic medicine for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis

- * Dupixent is the first and only biologic medicine approved to treat moderate-to-severe atopic dermatitis from infancy to adulthood
- * Children treated with Dupixent and topical corticosteroids (TCS) achieved clearer skin, and significantly reduced itch compared to TCS alone at week 16 in a Phase 3 trial
- * Long-term safety data from a 52-week open-label extension trial in this age group reinforce the well-established safety profile of Dupixent observed across all other approved age groups

Paris and Tarrytown, N.Y. June 7, 2022. The U.S. Food and Drug Administration (FDA) has approved Dupixent® (dupilumab) for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. A regulatory filing for this age group is under review by the European Medicines Agency and submissions to regulatory authorities in additional countries are underway.

Julie Block

President and Chief Executive Officer, National Eczema Association

“Moderate-to-severe atopic dermatitis in babies and young children is more than just a rash – the intense itch can make them scratch uncontrollably throughout the day and night and cause their skin to crack and bleed. Caregivers do their best to manage skincare routines multiple times a day, but for many, topical treatments are not enough. We’re pleased to see how scientific innovation and research continues to address unmet needs for the atopic dermatitis community, and we’re hopeful for the positive impact Dupixent can have for these children and their families.”

Atopic dermatitis is a chronic type 2 inflammatory skin disease. Eighty-five to ninety percent of patients first develop symptoms before 5 years of age, which can often continue through adulthood. Symptoms include intense, persistent itch and skin lesions that cover much of the body, resulting in skin dryness, cracking, pain, redness or darkening, and crusting and oozing, along with increased risk of skin infections. In the U.S., more than 75,000 children aged 5 years and younger have uncontrolled moderate-to-severe disease and are most in need of new treatment options.

Naimish Patel, M.D.

Senior Vice President, Head of Global Development, Immunology and Inflammation, Sanofi

“Until today, treatment options in the U.S. for infants and children under the age of 6 suffering from moderate-to-severe atopic dermatitis have been limited to topical steroids – which may be associated with significant safety risks when used long-term. This has left patients and their caregivers in desperate need of medicines that can better address the chronic, long-term nature of the disease. These young people, and their families, often struggle to cope with the significant impact itch can have on them. This approval means that Dupixent, with its well-established safety and efficacy profile, is now available to some of the youngest people living with this disease.”

George D. Yancopoulos, M.D., Ph.D.

President and Chief Scientific Officer, Regeneron

“Young children with moderate-to-severe atopic dermatitis are a significantly underserved population of patients, who spend vulnerable years of their lives suffering through the relentless and far-reaching effects of this chronic disease. Dupixent has changed the atopic dermatitis

treatment paradigm – significantly clearing skin and reducing itch – by targeting an underlying cause of this disease without broadly suppressing the immune system. Today’s approval brings the proven efficacy and, importantly, well-established safety profile of Dupixent to these young children, making it the first of its kind to be approved for any U.S. patient aged six months or older living with this debilitating disease.”

The FDA evaluated Dupixent under Priority Review, which is reserved for medicines that represent potentially significant improvements in efficacy or safety in treating serious conditions. The approval is based on data that include a Phase 3 trial evaluating Dupixent every four weeks (200 mg or 300 mg, based on body weight) plus low-potency topical corticosteroids (TCS) or TCS alone (placebo). The trial met the primary and all secondary endpoints. At 16 weeks, patients who received Dupixent with TCS experienced the following, compared to TCS alone:

- 28% achieved clear or almost-clear skin compared to 4% with placebo, the primary endpoint.
- 53% achieved 75% or greater improvement in overall disease severity from baseline compared to 11% with placebo TCS alone, the co-primary endpoint outside of the U.S.
- 48% achieved clinically meaningful reduction in itch compared to 9% with placebo.

The safety profile of Dupixent observed through 16 weeks in children aged 6 months to 5 years was similar to the safety profile in patients 6 years and older with atopic dermatitis. The long-term safety profile of Dupixent in children aged 6 months to 5 years through 52 weeks was also similar to the safety profile observed in the pivotal trial and consistent with what was observed in older patients with atopic dermatitis. Hand-foot-and-mouth disease and skin papilloma were, respectively, reported in 5% and 2% of Dupixent patients aged 6 months to 5 years, and none of these cases led to treatment discontinuation.

About the Dupixent Trial

The Phase 3 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent added to standard-of-care low-potency TCS compared to low-potency TCS alone (placebo) in 162 children aged 6 months to 5 years with uncontrolled moderate-to-severe atopic dermatitis.

The primary endpoints assessed the proportion of patients achieving an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and 75% improvement in Eczema Area and Severity Index (EASI-75) at week 16. Additional outcome measures included itch reduction which was assessed using a caregiver-reported 0 to 10 Numerical Rating Scale, with a clinically meaningful improvement defined as ≥ 4 -point improvement at week 16.

Children who completed the trials were eligible to enroll in an open-label extension trial to assess the safety and efficacy of long-term treatment with Dupixent in this age group.

About Dupixent

Dupixent is administered as an injection under the skin (subcutaneous injection) at different injection sites. In patients aged 6 months to 5 years, Dupixent is administered with a pre-filled syringe every four weeks based on weight (200 mg for children ≥ 5 to < 15 kg and 300 mg for children ≥ 15 to < 30 kg). 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 if given at home. Dupixent does not require initial lab testing or ongoing lab monitoring.

Sanofi and Regeneron are committed to helping patients in the U.S. who are prescribed Dupixent gain access to the medicine and receive the support they may need with the DUPIXENT MyWay[®] program. For more information, please call 1-844-DUPIXENT (1-844-387-4936) or visit www.DUPIXENT.com.

Dupixent is approved for use in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP) or eosinophilic esophagitis in different age populations in a number of countries around the world. Dupixent is currently approved across these indications in the U.S. and for one or more of these indications in the European Union and Japan and more than 60 countries. More than 400,000 patients have been treated globally.

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. The Dupixent development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent such as asthma, atopic dermatitis, CRSwNP and eosinophilic esophagitis, as well as investigational diseases such as prurigo nodularis.

Dupilumab Development Program

Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. To date, dupilumab has been studied across more than 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 in Phase 3 trials, including prurigo nodularis, pediatric eosinophilic esophagitis, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritis of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis and bullous pemphigoid. 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 is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for nearly 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and 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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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 moderate-to-severe atopic dermatitis in children aged 6 months to 5 years; 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) 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 hand and foot atopic dermatitis, prurigo nodularis, eosinophilic esophagitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, bullous pemphigoid, chronic obstructive pulmonary disease with evidence of type 2 inflammation, 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; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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® (afibercept) 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 and its Form 10-Q for the quarterly period ended March 31, 2022. 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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