

Press Release

Dupixent® (dupilumab) approved by European Commission as first and only targeted medicine for children as young as six months old with severe atopic dermatitis

- Approximately seven times as many patients aged 6 months to 5 years with severe atopic dermatitis treated with Dupixent experienced clear or almost clear skin and reduced overall disease severity compared to placebo
- Patients treated with Dupixent achieved rapid itch reduction as early as three weeks after start of therapy, with significant improvements at 16 weeks sustained through one year
- Dupixent is now a treatment option for the approximately 80,000 infants and young children living with uncontrolled severe atopic dermatitis in Europe
- Milestone marks third Dupixent European Commission approval in the past four months

Paris and Tarrytown, N.Y. March 21, 2023. The European Commission (EC) has approved Dupixent® (dupilumab) in the European Union (EU) to treat severe atopic dermatitis in children aged 6 months to 5 years old who are candidates for systemic therapy. With this approval, Dupixent is the first and only targeted medicine indicated to treat these young children in Europe and the [U.S.](#)

Korey Capozza, MPH

Founder and Executive Director of Global Parents for Eczema Research (GPER)
“Watching an infant or young child grapple with the debilitating and wide-reaching impacts of severe atopic dermatitis is heartbreaking. I’ve personally witnessed how this chronic skin disease can disrupt the lives of entire families when left uncontrolled. Intervening with effective treatments during infancy and early childhood can help manage the challenging impact this disease has on children and their families during such formative years.”

Atopic dermatitis is a chronic type 2 inflammatory skin disease. Between 85% and 90% 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, crusting and oozing, which can increase the risk of skin infection. Severe atopic dermatitis may also significantly impact the quality of life of young children and their caregivers. Treatment options in this age group are primarily topical corticosteroids (TCS), which can be associated with safety risks and may impair growth when used long-term.

Naimish Patel, M.D.

Head of Global Development, Immunology and Inflammation at Sanofi
“A vast majority of people with atopic dermatitis begin to develop symptoms during their earliest, most vulnerable years, and these symptoms can often continue through the rest of their lives. With this latest approval, Dupixent is the first-ever biologic medicine for people living with atopic dermatitis from infancy to adulthood. Given its well-established safety and efficacy profile, Dupixent has the potential to transform the landscape for people of all ages living with atopic dermatitis. We remain committed to exploring Dupixent for the treatment of other chronic inflammatory skin diseases.”

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

President and Chief Scientific Officer at Regeneron

“No infant or child should have to spend their earliest days suffering with the intense and unrelenting itch and skin pain of atopic dermatitis. Too often the parents and caregivers of children with severe atopic dermatitis are left desperate for new treatments to manage this chronic disease. In the pivotal trial, Dupixent reduced itch and skin pain, and improved health-related quality of life and sleep quality. Dupixent is currently being used to treat more than 600,000 patients around the world across approved indications. This latest EU approval brings the proven efficacy, and importantly, the long-term safety profile of Dupixent to this particularly vulnerable population.”

The approval is based on data from a [Phase 3 trial](#) evaluating Dupixent every four weeks (200 mg or 300 mg based on body weight) plus low-potency TCS or TCS alone (placebo) in 162 children aged 6 months to 5 years with moderate-to-severe atopic dermatitis. At 16 weeks, Dupixent improved skin clearance and reduced overall disease severity and itch compared to placebo in the overall enrolled population. In a subset of those with severe atopic dermatitis, patients randomized to Dupixent (n=63) experienced the following compared to placebo (n=62) at 16 weeks:

- 46% of patients achieved 75% or greater improvement in overall disease severity compared to 7% treated with placebo, a co-primary endpoint.
- 14% of patients achieved clear or almost clear skin compared to 2% treated with placebo, a co-primary endpoint.
- 55% average reduction in overall disease severity from baseline compared to 10% with placebo.
- 42% average reduction in itch from baseline compared to a 1% increase with placebo.

Dupixent also improved sleep quality, skin pain and health-related quality of life compared to placebo in both the overall and severe populations. Long-term efficacy data showed the clinical benefit at 16 weeks was sustained through 52 weeks.

The most common side effects across indications include injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes and eosinophilia. The safety results of the 6 months to 5 years old trial were generally consistent with the known safety profile of Dupixent in its approved indications; in the trial, adverse events more commonly observed ($\geq 5\%$) with Dupixent compared to placebo included eosinophilia and conjunctivitis. The long-term safety profile through 52 weeks was similar to the safety profile observed at 16 weeks, and consistent with what was observed in older patients with atopic dermatitis.

About the Pivotal Dupixent Atopic Dermatitis 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 moderate-to-severe atopic dermatitis.

The co-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 endpoints measured itch (assessed by a caregiver-reported worst scratch/itch numerical rating scale from 0-10), sleep quality (assessed by a caregiver-reported numerical rating scale from 0-10), skin pain (assessed by a caregiver-reported numerical rating scale from 0-10) and health-related quality of life (assessed by the Children's Dermatology Life Quality Index in patients aged 4 to 5 years and the Infants' Dermatitis Quality of Life Index in patients aged 6 months to 3 years, both scales from 0-30).

About Dupixent

Dupixent is an injection administered 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.

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 atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE) and prurigo nodularis.

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, CRSwNP, EoE or prurigo nodularis in different age populations. Dupixent is currently approved for one or more of these indications in more than 60 countries, including in Europe, the U.S. and Japan. More than 600,000 patients are being treated with Dupixent 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 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 pediatric EoE, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus 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 (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 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 more information, 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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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. 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, 2022. 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 severe atopic dermatitis in children 6 months to 5 years old; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products 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; 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 pediatric eosinophilic esophagitis, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, bullous pemphigoid, 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 and Bayer (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, 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, 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.

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>).