

Dupixent recommended for EU approval by the CHMP to treat eosinophilic esophagitis in children as young as 1 year old

- * Recommendation based on a phase 3 study showing a significantly greater proportion of children on Dupixent achieved histological remission, compared to placebo, consistent with improvements seen in adults and adolescents
- * If approved, Dupixent would be the first and only medicine in the EU indicated for EoE in this age group

Paris and Tarrytown, NY, September 20, 2024. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the expanded approval of Dupixent (dupilumab) in the European Union (EU) for eosinophilic esophagitis (EoE) in children down to 1 year of age. The recommendation is for children aged 1 to 11 years who weigh at least 15 kg and who are inadequately controlled by, intolerant to, or who are not candidates for conventional medicinal therapy. The European Commission is expected to announce a final decision in the coming months. Dupixent is already [approved](#) in the EU for certain adults and adolescents aged 12 years and older with EoE.

The positive CHMP opinion is supported by a two-part (Part A and B) EoE KIDS phase 3 study in children aged one to 11 years. In Part A, a significantly greater proportion of children receiving weight-based doses of Dupixent achieved histological disease remission at week 16, compared to placebo, with results sustained for up to one year in Part B. At week 16, caregivers of children treated with Dupixent also observed improvements in the frequency and severity of EoE signs, and fewer days with at least one sign of EoE, compared to placebo. These data established a bridge showing the response to Dupixent in children with EoE is similar to that of the approved adult and adolescent EoE populations.

The safety results in the EoE KIDS study were generally consistent with the known safety profile of Dupixent in adolescents and adults with EoE. AEs more commonly observed with Dupixent ($\geq 10\%$) in either weight-based dosing regimen compared to placebo during Part A were COVID-19, nausea, injection site pain and headache. The long-term safety profile of Dupixent evaluated in Part B was similar to that observed during Part A.

Results from the study were recently [published](#) in *The New England Journal of Medicine*.

The use of Dupixent in children aged one to 11 years with EoE is investigational in the EU and is not yet approved.

About EoE

EoE is a chronic, progressive disease associated with type-2 inflammation that is thought to be responsible for damaging the esophagus and impairing its function. Diagnosis is difficult, as symptoms can be mistaken for other conditions and there are delays in diagnosis. EoE can severely impact a child's ability to eat and may also cause vomiting, abdominal pain, difficulty swallowing, decreased appetite and challenges thriving. Continuous management of EoE may be needed to reduce the risk of complications and disease progression.

About Dupixent

Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL4) and interleukin-13 (IL13) 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 studies, establishing that IL4 and IL13 are key and central drivers of the type-2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, EoE, prurigo nodularis, chronic spontaneous urticaria, and chronic obstructive pulmonary disease in different age populations. More than 1,000,000 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 studies 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 studies, including chronic pruritus of unknown origin 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 by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*[®], which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center[®] and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on [LinkedIn](#), [Instagram](#), [Facebook](#) or [X](#).

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 the world, 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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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 or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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); the impact of the opinion adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use discussed in this press release on the potential approval by the European Commission of Dupixent to treat eosinophilic esophagitis ("EoE") in children aged 1 to 11 years; 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 EoE in the European Union as discussed in this press release as well as for the treatment of chronic pruritus of unknown origin, bullous pemphigoid, and other potential indications; 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 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; 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; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; 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), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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. 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