

# Dupixent® (dupilumab) sBLA for treatment of eosinophilic esophagitis in children aged 1 to 11 accepted for FDA Priority Review



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Dupixent® (dupilumab) sBLA for treatment of eosinophilic esophagitis in children aged 1 to 11 accepted for FDA Priority Review

- If approved, Dupixent would be the first and only treatment indicated in the U.S. for children aged 1- 11 with eosinophilic esophagitis, a disease driven by type 2 inflammation that impacts the ability to eat
- Of the approximately 21,000 children under the age of 12 in the U.S. currently being treated for EoE, about 9,000 do not satisfactorily respond to the unapproved therapies they have been treated with and potentially require advanced alternative therapy options

Paris and Tarrytown, N.Y. September 26, 2023. The U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) to treat children aged 1 to 11 years with eosinophilic esophagitis (EoE). The target action date for the FDA decision is January 31, 2024. Dupixent is the first and only treatment in the U.S. approved for children and adults aged 12 years and older with EoE, weighing at least 40kg.

The sBLA is supported by data from the Phase 3 EoE KIDS trial ( Parts A and B) evaluating the efficacy and safety of Dupixent in children aged 1 to 11 with EoE. In Part A, the primary endpoint was met for the proportion of patients achieving histological disease remission (defined as peak esophageal intraepithelial eosinophil count of  $\leq 6$  eosinophils [eos]/high power field [hpf]) at 16 weeks for tiered dosing regimens based on body weight, compared to placebo. Part B

was an active treatment extension period evaluating Dupixent for an additional 36 weeks and showed Dupixent maintained histologic remission for 52 weeks, a secondary endpoint. Dupixent also led to increases in body weight for age percentile, which was evaluated as an exploratory endpoint in Part A and a secondary endpoint in Part B.

Safety results in Parts A and B of the trial were generally consistent with the known safety profile of Dupixent in its FDA-approved EoE indication for children and adults aged 12 years and older who weigh at least 40 kg. Adverse events more commonly observed ( $\geq 5\%$ ) with Dupixent were COVID-19, rash, headache, viral gastroenteritis, diarrhea and nausea.

Priority review is granted to therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions.

The potential use of Dupixent in children with EoE aged 1 to 11 years is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority in this setting.

### About Eosinophilic Esophagitis

EoE is a chronic, progressive disease driven by type 2 inflammation that damages the esophagus and prevents it from working properly. In children, common symptoms of EoE include heart burn, vomiting, abdominal discomfort, trouble swallowing, food refusal and failure to thrive. These symptoms can impact growth and development and can cause food-related fear and anxiety, which can persist through adulthood. Dietary adjustments, including the elimination of many foods, are the standard treatment for EoE, as well as the use of treatments not approved for the disease. These include proton pump inhibitors, swallowed topical corticosteroids, or in severe cases, a feeding tube, which may be used to ensure proper caloric intake and weight gain. Continuous treatment of EoE may be needed to reduce the risk of complications and disease recurrence.

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the IL-4 and 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), prurigo nodularis and EoE.

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, Regeneron and Sanofi 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 spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation 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.

Regeneron 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, Regeneron's 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 Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its 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 Regeneron, please visit [www.regeneron.com](http://www.regeneron.com) or follow Regeneron on LinkedIn.

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 and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. 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, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that pandemics or other global crises may 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 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) for the treatment of children aged 1 to 11 years with eosinophilic esophagitis (“EoE

); 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 children aged 1 to 11 years with EoE (including potential approval by the U.S. Food and Drug Administration based on the supplemental Biologics License Application discussed in this press release), chronic spontaneous urticaria, chronic pruritus of unknown

origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, 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 or any potential regulatory approval of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates; 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 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 and its Form 10-Q for the quarterly period ended June 30, 2023. 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 ( <https://investor.regeneron.com>) and its LinkedIn page ( <https://www.linkedin.com/company/regeneron-pharmaceuticals>).

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