Press Release

Dupixent® (dupilumab) Phase 3 Results show sustained efficacy for up to one year in children 1 to 11 years of age with eosinophilic esophagitis (EoE)

- *Late-breaking presentation at ACG 2023 showed histologic and endoscopic improvements were maintained with no new safety signals to week 52 with higher dose Dupixent in these children*
- *Data reinforce the role of type 2 inflammation in EoE and the importance of targeting both IL-4 and IL-13 pathways*
- *sBLA for Dupixent to treat children aged 1 to 11 years with EoE is under Priority Review in the U.S.; if approved, Dupixent would be the first and only FDA-approved treatment for these children with EoE*

Paris and Tarrytown, N.Y. October 22, 2023. Positive results from a Phase 3 trial demonstrated the efficacy and safety profile of Dupixent® (dupilumab) for up to one year (52 weeks) in children aged 1 to 11 years with eosinophilic esophagitis (EoE) was consistent. These results represent the first analysis of longer-term data in this age group and will be featured in a late-breaking session on October 25 at the American College of Gastroenterology (ACG) 2023 Annual Scientific Meeting.

> ***Mirna Chehade, M.D., MPH***
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> *"Eosinophilic esophagitis, or EoE, is a chronic and debilitating condition that can impact children in their most vulnerable years of life, causing persistent difficulties with eating, abdominal pain, and/or failure to thrive. Dupilumab is the first and only therapeutic approved for adults and adolescents 12 years and older who weigh at least 40 kg with EoE. Some children with EoE may have sub-optimal response to currently unapproved standard of care therapies, underscoring the need for treatments targeting key pathways driving inflammation in EoE. Data from this Phase 3 trial support the potential of dupilumab to treat EoE in children, with sustained efficacy and safety, which is particularly critical for these children."*

The late-breaking data to be presented at ACG feature results from children enrolled in the extended active treatment period (Part B) of a Phase 3 trial, following 16 weeks of Dupixent treatment or placebo in Part A of the trial. All children in Part B were treated with higher or lower dose Dupixent for an additional 36 weeks, providing up to 52 weeks of data.

In Part B, there were 37 patients who continued on higher dose Dupixent and 18 who switched from placebo to higher dose Dupixent. At one year, outcomes of secondary endpoints (as evaluated with descriptive statistics based on all observed data) among

children who continued on higher dose Dupixent and for those switching from placebo to higher dose Dupixent was, respectively, as follows:

- 63% and 53% achieved histological disease remission
- 0.97 and 0.89 reduction from baseline in disease severity and 0.89 and 0.86 reduction from baseline in extent, respectively, as measured at the microscopic level in biopsy specimens
- 4.8 and 3.6-point reduction in abnormal endoscopic findings from baseline
- 0.30 and 0.47-point numerical improvement in caregiver reported pediatric signs and symptoms, as measured by PESQ-C
- 5.96 and 5.48 percentile increase in body weight for age percentile from baseline

Safety results in Part B of the trial were generally consistent with Part A and the known safety profile of Dupixent in its FDA-approved EoE indication for adult and adolescent patients aged 12 years and older who weigh at least 40 kg. AEs reported in ≥20% of patients who remained on higher dose Dupixent in Part B and those who switched from placebo to higher dose Dupixent in Part B, respectively, included: COVID-19 (n=11/37, n=5/18; all cases were mild or moderate and did not lead to study treatment discontinuation), injection site reaction (n=5/37, n=5/18), cough (n=3/37, n=4/18) and headache (n=3/37, n=4/18).

In September, the U.S. Food and Drug Administration accepted for Priority Review the supplemental Biologics License Application for higher dose Dupixent to treat children aged 1 to 11 years with EoE, with a target action date of January 31, 2024. This 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 in part by type 2 inflammation that damages the esophagus and prevents it from working properly. In children, common symptoms of EoE include heartburn, 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, which oftentimes include the elimination of food groups, are the standard treatment for EoE, as well as the use of treatments not approved for the disease, such as proton pump inhibitors and swallowed topical corticosteroids. Continuous treatment of EoE may be needed to reduce the risk of complications and disease recurrence.

About the Dupixent Pediatric Eosinophilic Esophagitis Trial
The Phase 3, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in children aged 1 to 11 years with EoE, as determined by histological, endoscopic and patient- or caregiver-reported measures. At baseline, 98% of these patients had at least one co-existing type 2 inflammatory disease such as food allergy, allergic rhinitis, asthma and atopic dermatitis.

Part A, a 16-week, double-blind treatment period, enrolled 102 patients and evaluated Dupixent subcutaneously at either a higher dose or lower dose regimen based on weight (ranging from ≥5 kg to <60 kg). The dosing frequency ranged between every two weeks and every four weeks, based on weight. The primary endpoint was histological disease remission, which was defined as peak esophageal intraepithelial eosinophil count of ≤6 eosinophils (eos)/high power field (hpf).

Part B was a 36-week extended active treatment period in which eligible children from Part A in the Dupixent group maintained their dose level; those in the placebo group were randomized to either a higher or lower dose. In Part B, secondary endpoints included:

- Histological disease remission (peak esophageal intraepithelial eosinophil count of ≤6 eosinophils [eos]/high power field [hpf])
- Histopathologic measures of the severity and extent of tissue scarring in the esophagus (EoE-HSS grade and stage scores, which measure changes in eight cellular and tissue features on 0-3 scales, respectively)
- Abnormal endoscopic findings (EoE Endoscopic Reference Score [EoE-EREFS] on a 0-18 scale)
- Changes in caregiver-reported symptoms (proportion of days with 1 or more EoE signs [e.g., stomach pain, vomiting, food refusal] by the Pediatric EoE Sign/Symptom Questionnaire-caregiver version [PESQ-C])
- Change from baseline in body weight for age percentile

The trial is ongoing with a 108-week open-label extension period (Part C) to evaluate longer-term outcomes.

About Dupixent
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 750,000 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 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.

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 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 or follow Regeneron on LinkedIn.

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.

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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 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 ("pediatric 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 pediatric EoE, 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® (aflibercept) 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.

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