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)

PUBLISHED OCT 22, 2023
BY SANOFI

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.

Mount Sinai Center for Eosinophilic Disorders, Icahn School of Medicine, Mount Sinai

> 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

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.

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.

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.

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Sally Bain | + 1 617 834 6026 |sally.bain@sanofi.com

Evan Berland | +1 215 432 0234 |evan.berland@sanofi.com Victor Rouault | + 33 6 70 93 71 40 |

Eva Schaefer-Jansen | + 33 7 86 80 56 39 |eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 06 73 69 36 93 |arnaud.delepine@sanofi.com

Corentine Driancourt | + 33 06 40 56 92 | corentine.driancourt@sanofi.com

Felix Lauscher | + 1 908 612 7239 |felix.lauscher@sanofi.com

Tarik Elgoutni | + 1 617 710 3587 |tarik.elgoutni@sanofi.com

Nathalie Pham | + 33 07 85 93 30 17 |nathalie.pham@sanofi.com

Sharon Chen | +1 914-847-1546| sharon.chen@regeneron.com

Regeneron Investor Relations

Vesna Tosic | + 914 847 5443 |vesna.tosic@regeneron.com

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> 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

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