Press Release

Dupixent® (dupilumab) recommended for EU approval by the CHMP for the treatment of eosinophilic esophagitis

- If approved, Dupixent would be the first and only targeted medicine specifically indicated for people aged 12 years and older with eosinophilic esophagitis in the European Union
- In the U.S., Dupixent is currently the only medicine indicated to treat eosinophilic esophagitis
- Approval recommendation based on pivotal trial data demonstrating patients on Dupixent 300 mg weekly experienced significantly improved ability to swallow and achieved histological disease remission compared to placebo
- In the European Union, about 50,000 adults and adolescents live with severe uncontrolled eosinophilic esophagitis

Paris and Tarrytown, N.Y. DECEMBER 16, 2022 The European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending the approval of Dupixent® (dupilumab) in the European Union (EU) to treat adults and adolescents with eosinophilic esophagitis (EoE). This positive opinion covers those who are 12 years and older, weighing at least 40 kg, and inadequately controlled by, are intolerant to or who are not candidates for conventional medicinal therapy. The European Commission is expected to announce a final decision on the Dupixent application in the coming months. In May 2022, Dupixent 300 mg weekly was approved by the U.S. Food and Drug Administration for the treatment of patients aged 12 years and older, weighing at least 40 kg.

EoE is a chronic, progressive inflammatory disease that damages the esophagus and prevents it from working properly. The results seen with Dupixent in adults and adolescents with EoE demonstrate that interleukin-4 (IL-4) and interleukin-13 (IL-13) are key and central drivers of the type 2 inflammation underlying this disease. For people with EoE, swallowing even small amounts of food can be a painful and worrisome choking experience. They are often left to contend with the frustration and anxiety of a constantly evolving list of foods to avoid, a poor quality of life and a higher risk of depression. In cases where EoE causes the esophagus to narrow, forced and potentially painful dilation (physical expansion) of the esophagus may be needed. In severe cases, a feeding tube may be the only option to ensure proper caloric intake and adequate nutrition.

The positive CHMP opinion is supported by 52-week data from a Phase 3 trial consisting of three parts – Part A and Part B investigated Dupixent 300 mg weekly compared to placebo for 24 weeks, and Part C observed patients from Parts A and B, all of whom were on Dupixent, having continued on or switched to Dupixent for an additional 28 weeks. The results demonstrated Dupixent-treated patients experienced improvements in their ability to swallow as early as four weeks, as well as histological disease remission, improvements in abnormal endoscopic findings of the esophagus and cellular improvements at 24 weeks compared to placebo, with outcomes maintained up to one year. The safety results of the trial were generally consistent with the known safety profile of Dupixent in its approved indications. Adverse events more commonly observed with Dupixent compared to placebo included infections.

The use of Dupixent in adults and adolescents with EoE is investigational in the EU and is not yet approved.

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) and prurigo nodularis, as well as investigational diseases such as EoE in the EU.

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 500,000 patients have been 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, 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 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 nearly 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](http://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 Announces Positive Two-Year Data from dupilumab in the Treatment of Eczema in Children

Sanofi, a leading research-driven biopharmaceutical company, today announced positive two-year data from the RENAL study, a randomized, double-blind, placebo-controlled, multi-center Phase 3 study of dupilumab (atopic dermatitis) injection in the treatment of pediatric atopic dermatitis (AD) aged 6 to 17 years. The study demonstrated the continued efficacy and safety of dupilumab in children. The results were presented today at the 35th Congress of the World Society of Pediatric Dermatology.

Methodology and Results

The RENAL study was a randomized, double-blind, placebo-controlled, multi-center Phase 3 study of dupilumab injection in the treatment of pediatric atopic dermatitis (AD) aged 6 to 17 years. The study included 256 patients randomized to either dupilumab 200 mg injection (Q2W) or placebo. The primary endpoint was the proportion of patients who achieved 75% improvement in Investigator’s Global Assessment (IGA) at 16 weeks. The primary analysis showed that dupilumab achieved the primary endpoint at week 16 and at week 52, with a responder rate of 62% versus 4% for placebo. At week 52, patients treated with dupilumab showed a significant reduction in severity of AD compared with placebo, as measured by the Severe Disease Activity Score for AD (SDAS-AD) (p<0.001).

The safety profile of dupilumab was consistent with the known profile of dupilumab in adults. No new safety signals were identified.

Conclusion

The results of the RENAL study demonstrate the continued efficacy and safety of dupilumab in children aged 6 to 17 years with atopic dermatitis. The findings support the potential for dupilumab to provide meaningful benefits to the large and growing population of children with AD.

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 "expects," "anticipates," "intends," "plans," "seeks," "believes," "projects," "estimates," "potential," "should," "likely," "will," "likely," "ongoing," or "ongoing," or the negations of these words, and similar expressions are intended to identify forward-looking statements. Although not all forward-looking statements contain these identifying words, all forward-looking statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Regeneron, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking statements contained in this press release. These risks and uncertainties include among other things, risks associated with the regulation or approval of the Company’s and/or its collaborator’s or licensor’s products and product candidates, the impact of competing products and product candidates, the impact of government or regulatory actions or delays in 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, litigation, and volatile economic and market conditions, and the impact and volatility of foreign exchange rates.

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