



## **CHMP Recommends Approval of Dupixent® (dupilumab) for Children Aged 6 to 11 Years with Severe Atopic Dermatitis**

October 16, 2020

**Recommendation based on pivotal trial that showed Dupixent plus topical corticosteroids (TCS) significantly improved measures of overall disease severity, skin clearance, itch and health-related quality of life, compared to TCS alone**

**Data further reinforce the well-established safety profile of Dupixent in adult and adolescent atopic dermatitis patients**

**If approved, Dupixent would be the first biologic medicine available in the EU to treat this patient group and remains the only biologic medicine approved in moderate-to-severe atopic dermatitis for adolescents and adults**

TARRYTOWN, N.Y. and PARIS, Oct. 16, 2020 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Dupixent® (dupilumab), recommending to extend the approval in the European Union (EU) to include children aged 6 to 11 years with severe atopic dermatitis who are candidates for systemic therapy.

Dupixent is the first and only biologic approved for the treatment of uncontrolled moderate-to-severe atopic dermatitis for people 12 years of age and older in the EU and 6 years of age and older in the U.S. Dupixent is also approved in the EU for certain patients with severe asthma and severe chronic rhinosinusitis with nasal polyps (CRSwNP), two other type 2 inflammatory diseases.

The European Commission is expected to announce a final decision on the Dupixent application in the coming months. The positive CHMP opinion is supported by data that include pivotal Phase 3 results on the efficacy and safety of Dupixent combined with topical corticosteroids (TCS) in children aged 6 to 11 years with severe atopic dermatitis that is uncontrolled on topical prescription therapies. In the trial, children treated with Dupixent and TCS experienced significantly improved measures of overall disease severity (Eczema Area and Severity Index), skin clearance, itch and health-related quality of life measures, compared to TCS alone. Adverse events more commonly observed with Dupixent included conjunctivitis, nasopharyngitis and injection site reactions. These data are consistent with the well-established efficacy and safety profile of Dupixent observed across adult and adolescent atopic dermatitis trials. The use of Dupixent in children aged 6 to 11 years is investigational and its efficacy and safety have not yet been fully evaluated in the EU.

Atopic dermatitis is a chronic inflammatory disease of the skin that can be debilitating. The current standard of care for children with severe atopic dermatitis in Europe is limited to TCS, leaving those with poorly controlled disease to cope with intense, unrelenting itch and skin lesions that cover much of the body resulting in skin cracking, redness or darkening, crusting and oozing. In addition, uncontrolled severe atopic dermatitis can have a significant emotional and psychosocial impact, causing sleep disturbance, symptoms of anxiety and depression, and feelings of isolation for children and their families.

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins, and is not an immunosuppressant. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and CRSwNP. Dupixent is currently approved in more than 60 countries, and more than 170,000 patients have been treated globally.

### **About Dupixent**

Dupixent is currently approved in the EU for use in adults and adolescents 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. It is also approved in the EU for adults and adolescents 12 years and older as an add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroid (ICS) plus another medicinal product for maintenance treatment. Dupixent is also approved in the EU for adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Outside of the EU, Dupixent is approved for use in specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including the U.S. and Japan. Dupixent is also approved in the U.S. and Japan to treat certain adults with severe CRSwNP.

### **Dupilumab Development Program**

To date, dupilumab has been studied in more than 10,000 patients aged 6 and up across 50 clinical trials in various chronic diseases driven by type 2 inflammation.

In addition to the currently approved indications, Regeneron and Sanofi are also studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes, including pediatric asthma (6 to 11 years of age, Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 2/3), eosinophilic esophagitis (Phase 3), chronic obstructive pulmonary disease (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), and food and environmental allergies (Phase 2). These potential uses are investigational, and the safety and efficacy of dupilumab in these conditions have not been evaluated by any regulatory authority. Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

Dupilumab was invented using Regeneron's *VelocImmune*® technology that utilizes a proprietary genetically-engineered mouse platform endowed

with a genetically-humanized immune system to produce optimized fully-human antibodies. *VelocImmune* technology has been used to create multiple antibodies including Libtayo<sup>®</sup> (cemiplimab-rwlc), Praluent<sup>®</sup> (alirocumab) and Kevzara<sup>®</sup> (sarilumab), which are approved in multiple countries around the world. Regeneron previously used these technologies to rapidly develop a [treatment](#) for *Zaire ebolavirus* infection, which is approved by the FDA, and to create REGN-COV2, a potentially preventative and therapeutic investigational medicine for COVID-19 that was recently submitted to the FDA for an Emergency Use Authorization (EUA).

## U.S. Indications

DUPIXENT is a prescription medicine used:

- to treat people aged 6 years and older with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 6 years of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in people aged 12 years and older whose asthma is not controlled with their current asthma medicines. DUPIXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. DUPIXENT is not used to treat sudden breathing problems. It is not known if DUPIXENT is safe and effective in children with asthma under 12 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.

## IMPORTANT SAFETY INFORMATION FOR U.S. PATIENTS

**Do not use** if you are allergic to dupilumab or to any of the ingredients in DUPIXENT<sup>®</sup>.

**Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:**

- have eye problems
- have a parasitic (helminth) infection
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
  - There is a pregnancy exposure registry for women who take DUPIXENT during pregnancy to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself. To get more information about the registry call 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/dupixent/>.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Especially tell your healthcare provider if you are taking oral, topical, or inhaled corticosteroid medicines; have asthma and use an asthma medicine; or have atopic dermatitis or CRSwNP, and also have asthma. **Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

**DUPIXENT can cause serious side effects, including:**

- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following symptoms: breathing problems, fever, general ill feeling, swollen lymph nodes, swelling of the face, mouth and tongue, hives, itching, fainting, dizziness, feeling lightheaded (low blood pressure), joint pain, or skin rash.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have: rash, shortness of breath, persistent fever, chest pain, or a feeling of pins and needles or numbness of your arms or legs.

**The most common side effects by indications are as follows:**

- **Atopic dermatitis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, and cold sores in your mouth or on your lips.
- **Asthma:** injection site reactions, pain in the throat (oropharyngeal pain), and high count of a certain white blood cell (eosinophilia).

- **Chronic rhinosinusitis with nasal polyposis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, high count of a certain white blood cell (eosinophilia), trouble sleeping (insomnia), toothache, gastritis, and joint pain (arthralgia).

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed. Your healthcare provider will tell you how much DUPIXENT to inject and how often to inject it. DUPIXENT is an injection given under the skin (subcutaneous injection). If your healthcare provider decides that you or a caregiver can give DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. **Do not** try to inject DUPIXENT until you have been shown the right way by your healthcare provider. In children 12 years of age and older, it is recommended that DUPIXENT be administered by or under supervision of an adult. In children younger than 12 years of age, DUPIXENT should be given by a caregiver.

Please see full [Prescribing Information](#) including Patient Information.

#### About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to eight FDA-approved treatments and numerous product candidates in development, 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, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*<sup>®</sup> technologies, such as *VelocImmune*<sup>®</sup>, 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 the company, please visit [www.regeneron.com](http://www.regeneron.com) or follow @Regeneron on Twitter.

#### About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

#### 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Dupixent<sup>®</sup> (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 European Commission's decision regarding the application to extend Dupixent's approval in the European Union to include children aged 6 to 11 years with severe atopic dermatitis who are candidates for systemic therapy; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products (such as Dupixent) and product candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates and new indications for Regeneron's Products, including possible regulatory approval of Dupixent for children aged 6 to 11 years with severe atopic dermatitis who are candidates for systemic therapy in the European Union discussed in this press release and possible regulatory approval of Dupixent in other jurisdictions and indications (such as for the treatment of pediatric asthma, pediatric atopic dermatitis, eosinophilic esophagitis, chronic obstructive pulmonary disease, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications); safety issues resulting from the administration of Regeneron's Products (such as Dupixent) and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 (such as Dupixent) and 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 product candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and product candidates; 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 or collaboration agreement, including*

Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated; 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, Dupixent, and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended June 30, 2020. 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 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 (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

### **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 COVID-19 will 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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. 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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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