



## **FDA Grants Dupixent® (dupilumab) Breakthrough Therapy Designation for Eosinophilic Esophagitis**

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### **Designation based on positive results from Part A of pivotal Phase 3 trial**

**Dupixent is the first and only biologic to show positive and clinically-meaningful Phase 3 results in patients 12 years and older with eosinophilic esophagitis (EoE)**

**There are currently no FDA-approved treatments for this chronic type 2 inflammatory disease that damages the esophagus and impacts the ability to swallow and eat**

### **Designation supports Dupixent's potential in another disease driven by type 2 inflammation**

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to Dupixent® (dupilumab) for the treatment of patients 12 years and older with eosinophilic esophagitis (EoE). The designation for this investigational use is based on positive results from Part A of a Phase 3 trial in patients with EoE.

There are currently no FDA-approved medicines for EoE, a chronic and progressive type 2 inflammatory disease that damages the esophagus and prevents it from working properly. Over time, excessive type 2 inflammation causes scarring and narrowing of the esophagus, making it difficult to swallow. If left untreated, EoE can affect a patient's ability to eat and cause food to become stuck after being swallowed (food impaction), which can lead to a medical emergency. In the U.S. alone, there are approximately 160,000 patients with EoE who are currently being treated with various unapproved therapies or diet modification. Of these patients, approximately 50,000 have failed multiple treatments.

Regeneron and Sanofi [previously reported](#) positive results from Part A of the pivotal Phase 3 trial evaluating Dupixent in patients 12 years and older with EoE. Part A of the randomized, double-blind, placebo-controlled trial of 81 patients met both of its co-primary endpoints, as well as all key secondary endpoints. Patients treated weekly with Dupixent 300 mg over a 24-week treatment period experienced a reduction in symptoms, esophageal inflammation and abnormal endoscopic findings in the esophagus. The trial demonstrated safety results consistent with the known safety profile of Dupixent in its approved indications. The EoE trial is ongoing, with additional patients enrolling in Part B as well as patients continuing in a 28-week extended active treatment period (Part C) after completing either Part A or Part B.

Breakthrough Therapy designation is designed to expedite the development and review of drugs in the U.S. that target serious or life-threatening conditions. Drugs qualifying for this designation must show preliminary clinical evidence that it may demonstrate a substantial improvement on clinically significant endpoints over available therapies, or over placebo if there are no available therapies. In 2017, Dupixent also was granted Orphan Drug Designation for the potential treatment of EoE. This is given to investigational medicines intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S.

The potential use of Dupixent in eosinophilic esophagitis is currently under clinical development, and its safety and efficacy for this indication have not been evaluated by any regulatory authority.

### **About Dupixent**

Dupixent is approved in the U.S. to treat patients aged 6 years and older with moderate-to-severe atopic dermatitis that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies; for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma medicines; and for use with other medicines for the maintenance treatment of CRSwNP in adults whose disease is not controlled. In adolescents 12 years of age or older, it is recommended that Dupixent be administered by or under the supervision of an adult. In children younger than 12 years of age, Dupixent should be administered by a caregiver.

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

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins. 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 asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP) and atopic dermatitis.

Dupilumab was invented using Regeneron's *VelocImmune*<sup>®</sup> 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 Ebola virus infection, which is currently under review by the FDA, and to create REGN-COV2, a potentially preventative and therapeutic medicine for COVID-19.

### Dupilumab Development Program

To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven 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, including pediatric asthma (6 to 11 years of age, Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 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.

### 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/dupilumab/>.
- 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 indication 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 seven 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) for the treatment of patients 12 years and older with eosinophilic esophagitis; 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 dupilumab for the treatment of eosinophilic esophagitis, pediatric asthma, pediatric atopic dermatitis, chronic obstructive pulmonary disease, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other*

potential indications; the impact (if any) of the Breakthrough Therapy designation status granted to Dupixent for the treatment of patients 12 years and older with eosinophilic esophagitis by the U.S. Food and Drug Administration (the "FDA") on whether Dupixent will receive FDA approval in this indication and the timing of such potential approval; 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; 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 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 without any further product success; 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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