Dupixent® (dupilumab) Recommended for EU Approval to Treat Chronic Spontaneous Urticaria (CSU) in Young Children with Ongoing Symptoms Despite Treatment

February 27, 2026 at 7:00 AM EST

If approved, Dupixent would be the first targeted medicine in the EU indicated for children aged 2 to 11 years with CSU inadequately controlled by standard-of-care antihistamine treatment

CSU is a chronic skin disease with underlying type 2 inflammation that can cause debilitating hives and recurring itch in young children

TARRYTOWN, N.Y. and PARIS, Feb. 27, 2026 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of Dupixent® (dupilumab) in the European Union (EU) for the treatment of chronic spontaneous urticaria (CSU). This recommendation covers children aged 2 to 11 years with moderate-to-severe CSU, an inadequate response to histamine-1 antihistamines (H1AH) and who are naïve to anti-immunoglobulin E (IgE) therapy for CSU. A final decision is expected in the coming months.

The positive CHMP opinion in young children is supported by data from the LIBERTY-CUPID clinical trial program, including two Phase 3 trials, Study A and Study C, in which children aged 6 to 11 years participated, and the single-arm, CUPIDKids Phase 3 trial in children aged 2 to 11 years with CSU.

Dupixent is approved for CSU in certain adults and adolescents in several jurisdictions, including the United States (U.S.), the EU and Japan.

In the U.S., a supplemental Biologics License Application (sBLA) has been accepted for review seeking approval for Dupixent in certain children aged 2 to 11 years with CSU. The U.S. Food and Drug Administration (FDA) decision is expected by April 2026.

The safety and efficacy of Dupixent for CSU in adults and adolescents have not been fully evaluated outside of jurisdictions where it has been approved. The safety and efficacy of Dupixent for CSU in children aged 2 to 11 years have not been fully evaluated by any regulatory authority.

About CSU
CSU is a chronic, inflammatory skin disease driven in part by type 2 inflammation, which causes sudden and debilitating hives and recurring itch. CSU is typically treated with H1AH, medicines that target H1 receptors on cells to control symptoms of itch and urticaria. However, the disease remains uncontrolled despite H1AH treatment in many patients, some of whom are left with limited alternative treatment options. These individuals continue to experience symptoms that can be debilitating and significantly impact their quality of life.

About Dupixent
Dupixent, which was invented using Regeneron's proprietary *VelocImmune*® technology, is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (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 two of the key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis, CSU, chronic obstructive pulmonary disease (COPD) bullous pemphigoid (BP) and allergic fungal rhinosinusitis (AFRS) in different age populations. More than 1,400,000 patients are being treated with Dupixent globally.[1]

About Regeneron's *VelocImmune* Technology
Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's co-Founder, Board co-Chair, President and Chief Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985, they were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite*® technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create a substantial proportion of all original, FDA-approved fully human monoclonal antibodies. This includes

Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg). In addition, REGEN-COV® (casirivimab and imdevimab) had been authorized by the FDA during the COVID-19 pandemic until 2024.

Dupilumab Development Program
Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. To date, dupilumab has been studied across more than 60 clinical trials involving more than 12,000 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 chronic pruritus of unknown origin and lichen simplex chronicus. 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.

U.S. INDICATIONS

DUPIXENT is a prescription medicine used:

- to treat adults and children 6 months of age and older with moderate-to-severe eczema (atopic dermatitis or AD) 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 AD under 6 months of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in adults and children 6 years of age 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. It is not known if DUPIXENT is safe and effective in children with asthma under 6 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adults and children 12 years of age and older whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with CRSwNP under 12 years of age.
- to treat adults and children 1 year of age and older with eosinophilic esophagitis (EoE), who weigh at least 33 pounds (15 kg). It is not known if DUPIXENT is safe and effective in children with EoE under 1 year of age, or who weigh less than 33 pounds (15 kg).
- to treat adults with prurigo nodularis (PN). It is not known if DUPIXENT is safe and effective in children with PN under 18 years of age.
- with other medicines for the maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and a high number of blood eosinophils (a type of white blood cell that may contribute to your COPD). DUPIXENT is used to reduce the number of flare-ups (the worsening of your COPD symptoms for several days) and can improve your breathing. It is not known if DUPIXENT is safe and effective in children with COPD under 18 years of age.
- to treat adults and children 12 years of age and older with chronic spontaneous urticaria (CSU) who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if DUPIXENT is safe and effective in children with CSU under 12 years of age, or who weigh less than 66 pounds (30 kg).
- to treat adults with bullous pemphigoid (BP). It is not known if DUPIXENT is safe and effective in children with BP under 18 years of age.
- to treat adults and children 6 years of age and older with allergic fungal rhinosinusitis (AFRS), who have had surgery on their nose or sinuses in the past. It is not known if DUPIXENT is safe and effective in children with AFRS under 6 years of age.

DUPIXENT is not used to relieve sudden breathing problems and will not replace an inhaled rescue medicine **or** to treat any other forms of hives (urticaria).

IMPORTANT SAFETY INFORMATION

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

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” right before and during treatment with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
    - A pregnancy registry for women who take DUPIXENT during pregnancy collects information about the health of you and your baby.
- 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 AD, CRSwNP, EoE, PN, COPD, CSU, BP, or AFRS and also have asthma. **Do not** change or stop your other medicines, including corticosteroid medicine or other asthma medicine, without talking to your healthcare provider. This may cause other symptoms that were controlled by those medicines to come back.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions. DUPIXENT can cause allergic reactions, including skin reactions, that can sometimes be severe.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms: breathing problems or wheezing, swelling of the face, lips, mouth, tongue or throat, fainting, dizziness, feeling lightheaded, fast pulse, fever, hives, skin rash, including rash that looks like a bullseye, painful red or blue bumps under the skin, or red pus-filled spots on the skin, general ill feeling, itching, swollen lymph nodes, nausea or vomiting, joint pain, or cramps in your stomach area.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision. Your healthcare provider may send you to an ophthalmologist for an exam if needed.
- **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. Tell your healthcare provider right away if you get: rash, chest pain, worsening shortness of breath, brown or dark colored urine, persistent fever, or a feeling of pins and needles or numbness of your arms or legs.
- **Psoriasis.** This can happen in people with atopic dermatitis and asthma who receive DUPIXENT. Tell your healthcare provider about any new skin symptoms. Your healthcare provider may send you to a dermatologist for an examination if needed.
- **Joint aches and pain.** Some people who use DUPIXENT have had trouble walking or moving due to their joint symptoms, and in some cases needed to be hospitalized. Tell your healthcare provider about any new or worsening joint symptoms. Your healthcare provider may stop DUPIXENT if you develop joint symptoms.

The most common side effects include:

- **Eczema:** injection site reactions, eye problems, including eye and eyelid inflammation, redness, swelling, itching, eye infection, dry eye, and blurred vision, cold sores in your mouth or on your lips, and high count of a certain white blood cell (eosinophilia).
- **Asthma:** injection site reactions, high count of a certain white blood cell (eosinophilia), pain in the throat (oropharyngeal pain), and parasitic (helminth) infections.
- **Chronic Rhinosinusitis with Nasal Polyps:** injection site reactions, eye problems, including eye and eyelid inflammation, redness, swelling, itching, eye infection, and blurred vision, high count of a certain white blood cell (eosinophilia), stomach problems (gastritis), joint pain (arthralgia), trouble sleeping (insomnia), and toothache.
- **Eosinophilic Esophagitis:** injection site reactions, upper respiratory tract infections, cold sores in your mouth or on your lips, and joint pain (arthralgia).
- **Prurigo Nodularis:** eye problems, including eye and eyelid inflammation, redness, swelling, itching, and blurred vision, herpes virus infections, common cold symptoms (nasopharyngitis), dizziness, muscle pain, and diarrhea.
- **Chronic Obstructive Pulmonary Disease:** injection site reactions, common cold symptoms (nasopharyngitis), high count of a certain white blood cell (eosinophilia), viral infection, back pain, inflammation inside the nose (rhinitis), diarrhea, stomach problems (gastritis), joint pain (arthralgia), toothache, headache, and urinary tract infection.
- **Chronic Spontaneous Urticaria**: injection site reactions.
- **Bullous Pemphigoid**: joint pain (arthralgia), eye problems, including eye and eyelid inflammation, redness, swelling, itching, and blurred vision, and herpes virus infections.
- **Allergic Fungal Rhinosinusitis**: injection site reactions, eye problems, including eye and eyelid inflammation, redness, swelling, itching, eye infection, and blurred vision, high count of a certain white blood cell (eosinophilia), stomach problems (gastritis), joint pain (arthralgia), trouble sleeping (insomnia), and toothache.

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, or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed by your healthcare provider. It's an injection given under the skin (subcutaneous injection). Your healthcare provider will decide if you or your caregiver can inject DUPIXENT. **Do not** try to prepare and inject DUPIXENT until you or your caregiver have been trained by your healthcare provider. In children 12 years of age and older, it's recommended DUPIXENT be administered by or under supervision of an adult. In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.

Please see accompanying full Prescribing Information including Patient Information.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming

medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite,* which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

About Sanofi
Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY.

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); 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 potential approval by the European Commission of Dupixent for the treatment of children aged 2 to 11 years with moderate-to-severe chronic spontaneous urticaria ("CSU") ; 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 Dupixent for the treatment of children aged 2 to 11 years with moderate-to-severe CSU in the European Union as discussed in this press release as well as Dupixent for the treatment of chronic pruritus of unknown origin, lichen simplex chronicus, and other potential indications; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Dupixent) 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 and risks associated with tariffs and other trade restrictions; 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes to drug pricing regulations and requirements and Regeneron's pricing strategy; other changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates (including biosimilar products) 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 on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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, 2025. 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.

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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

Sanofi Disclaimers or Forward-Looking Statements
This press release contains forward-looking statements within the meaning of applicable securities laws, including 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 and their underlying assumptions regarding the marketing and other potential of the product; regarding potential future events and revenues from the product. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these and similar expressions are intended to identify forward-looking statements.

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, uncertainties and assumptions 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; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; 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 pending or future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that 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 French Markets Authority (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, 2025 or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.

All trademarks mentioned in this press release are the property of the Sanofi group except for VelociSuite and Regeneron Genetics Center.

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[1] Data on File

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Source: Regeneron Pharmaceuticals, Inc.