



Positive Phase 3 Dupixent® (dupilumab) Data in Children 6 Months to 5 Years with Moderate-to-severe Atopic Dermatitis Featured in RAD 2021 Late-breaking Session

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Dupixent significantly improved skin clearance and reduced overall disease severity and itch in pivotal trial that met all primary and secondary endpoints

Global regulatory filings planned in the coming months, starting with the U.S. by the end of 2021

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced detailed positive Phase 3 results that showed adding Dupixent® (dupilumab) to standard-of-care topical corticosteroids (TCS) significantly improved skin clearance and reduced overall disease severity and itch in infants and children aged 6 months to 5 years with uncontrolled moderate-to-severe atopic dermatitis. These data will be presented today in a late-breaking session at the 2021 Revolutionizing Atopic Dermatitis Conference (RAD 2021).

"One of most challenging aspects of my job as a physician is having limited treatment options to help babies and young children suffering from moderate-to-severe atopic dermatitis, which can disrupt their ability to fully thrive in these early years of life," said Amy S. Paller, M.D., Walter J. Hamlin Professor and Chair of Dermatology and Professor of Pediatrics at Northwestern University Feinberg School of Medicine, and principal investigator of the trial. "These results show dupilumab can significantly improve the signs and overall severity of atopic dermatitis in children as young as 6 months. Safety is of paramount importance when treating children at such a young age. We are encouraged that these data show a safety profile consistent with what has been seen in other age groups. We will continue to follow these patients for up to 5 years in an open-label trial."

Eighty-five to 90% of patients with atopic dermatitis develop symptoms before the age of 5, which can often continue through adulthood. Symptoms include intense, persistent itch and skin lesions that cover much of the body (58% on average for the patients in this trial at baseline), resulting in skin dryness, cracking, redness or darkening, and crusting and oozing, along with increased risk of skin infections. Moderate-to-severe atopic dermatitis may also significantly impact the quality of life of a young child, their parents and caregivers. In addition, the underlying type 2 inflammation involved in atopic dermatitis can contribute to the development of other diseases, like asthma and certain allergies, that may also appear throughout a person's life.

Topline results from the randomized, placebo-controlled pivotal trial, which met all primary and secondary endpoints, were [announced](#) in August 2021. Data presented at RAD 2021 showed that at 16 weeks, patients who added Dupixent to low-potency TCS experienced the following, compared to low-potency TCS alone (placebo):

- 28% achieved clear or almost-clear skin compared to 4% with placebo ($p < 0.0001$), the primary endpoint.
- 70% average improvement from baseline in disease severity compared to 20% improvement with placebo ($p < 0.0001$), a key secondary endpoint.
- 53% achieved 75% or greater improvement in overall disease severity from baseline compared to 11% with placebo ($p < 0.0001$), the co-primary endpoint outside of the U.S.
- 49% average improvement from baseline in itch compared to 2% improvement with placebo ($p < 0.0001$).

The safety profile observed in the randomized, placebo-controlled trial was consistent with the well-established safety profile of Dupixent in adults, adolescents and children 6 years and older with moderate-to-severe atopic dermatitis. Overall rates of adverse events (AEs) were 64% for Dupixent and 74% for placebo. Most common AEs and AEs of special interest included nasopharyngitis (8% Dupixent, 9% placebo), upper respiratory tract infection (6% Dupixent, 8% placebo), conjunctivitis (5% Dupixent, 0% placebo) and herpes viral infections (6% Dupixent, 5% placebo).

These results will form the basis of global regulatory submissions for this age group, beginning with the U.S. in 2021 and European Union in the first half of 2022.

Additionally, long-term data from the Phase 3 trial in patients aged 6 to 11 years with moderate-to-severe atopic dermatitis are also being presented in a late-breaking session. Efficacy and safety results at one year were consistent with the known profile of Dupixent in atopic dermatitis.

The data from these trials add to the extensive LIBERTY AD clinical program – the largest Phase 3 clinical trial program in atopic dermatitis, involving approximately 3,500 infants, children, adolescents and adults to date.

Dupixent is the first biologic medicine to demonstrate positive results in this young patient population. The efficacy and safety of Dupixent in children below the age of 6 years have not been fully evaluated by any regulatory authority.

About the Dupixent Trial

LIBERTY AD PRESCHOOL is a two-part Phase 2/3 trial. The Phase 3 randomized, double-blind, placebo-controlled part of the trial (Part B) evaluated the efficacy and safety of Dupixent added to standard-of-care low-potency TCS compared to low-potency TCS alone (placebo) in 162 children aged 6 months to 5 years with uncontrolled moderate-to-severe atopic dermatitis.

The primary endpoints assessed the proportion of patients achieving an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and 75% improvement in Eczema Area and Severity Index (EASI-75) at week 16. EASI measures extent and severity of the disease. Itch was assessed using a caregiver-reported 0 to 10 Numerical Rating Scale. Patients treated with Dupixent received either 200 mg (for children weighing ≥ 5 to < 15 kg) or 300 mg (for children weighing ≥ 15 to < 30 kg) every four weeks.

In total, there were 162 patients in the trial (83 Dupixent, 79 placebo), the average age was 3.8 years and 61% were male. Approximately 12% of patients were Latino/Hispanic and 19% were Black/African American. At the start of the trial, 77% of patients had severe disease and 29% had previously used systemic immunosuppressants for their atopic dermatitis, and on average, patients had atopic dermatitis covering 58% of their body. Furthermore, 81% of these patients had at least one concurrent type 2 inflammatory and/or allergic condition such as allergic rhinitis and asthma.

Part B of the Phase 3 trial was informed by [Part A](#), which was an open-label, single-ascending-dose, sequential cohort Phase 2 trial designed to assess the pharmacokinetics and safety of Dupixent in children aged 6 months to 5 years with uncontrolled severe atopic dermatitis.

Children who completed Part A or Part B of the trial were eligible to enroll in an open-label extension trial to assess the safety and efficacy of long-term treatment with Dupixent in this age group for an additional five years.

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. Dupixent is not an immunosuppressant and does not require lab monitoring. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP).

Dupixent is currently approved in the U.S., Europe, Japan and other countries around the world for use in specific patients with moderate-to-severe atopic dermatitis, as well as certain patients with asthma or CRSwNP in different age populations. Dupixent is also approved in one or more of these indications in more than 60 countries around the world and more than 300,000 patients have been treated globally.

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 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 approximately a quarter of all original, FDA-approved or authorized fully human monoclonal antibodies currently available. This includes Dupixent, REGEN-COV[®] (casirivimab and imdevimab), Libtayo[®] (cemiplimab-rwlc), Praluent[®] (alirocumab), Kevzara[®] (sarilumab), Evkeeza[®] (evinacumab-dgnb) and Inmazeb[™] (atoltivimab, maftivimab, and odesivimab-ebgn).

Dupilumab Development Program

Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. To date, dupilumab has been studied across 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, including pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), eosinophilic esophagitis (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), chronic inducible urticaria-cold (Phase 3), chronic rhinosinusitis without nasal polyposis (Phase 3), allergic fungal rhinosinusitis (Phase 3), allergic bronchopulmonary aspergillosis (Phase 3) and peanut allergy (Phase 2). 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 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 6 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 6 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®.

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.
 - A pregnancy registry for women who take DUPIXENT during pregnancy collects information about the health of you and your baby. To enroll or get more information 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 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), high count of a certain white blood cell (eosinophilia), and parasitic (helminth) infections.
- **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, 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 accompanying 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 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 additional information about the company, please visit 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.

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 or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of 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) for the treatment of moderate-to-severe atopic dermatitis in children aged 6 months to 5 years; 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 for the treatment of pediatric atopic dermatitis, chronic obstructive pulmonary disease with evidence of type 2 inflammation, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, peanut allergy, 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 study discussed 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, including without limitation Dupixent; 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 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, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as its REGEN-COV® (casirivimab and imdevimab) supply agreement with the U.S. government, 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, Praluent® (alirocumab), and REGEN-COV), 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, 2020 and its Form 10-Q for the quarterly period ended September 30, 2021. 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 (<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, 2020. 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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[6-months-to-5-years-with-moderate-to-severe-atopic-dermatitis-featured-in-rad-2021-late-breaking-session-301442669.html](https://www.regeneron.com/press-releases/6-months-to-5-years-with-moderate-to-severe-atopic-dermatitis-featured-in-rad-2021-late-breaking-session-301442669.html)

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