# Dupixent® (dupilumab) Data at Revolutionizing Atopic Dermatitis (RAD) Conference Reinforce Use in Atopic Dermatitis Patients with Skin of Color

June 7, 2025 at 6:30 PM EDT

**Atopic dermatitis is a chronic disease that disproportionately impacts communities of color**

**Dupixent achieved 75% or greater improvement in overall disease severity, the primary endpoint, in more than three-quarters of treated patients**

**Patients experienced substantial reductions in hyperpigmentation, dry skin and itch from baseline**

**Results support commitment to enhance clinical understanding of chronic diseases in communities of color**

TARRYTOWN, N.Y. and PARIS, June 07, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today presented results from the DISCOVER Phase 4, single-arm, open-label trial assessing Dupixent® (dupilumab) in adults and adolescents with moderate-to-severe atopic dermatitis with skin of color. These are the first clinical trial results for Dupixent in a large population of patients with darker skin tones. The results, along with the Dupixent Phase 3 trials, demonstrated patients taking Dupixent experienced improvements in signs and symptoms of atopic dermatitis from baseline across many skin tones. The data were shared in an oral presentation at the 2025 Revolutionizing Atopic Dermatitis (RAD) Conference.

“Atopic dermatitis, a chronic disease with underlying type 2 inflammation, has a high prevalence and quality of life impact on patients with skin of color. Unique clinical features like darker patches of hyperpigmentation versus redness typically seen on lighter skin may lead to less accurate diagnoses and underestimation of disease severity,” said Andrew Alexis, M.D., M.P.H. “The results from the DISCOVER trial showed that Dupixent patients with atopic dermatitis and darker skin not only experienced reduced disease severity and itch but also saw improvements in areas of particular concern including dyspigmentation and dry skin. These data deepen the clinical understanding of atopic dermatitis within this underserved population, including use of newly validated scales.”

In the trial, 120 patients with atopic dermatitis and skin of color (82% Black, 11% Asian, 2% American Indian/Alaska Native, 5% Arab, Central American or other) were treated with Dupixent every two weeks using a weight-based dosing regimen. At 24 weeks:

- 76% achieved a ≥75% improvement in overall disease severity (EASI-75), the primary endpoint. Improvements were seen by some patients as early as two weeks.
- 53% achieved clinically meaningful improvement in itch (≥4-point reduction on the peak-pruritus numerical rating scale [PP-NRS]). Improvements were seen by some patients as early as two weeks.
- Patients experienced a 53% reduction from baseline in post-inflammatory hyperpigmentation, dropping from 5.1 points (moderate/marked) to 2.4 points (mild).
- 18% were very or extremely bothered by dry skin vs. 78% at baseline, based on patient reporting.

The safety results in the DISCOVER trial were generally consistent with the known safety profile of Dupixent in its approved dermatological indications. The overall rate of adverse events (AEs; n=124) in the DISCOVER trial was 42%, with the most common (≥2%) AEs being headache (3%), upper respiratory tract infection (2%), eczema (2%), conjunctivitis (3%) and allergic conjunctivitis (2%).

**About Atopic Dermatitis in Skin of Color**
Atopic dermatitis is a chronic skin disease with underlying type 2 inflammation that causes intense, persistent itch and skin lesions that cover much of the body, resulting in skin dryness, cracking, pain, crusting and oozing. In patients with skin of color, the type and location of the lesions can vary, and they are more likely to have hardened skin lesions and severe skin dryness, itch, dyspigmentation and greater disease severity than those with lighter skin. Additionally, redness that is observed on lighter skin typically appears as darkened, grey or violet on darker skin tones. Because the disease presents differently in people with skin of color, it can be misdiagnosed or the severity underestimated, which can contribute to higher levels of healthcare resource utilization.

**About the DISCOVER Clinical Trial**
The DISCOVER Phase 4 open-label, single-arm trial evaluated the efficacy and safety of Dupixent in adults and adolescents aged 12 years and older with moderate-to-severe atopic dermatitis and skin of color, as defined by Fitzpatrick skin types IV-VI (those with high melanin; light brown to black). During the 24-week treatment period, all patients in the trial received Dupixent monotherapy every two weeks based on weight after a loading dose: patients weighing ≥30 to <60 kg received 200 mg and patients weighing ≥60 kg received 300 mg.

The primary endpoint assessed the proportion of patients who achieved at least 75% improvement on the Eczema Area and Severity Index (EASI-75) at 24 weeks. Secondary endpoints included the proportion of patients who achieved ≥4-point improvement on the Peak-Pruritus Numerical Rating Scale (PP-NRS) at 24 weeks. Additional endpoints included pigmentary changes on the clinician-reported Post-Inflammatory Hyperpigmentation Severity Scale (PHSS; scale: 0-8) and skin dryness on the newly developed patient-reported Xerosis NRS (X-AD; scale: 0-10) at 24 weeks.

**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, chronic spontaneous urticaria (CSU) and chronic obstructive pulmonary disease (COPD) in different age populations. More than 1,000,000 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, 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 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 in Phase 3 trials, including chronic pruritus of unknown origin, bullous pemphigoid, 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 atopic dermatitis 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 chronic rhinosinusitis with nasal polyps 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 eosinophilic esophagitis 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 prurigo nodularis 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 chronic obstructive pulmonary disease 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

chronic spontaneous urticaria under 12 years of age, or who weigh less than 66 pounds (30 kg).

DUPIXENT is not used to relieve sudden breathing problems and will not replace an inhaled rescue medicine.

DUPIXENT is not used 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. 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, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic obstructive pulmonary disease, or chronic spontaneous urticaria, 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 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, joint pain, general ill feeling, itching, skin rash, swollen lymph nodes, nausea or vomiting, 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 have: 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 and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, dry eye, 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 and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, high count of a certain white blood cell (eosinophilia), 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 and eyelid inflammation, including redness, swelling, and itching, sometimes with 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, gastritis, joint pain (arthralgia), toothache, headache, and urinary tract infection.
- **Chronic Spontaneous Urticaria**: injection site reactions.

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.

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*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 in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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, 2024 and its Form 10-Q for the quarterly period ended March 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.*

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[1] Data on File

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Source: Regeneron Pharmaceuticals, Inc.