Media Update

RAD: Dupixent data reinforce use in atopic dermatitis patients with skin of color

- Atopic dermatitis is a chronic disease with underlying type 2 inflammation 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

Paris and Tarrytown, NY, June 8, 2025. Results from the DISCOVER phase 4, single-arm, open-label study assessing Dupixent (dupilumab) in adults and adolescents with moderate-to-severe atopic dermatitis with skin of color, were shared in an oral presentation at the 2025 Revolutionizing Atopic Dermatitis (RAD) Conference. These are the first clinical study results for Dupixent in a large population of patients with darker skin tones. The results, along with the Dupixent phase 3 studies, demonstrated patients taking Dupixent experienced improvements in signs and symptoms of atopic dermatitis from baseline across many skin tones.

> ***Andrew Alexis, MD, MPH***
> Professor of Clinical Dermatology at Weill Cornell Medicine
> *"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. The results from the DISCOVER study 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 study, 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 study 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 study 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 study

The DISCOVER phase 4 open-label, single-arm study 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 study 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 (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL4) and interleukin-13 (IL13) 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 studies, establishing that IL4 and IL13 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, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and chronic obstructive pulmonary disease in different age populations. More than one million patients are being treated with Dupixent globally.

Dupilumab development program

Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. To date, dupilumab has been studied across more than 60 clinical studies

involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation.

In addition to the currently approved indications, Sanofi and Regeneron are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in phase 3 studies, 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.

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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