

Press Release: Dupixent phase 3 study confirms significant improvements in itch and hives for patients with CSU

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Dupixent phase 3 study confirms significant improvements in itch and hives for patients with CSU

- Confirming the results of CUPID-A, this second pivotal study in biologic-naïve patients met primary and key secondary endpoints, showing treatment with Dupixent resulted in a nearly 50% reduction in itch and urticaria activity scores compared to placebo
- More than 300,000 people in the US suffer from chronic spontaneous urticaria (CSU) that is inadequately controlled by antihistamines
- Data will support regulatory resubmission in the US by year-end; if approved, Dupixent would be the first targeted therapy for CSU in a decade

Paris and Tarrytown, NY, September 11, 2024. A Dupixent (dupilumab) confirmatory phase 3 study (LIBERTY-CUPID Study C) met the primary and key secondary endpoints for the investigational treatment of patients with uncontrolled, biologic-naïve CSU receiving background therapy with antihistamines. CSU is a chronic skin condition that causes sudden and debilitating hives and persistent itch, which can impact quality of life. This positive study confirms **results** from Study A, the first phase 3 study of Dupixent in this setting. Earlier this year, Japan was the first country in the world to **approve** and launch Dupixent for adult and adolescent CSU patients based on the results from Study A.

Dietmar Berger, M.D., Ph.D.

Chief Medical Officer, Global Head of Development at Sanofi

“The positive pivotal data from this study reinforce the potential of Dupixent to offer a new treatment option for the many people suffering from chronic spontaneous urticaria who do not respond to standard-of-care antihistamines. With clinically meaningful reductions in itch and hives for patients receiving Dupixent, we look forward to sharing these data with the FDA to bring Dupixent to patients with CSU in the US as soon as possible. With Dupixent now treating 1 million patients across seven approved indications, these new results underscore there are still many more patients that Dupixent can potentially benefit.”

Study C enrolled 151 children and adults randomized to receive Dupixent (n=74) or placebo (n=77) added to standard-of-care histamine-1 (H1) antihistamines. At 24 weeks, efficacy among patients receiving Dupixent compared to placebo was as follows:

- 8.64-point reduction in itch severity from baseline with Dupixent versus a 6.10-point reduction with placebo (p=0.02)
- 15.86-point reduction in urticaria activity (itch and hive) severity from baseline with Dupixent versus an 11.21-point reduction with placebo (p=0.02)

Notably, 30% of Dupixent-treated patients reported no urticaria (complete response), compared to 18% of those on placebo (p=0.02).

The safety results were generally consistent with the known safety profile of Dupixent in its approved dermatological indications. Overall rates of treatment emergent adverse events (AE) were 53% for Dupixent and 53% for placebo. AEs more commonly observed with Dupixent ($\geq 5\%$) compared to placebo included injection site reactions (12% vs. 4%), accidental overdose (7% vs. 3%), and COVID-19 infection (8% vs. 5%).

Detailed results from this study will be provided to the US Food and Drug Administration in response to the **additional data requested** for inclusion in the supplemental biologics application for Dupixent in CSU. These data are also planned for presentation at a forthcoming medical meeting.

George D. Yancopoulos, M.D., Ph.D.

Board Co-Chair, President, and Chief Scientific Officer at Regeneron

“Patients with uncontrolled chronic spontaneous urticaria experience debilitating itch and hives that appear without warning and disrupt their lives. With a nearly 50% reduction in itch and urticaria activity scores compared to placebo, these positive phase 3 results reaffirm the potential of Dupixent to bring relief and its well-established safety profile to those living with this chronic inflammatory skin disease.”

Outside of Japan, the safety and efficacy of Dupixent for CSU has 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 persistent itch. CSU is typically treated with H1 antihistamines, medicines that target H1 receptors on cells to control symptoms of urticaria. However, the disease remains uncontrolled despite antihistamine 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 the Dupixent phase 3 CSU program (LIBERTY-CUPID)

The LIBERTY-CUPID Phase 3 study program evaluating Dupixent in CSU consists of Study A, **Study B**, and Study C.

Study C was a randomized, double-blind, placebo-controlled clinical study that evaluated the efficacy and safety of Dupixent as an add-on to standard-of-care antihistamines compared to antihistamines alone in 151 patients aged six years and older with CSU who remained symptomatic despite antihistamine use and were not previously treated with omalizumab (i.e., biologic-naïve). The primary endpoint assessed the change from baseline in itch at 24 weeks (measured by the weekly itch severity score [ISS7], 0-21 scale). A key secondary endpoint was the change from baseline in itch and hives at 24 weeks (measured by the weekly urticaria activity score [UAS7], 0-42 scale).

Study A supported the **approval** of Dupixent in Japan for the treatment of CSU in people aged 12 years and older whose disease is not adequately controlled with existing therapy.

Results from Study A and Study B, which assessed Dupixent in patients aged 12 years and older who were uncontrolled on standard-of-care H1 antihistamines and refractory to omalizumab, were **published** in The Journal of Allergy and Clinical Immunology.

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 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 polyposis, eosinophilic esophagitis, prurigo nodularis, CSU, and chronic obstructive pulmonary disease in different age populations. More than

1,000,000 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 and bullous pemphigoid. 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

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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Attachment

- **Press Release**

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