News Releases

Dupixent® approved in Canada as targeted therapy for chronic spontaneous urticaria (CSU)

- Dupixent is the first new targeted therapy in over a decade for people aged 12 years and older living with CSU who remain symptomatic despite H1 antihistamine treatment
- Approval based on phase 3 studies demonstrating Dupixent® significantly reduced itch and hives compared to placebo
- Between 0.5%-1% of Canadians aged 12 years and older living with CSU who remain symptomatic despite H1 antihistamine treatment[1]
- CSU is the seventh disease with underlying type 2 inflammation in which Dupixent® is approved in Canada

Toronto, Canada, November 3, 2025. Health Canada has issued a Notice of Compliance for Dupixent® (dupilumab) for the treatment of chronic spontaneous urticaria (CSU) in patients aged 12 years and older who remain symptomatic despite H1 antihistamine treatment. It is the first new target therapy in over a decade for this patient population.

CSU is a chronic inflammatory skin disease, partially driven by type 2 inflammation, which causes sudden and debilitating flare-ups which include hives and recurring itch, and in some cases, angioedema also known as swelling of the lips and eyes, with no known cause. Currently, CSU affects up to between 0.5%-1% of Canadians[2]. Approximately 50% of patients have an insufficient response to H1 antihistamines[3] There is a huge mental burden associated with CSU; 17% of patients present with depressive disorders and 30% of patients present with anxiety[4]

Dr. Jason Lee
Allergist
"Many people don't realize that chronic spontaneous urticaria isn't a typical allergic reaction –it's a dysregulated imbalance in the immune system. The hives appear spontaneously, and for many patients, antihistamines alone don't provide sufficient control. Having additional treatment approaches available allows us to better address the needs of this patient population."

Dr. Elena Netchiporouk
Dermatologist
"As a dermatologist, I see the challenges that chronic spontaneous urticaria presents to patients in my practice. The availability of a new treatment option is welcome news for the medical community. This approval adds to our available tools when working with CSU patients who remain symptomatic despite antihistamine treatment."

Dana Gies
Executive Director, Canadian Skin Patient Alliance
"For too long, people with chronic spontaneous urticaria have lived in uncertainty - never knowing when the next flare will strike, canceling plans, missing important moments, and feeling isolated by a condition that others can't always understand. Today's approval represents an important day for the CSU community in Canada. It means that those who have been suffering in silence, those who have tried existing treatments without finding relief, now have another option to discuss with their healthcare providers."

James Guy
Country Lead & General Manager, Specialty Care, Sanofi Canada
"As Dupixent®'s seventh approved indication in Canada, this represents an important milestone for the CSU community. The challenges patients face and the impact this condition can have on their daily lives drive our team's continued pursuit of innovative solutions. We are committed to addressing the needs of Canadians affected by type 2 inflammatory diseases and are proud to offer healthcare providers a new treatment option."

The Health Canada approval is based on data from two phase 3 clinical studies, LIBERTY- CUPID Study A (n=136) and (n=136) and Study C (n=148), which included biologic-naïve patients aged 12 years and older who were symptomatic despite the use of antihistamines and assessed DUPIXENT® as an add-on therapy to standard-of-care antihistamines, compared to antihistamines alone. Both studies met their primary and key secondary endpoints with Dupixent® demonstrating reductions in itch severity and urticaria activity (a composite of itch and hives) compared to placebo at 24 weeks. Dupixent® also increased the likelihood of well-controlled disease or complete response compared to placebo at 24 weeks. Study B (n=108) provided additional safety data and evaluated Dupixent® in patients aged 12 years and older who were inadequate responders or intolerant to anti-IgE therapy and symptomatic despite H1 antihistamine use.ïve patients aged 12 years and older who were symptomatic despite the use of antihistamines and assessed DUPIXENT® as an add-on therapy to standard-of-care antihistamines, compared to antihistamines alone. Both studies met their primary and key secondary endpoints with Dupixent® demonstrating reductions in itch severity and urticaria activity (a composite of itch and hives) compared to placebo at 24 weeks.

Dupixent® also increased the likelihood of well-controlled disease or complete response compared to placebo at 24 weeks. Study B (n=108) provided additional safety data and evaluated Dupixent® in patients aged 12 years and older who were inadequate responders or intolerant to anti-IgE therapy and symptomatic despite H1 antihistamine use.

Safety results from Study A, Study B, and Study C were generally consistent with the known safety profile of Dupixent® in its approved indications. In pooled data from all three studies, the most common adverse event (≥2%) more frequently observed in patients on Dupixent® compared to placebo was injection site reactions.

Dupixent® is already approved for CSU in the United States, Japan, the United Arab Emirates, and Brazil. Submissions are currently under review with other regulatory authorities around the world.

Dupixent® (dupilumab) is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. In Canada, Dupixent® is jointly commercialized by sanofi-aventis Canada Inc. and Regeneron Canada.

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 H1 antihistamines, medicines that target H1 receptors on cells to control symptoms of itch and 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® CSU phase 3 study program
The LIBERTY-CUPID phase 3 program evaluating DUPIXENT® for CSU consists of Study A, Study B, and Study C. These studies were randomized, double-blind, placebo-controlled clinical studies that evaluated the efficacy and safety of DUPIXENT® as an add-on therapy to standard-of-care antihistamines compared to antihistamines alone. Studies A and C were replicate studies that assessed patients aged 12 years and older who remained symptomatic despite the use of antihistamines. Study B was conducted in patients aged 12 years and older who were symptomatic despite use of antihistamines and were inadequate responders or intolerant to anti-IgE therapy. During the 24-week treatment period in all three studies, patients received an initial loading dose followed by 300 mg DUPIXENT® every two weeks, except for pediatric patients weighing <60 kg who received 200 mg every two weeks.

In all three studies, the primary endpoint assessed the change from baseline in itch at 24 weeks (measured by the weekly itch severity score, 0-21 scale). The key secondary endpoints (also assessed at 24 weeks) included change from baseline in itch and hives (weekly urticaria activity score [UAS7], 0-42 scale). Additional secondary endpoints assessed at 24 weeks evaluated the proportion of patients achieving well-controlled disease status (UAS7 ≤6) and the proportion of patients with complete response (UAS7=0).

About DUPIXENT®
Dupixent® 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.

In Canada, Dupixent® has received regulatory approvals for certain patients in the following indications atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, prurigo nodularis and COPD in different age populations.

For more information about Dupixent®, please refer to the Canadian Product Monograph.

Dupixent® is a registered trademark owned by Sanofi Biotechnology and used under license.

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.

Sanofi is the largest biopharma manufacturer in Canada, and the only company investing, innovating and operating across the full life sciences value chain. We are 2,000+ employees strong, invest 20% of our revenue annually in biopharma research, and are on track to deliver over $2 billion in new infrastructure investments by 2028. Sanofi is committed to our community and is working with partners to foster a long-term sustainable ecosystem and build a healthier Canada.

For more information and media inquiries, please contact:
Bethany Rubin | +1 437-518-4769 | bethany.rubin@sanofi.com

Julien Guyomard |+1 416-434-3134 | julien.guyomard@sanofi.com

---

[1] *Insights and advances in chronic urticaria: a Canadian perspective*
[2] *Insights and advances in chronic urticaria: a Canadian perspective*
[3] Maurer et al, Allergy. 2011 (66); 317-330
[4] Staubach et al, Acta Derm Venereol. 2011 (91) 557-561