News Releases

Dupixent® (dupilumab injection) approved in Canada for adults with inadequately controlled Chronic Obstructive Pulmonary Disease (COPD)

- Dupixent® is the first and only biologic approved for adults living with inadequately controlled chronic obstructive pulmonary disease (COPD) characterized by elevated blood eosinophiles – and the first new treatment option approved in over a decade
- COPD is the 5th leading cause of death inCanada[1,2]
- COPD represents the sixth approved indication overall and third indication in respiratory disease for Dupixent® in Canada

TORONTO, Oct. 22, 2025 /CNW/ - Health Canada has approved Dupixent® (dupilumab injection) as an add-on maintenance treatment in adult patients with chronic obstructive pulmonary disease (COPD) characterized by raised blood eosinophils inadequately controlled by the combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate. COPD is a respiratory disease that damages the lungs, causes progressive lung function decline and is the fifth leading cause of death in Canada[3].

This approval was based on findings from two clinical studies conducted in adult patients already receiving maximal standard-of-care inhaled therapy. The BOREAS and NOTUS studies showed a 30% and 34% reduction in moderate or severe exacerbations over one year[4].

COPD with Type 2 inflammation, characterized by elevated blood eosinophil levels, has limited treatment options — especially for patients who remain uncontrolled despite triple therapy. The approval of Dupixent® covers inadequately controlled patients who are already on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate.

Dr. Ken Chapman
Director, Asthma & Airway Centre, University Health Network,
Professor of Medicine, University of Toronto

"This is an exciting discovery for some of my most at-risk patients living with COPD. Although we've made slow and steady progress to improve the lives of those who struggle with chronic bronchitis or emphysema, we've had little to offer the most vulnerable of them who have exacerbations frequently. We know that these frequent visits to the walk-in clinic, emergency room or hospital ward mark a period of rapid decline. Research with Dupixent® shows that a simple blood test will identify which of these vulnerable patients is most likely to enjoy fewer flareups, better lung function, and improved quality of life when treated with this novel therapy."

Dr. Jean Bourbeau
Director, COPD clinic and Pulmonary Rehabilitation, McGill University Health Centre (MUHC)
Respirologist, Respiratory Division, Department of Medicine, MUHC

"The unmet need in COPD with acute exacerbations is huge considering not only the patient impact and premature death but COPD being the number one cause of hospital admissions in Canada. Identifying treatable traits of type 2 inflammation and considering a targeted specific therapy strategy in COPD is now possible with a novel biologic therapy such as dupilumab. Let's not accept that it is normal for our patients to continue to have recurrent and/or severe exacerbations, let's take action."

Henry Roberts
Managing Director, Chronic Obstructive Pulmonary Disease Association Canada (COPD Canada)

"Our community members often share how breathlessness forces them into isolation, missing family gatherings and

simple pleasures like walking outdoors. The approval of Dupixent® represents a beacon of hope for Canadians living with uncontrolled COPD who have been waiting far too long for meaningful treatment advancements."

James Guy
General Manager Specialty Care and Sanofi Country Lead Canada

"This approval marks a pivotal moment in COPD management for patients inCanada. By advancing breakthrough science in respiratory medicine, we're delivering meaningful solutions for Canadian patients whose condition is not being effectively managed by existing treatments. We are committed to working alongside healthcare providers to ensure this new option reaches patients living with uncontrolled COPD."

About BOREAS and NOTUS Phase 3 Trials

The approval is based on results from the landmark phase 3 BOREAS and NOTUS studies, which were separately published in *The New England Journal of Medicine* and evaluated the efficacy and safety of Dupixent® in adults with uncontrolled COPD with evidence of type 2 inflammation (i.e., blood eosinophils ≥300 cells per µL). All patients were on background maximal standard-of-care inhaled therapy (with nearly all on triple therapy). In terms of efficacy, Dupixent® patients in BOREAS (n=468) and NOTUS (n=470) experienced the following, respectively, compared to placebo (BOREAS n=471; NOTUS n=465):

- 30% and 34% reduction in the annualized rate of moderate or severe COPD exacerbations over 52 weeks, the primary endpoint.
- Improvements in lung function (pre-bronchodilator FEV_1) from baseline by 160 mL and 139 mL at 12 weeks compared to 77 mL and 57 mL. These improvements were observed as early as week 2 and 4 and were sustained at 52 weeks in both studies.
- Improvements in health-related quality of life (statistically significant in BOREAS and nominally significant in NOTUS), as assessed by the St. George's Respiratory Questionnaire.

Safety results in both studies were generally consistent with the known safety profile of Dupixent® in its approved indications. The most common side effects across indications include injection site reactions, conjunctivitis, conjunctivitis allergic, arthralgia, oral herpes, and eosinophilia. Adverse events more commonly observed with Dupixent® (≥5%) compared to placebo in either COPD study were back pain, COVID-19, diarrhea, headache and nasopharyngitis. Additional adverse reactions of injection site bruising, injection site induration, injection site rash and injection site dermatitis were reported in the COPD studies.

Dupixent® for COPD patients have been approved by other regulatory authorities around the world including the European Union, the US, China and Japan.

About COPD
COPD is a respiratory disease that damages the lungs and causes progressive lung function decline and is the fourth leading cause of death worldwide. Symptoms include persistent cough, excessive mucus production and shortness of breath that may impair the ability to perform routine daily activities, which may lead to sleep disturbances, anxiety, and depression. COPD is also associated with a significant health and economic burden due to recurrent acute exacerbations that require systemic corticosteroid treatment and/or lead to hospitalization. Smoking and exposure to noxious particles are key risk factors for COPD, but even individuals who quit smoking can still develop or continue having the disease. There have been no new treatment approaches approved for more than a decade.

COPD in Canada carries significant economic costs, with exacerbations costing $646-$736 million annually.[5] As the 5th leading cause of death in Canada,[6] COPD hospitalizations range from $10,000-$15,000 per stay.[7] Beyond direct healthcare costs, approximately 20% of patients retire early, while caregivers face annual income losses of approximately $16,000.[8]

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.

More than 1,000,000 patients are being treated with Dupixent® globally.

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.

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.

[1] Hospital stays in Canada. Canadian Institute for Health Information. 2020. https://www.cihi.ca/en/hospital-stays-in-canada. Accessed 31 July 2020.

[2] Leading causes of death, total population, by age group. Statistics Canada. 2018. https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310039401. Accessed 31 July 2020.

[3] Lung Health Foundation.

[4] Dupixent®. Product Monograph. Sanofi. October 2025.

[5] Mittmann N., et al. The cost of moderate and severe COPD exacerbations to the Canadian healthcare system. Respir Med. 2008;102:413–21

[6] Lung Health Foundation.

[7] Yan C., et al. Pharmacoecon Open. 2023;7(3):493-505.

[8] Fletcher MJ., et al. BMC Public Health. 2011;11:612.

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For further information: 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