

DUPIXENT® (dupilumab injection) now approved in Canada for children as young as six months old with severe atopic dermatitis

*** This is the seventh indication for Dupixent® in Canada**

TORONTO, April 20, 2023 /CNW/ - Sanofi-aventis Canada Inc. (Sanofi Canada) announced today that Health Canada has issued a Notice of Compliance for the treatment of patients aged 6 months to 5 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.¹

Atopic dermatitis, the most common form of eczema, is a chronic inflammatory disease.² Between 85% and 90% of patients first develop symptoms before 5 years of age, which can often continue through adulthood.³ In its moderate-to-severe form, it is characterized by rashes that can potentially cover much of the body, and can include intense, persistent itching, skin lesions and skin dryness, cracking redness, crusting and oozing.² Inadequately controlled atopic dermatitis negatively impacts children's mood, behaviour, attention at school, ability to participate in sports, and sleep.^{4,5}

Dr. Danielle Marcoux, MD, FRCPC, FAAD

Clinical Professor, University of Montreal and Sainte-Justine University Medical Centre, Department of Pediatrics, Dermatology Division

"Dupixent® is already an important treatment for adults, adolescents and children impacted by moderate-to-severe atopic dermatitis, and expanding its indication is a promising new option for treating infants and children (6 months and up) who are living with this chronic disease that significantly impacts the quality of life of the patient and care-giver. This treatment will help young patients and their families gain more control over their symptoms during a pivotal time in their development."

Amanda Cresswell-Melville

Executive Director of Eczema Society of Canada (ESC)

"Atopic dermatitis can be challenging, disruptive, and painful, in addition to the burdensome itch and skin symptoms. It can be especially challenging when a child is suffering, and advancements in research and therapies offer hope to patients."

Stephanie Veyrun-Manetti

Canada Country Lead and General Manager of Specialty Care at Sanofi Canada

"Atopic dermatitis can be devastating to infants, children and their families. With Dupixent®, we're proud to be able to provide this medicine that has the potential to transform the landscape for people of all ages living with this disease."

The approval is based on data from a [Phase 3 trial](#) evaluating Dupixent® every four weeks (200 mg or 300 mg based on body weight) plus low-potency TCS or TCS alone (placebo) in 162 children ages 6 months to 5 years with moderate-to-severe atopic dermatitis.

About Dupixent®

Dupixent® 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.

Dupixent® was first approved in Canada in 2017 for the treatment of adults with moderate-to-severe atopic dermatitis. Dupixent® has since been approved for the treatment of adolescents and children aged six and older with moderate-to-severe atopic dermatitis; adults with chronic rhinosinusitis with nasal polyps (CRSwNP); adults, adolescents, children aged six and older with severe asthma; and now infants and children aged 6 months to 5 years old for moderate-to-severe atopic dermatitis.

Dupixent® is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. In Canada, Dupixent® is jointly commercialized by Sanofi Canada and Regeneron Canada Company.

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 some 100 countries, 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.

In Canada, Sanofi employs approximately 2,000 people and in 2020, we invested more than \$145 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

Follow us on Twitter [@SanofiCanada](https://twitter.com/SanofiCanada)

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.

For more information and media inquiries, please contact:

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¹ Dupixent[®] Product Monograph, March 31, 2023.

² Mount Sinai. Patient Care Atopic Dermatitis. Available at: <http://www.mountsinai.org/patient-care/health-library/diseases-and-conditions/atopic-dermatitis#risk>. Accessed March 31, 2023.

³ American Academy of Dermatology. Skin Conditions By the Numbers. Available at: <https://www.aad.org/media/stats-numbers>. Accessed April 14, 2023

⁴ Eczema Society of Canada. Quality of Life Report Moderate-to-Severe Disease 2016/2017 Survey Results. Self-Published; 2017.

⁵ Eczema Society of Canada. Atopic Dermatitis Patient Journey. Self-Published; 2020.

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