News Releases

Dupixent® (dupilumab injection) now approved in Canada for the treatment of severe asthma in children aged six to 11 years with type 2 inflammation

- This is the sixth indication for Dupixent in Canada, its second in asthma, and its second in children aged six to 11 years[i]
- Dupixent is the only biologic approved in Canada to treat severe asthma with type 2 / eosinophilic phenotype, or oral corticosteroid-dependent asthma

MISSISSAUGA, ON, March 28, 2022 /CNW/ - Today sanofi-aventis Canada Inc. (Sanofi Canada) announced the expanded approval of Dupixent® (dupilumab injection) as an add-on maintenance treatment in patients aged six to 11 years with severe asthma with a type 2 / eosinophilic phenotype or oral corticosteroid-dependent asthma. The approval is based on the pivotal VOYAGE phase 3 trial which enrolled 408 children aged six to 11 years with uncontrolled moderate- to severe asthma. The primary endpoint of the trial was the annualized rate of severe asthma exacerbations[ii].

Reza Alizadehfar, MD FRCPC
Training Program Director, Associate Professor of Pediatrics, Division of Allergy and Clinical Immunology, Montreal Children's Hospital
"Dupixent is already an important treatment option for adults and adolescents disabled by severe asthma, and expanding its clinical applicability to include children aged six to 11 creates opportunities to make life better for some of the many Canadian children whose lives are restricted by their severe asthma."

Sixth indication for Dupixent, its second in asthma, and its second indication in children aged six to 11 years

Dupixent was first approved in Canada in 2017 for the treatment of adults with atopic dermatitis. Dupixent has since been approved for the treatment of adolescents and children aged six and older with atopic dermatitis; adults with chronic rhinosinusitis with nasal polyposis (CRSwNP); and adults, adolescents and now children aged six and older with severe asthma. Dupixent is the first medicine approved for the treatment of severe asthma with a type 2 inflammation phenotype. More than 8,500 Canadians have been treated with Dupixent across its various indications.

Eric Trottier, PhD
Head of Medical Affairs, Specialty Care at Sanofi Canada
"Almost every single day, we at Sanofi hear a new story about Dupixent making a profound impact in someone's life. Now, with this pediatric indication for Dupixent, we're excited at the opportunity to potentially help Canadian children with severe asthma to have fewer attacks, and to help their parents breathe easier, too."

About asthma

Asthma is a chronic inflammatory disease of the airways that causes symptoms like shortness of breath, chest tightness, coughing and wheezing. Asthma causes inflammation and narrowing of the bronchial tubes, which leads to limited airflow and difficulty breathing[iii]. People with severe asthma experience difficulty breathing, coughing, wheezing, and are at risk for life-threatening asthma attacks, which may require visits to the emergency room or hospitalization[iv,v]. Some people with severe asthma can manage their symptoms with inhaled corticosteroids, while other people require different or additional kinds of medicine to manage their disease.

Asthma is the third-most common chronic disease among Canadians[vi,vii], and the most common chronic disease in Canadian children: 15% - 25% of Canadian children are diagnosed with asthma[viii].

Sheila DeVries
Mother of a child with severe asthma
"My daughter Payton's severe asthma has definitely affected everyone in our family as we help protect her and keep her healthy, so she doesn't suffer more than she already does. From wheezing and coughing episodes to numerous trips to

emergency and overnight hospital stays—we just want her to be able to run and play without constantly being wheezy and struggling to catch her breath."

Vanessa Foran
President and CEO, Asthma Canada
"It's exciting to see innovation in this space and a new medication to help children living with severe asthma, where there are very few treatment options. Anything that makes life easier for a child to run around, play, and go to school—the way kids should be able to—is a tool worth having."

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. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in severe asthma, atopic dermatitis, and chronic rhinosinusitis with nasal polyposis (CRSwNP).

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.

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Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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

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[i] Dupixent product monograph March 25, 2022

[ii] Bacharier, Leonard B., M.D., Jorge F. Maspero, M.D., Constance H. Katelaris, M.D., Alessandro G. Fiocchi, M.D., Remi Gagnon, M.D., Ines de Mir, M.D., Neal Jain, M.D., Lawrence D. Sher, M.D., Xuezhou Mao, Ph.D., Dongfang Liu, M.S., Yi Zhang, Ph.D., M.P.H., Asif H. Khan, M.B., B.S., M.P.H., et al. for the Liberty Asthma VOYAGE Investigators. Dupilumab in Children with Uncontrolled Moderate-to-Severe Asthma, December 9, 2021 N Engl J Med 2021; 385:2230-2240 DOI: 10.1056/NEJMoa2106567

[iii] Asthma Canada: Understanding Asthma. Accessed March 7, 2022

[iv] Asthma Canada: Asthma Facts and Statistics. Accessed March 7, 2022

[v] Asthma Canada: Severe Asthma. Accessed March 7, 2022

[vi] Government of Canada, Statistics Canada. (2010) Canadian community health survey (CCHS)—annual component. Ottawa: Statistics Canada

[vii] Government of Canada, Public Health Agency of Canada. (2007, November 21). Life and Breath: Respiratory Disease in Canada

[viii] Gershon AS, Guan J, Wang C, et al. (2010) Trends in asthma prevalence and incidence in Ontario, Canada, 1996–2005: a population study. *Am J Epidemiol* 172:728–36.

SOURCE Sanofi-Aventis Canada Inc.

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