News Releases

DUPIXENT® (dupilumab injection) approved in Canada for the treatment of children aged 1 year and older with eosinophilic esophagitis (EoE)

- This is the ninth indication for DUPIXENT® in Canada and its second in gastroenterology[1]
- Expanded indication marks second disease for which DUPIXENT® is approved in children this young in the country[1]

TORONTO, Sept. 12, 2024 /CNW/ - Health Canada has issued a Notice of Compliance (NOC) for DUPIXENT® (dupilumab injection) for the treatment of patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE). This approval expands the initial Health Canada Notice of Compliance for EoE in May 2023 for patients aged 12 years and older, weighing at least 40 kg.

EoE is a chronic, progressive disease driven in part by type 2 inflammation that damages the esophagus and impairs its function. EoE can severely impact a child's ability to eat, and they may experience heartburn, vomiting, abdominal discomfort, trouble swallowing, food refusal and failure to thrive as a result. These symptoms can adversely impact their growth and development. Continuous treatment of EoE may be needed to reduce the risk of complications and disease progression.

Dr. Nicholas Carman, MBBS
Pediatric Gastroenterologist, The Hospital for Sick Children,Toronto

"As a medical professional, I have witnessed firsthand the struggles faced by young patients and their families in managing EoE, which can severely impact their quality of life. Until now, therapeutic options for pediatric patients suffering with EoE have been limited and focused on managing symptoms as much as possible. DUPIXENT® offers a targeted therapy that addresses the underlying inflammation associated with EoE, providing a new and effective option for treatment. It's a pivotal step forward in our ongoing effort to improve care and outcomes for pediatric patients with this challenging condition."

Dr. Kelly Grzywacz, MD, MSc, FRCPC
Pediatric Gastroenterologist, CHU Sainte Justine

"The approval of DUPIXENT® for treating eosinophilic esophagitis in children is an important advancement for this community because we now have an effective medication for young patients who do not respond to first-line therapies. This advancement offers new hope and improved quality of life for our pediatric patients and their families."

Stephanie Veyrun-Manetti
Country Lead and General Manager of Specialty Care, Sanofi Canada

"We are deeply committed to our vision of becoming an industry leader in immunology, and the recent approval of DUPIXENT® for the treatment of pediatric eosinophilic esophagitis is a significant milestone in that journey. This approval represents a crucial step forward in our mission to advancing care for children and their families grappling with this difficult condition."

The DUPIXENT® product monograph includes data from the Phase 3 EoE KIDS trial with two parts (Part A and Part B) evaluating the efficacy and safety of DUPIXENT® in children aged 1 to 11 years with EoE. At 16 weeks, 67.6% of children who received high exposure, DUPIXENT® at tiered dosing regimens based on weight (n=37) achieved histological disease remission (≤6 eosinophils/high power field), the primary endpoint, compared to 3% for placebo (n=34).

Histological remission was sustained at week 52 in 62.9% of children treated with DUPIXENT® in Parts A and continued in the active treatment extension in Part B (n=32). In addition, a greater decrease in the proportion of days with one or more signs of EoE based on Pediatric EoE Sign/Symptom Questionnaire-caregiver version (PESQ-C) was observed in children treated with DUPIXENT® at 16 weeks compared to placebo.

The safety profile of DUPIXENT® observed through 16 weeks in children aged 1 to 11 years weighing at least 15 kg was generally similar to the safety profile of DUPIXENT® observed through 24 weeks in adult and patients aged 12 years and older with EoE.

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[1] DUPIXENT®. Product Monograph. Sanofi. August 2024.

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.

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, children and infants aged 6 months and older with moderate-to-severe atopic dermatitis; adults with chronic rhinosinusitis with nasal polyposis (CRSwNP); adults, adolescents, and children aged six years and older with severe asthma; adults and adolescents aged 12 years and older and children aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE) and adult patients with moderate-to-severe prurigo nodularis (PN) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

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

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.

In Canada, we employ over 2,000 people. We invest 20% of our revenue annually in biopharma research (representing $1.2 billion CAD in R&D investment over the last decade) creating jobs, business, and opportunities throughout the country. We are also on track to deliver over $2 billion CAD in new infrastructure investments by 2028.

In 2024, we are celebrating 110 years of heritage dedicated to developing innovative health solutions for Canadians. What started as a small laboratory in May of 1914, recognized for having advanced some of the greatest contributions to public health, both nationally and globally, has evolved to become the largest biomanufacturing facility in Canada.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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

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