News Releases

DUPIXENT® (dupilumab injection) now approved by Health Canada for patients with severe asthma

- Only biologic approved in Canada to treat severe asthma with type 2 / eosinophilic phenotype, or oral corticosteroid-dependent asthma
- Fourth indication for DUPIXENT[®] in Canada following approvals for moderate-to-severe atopic dermatitis in adults and adolescents and severe chronic rhinosinusitis with nasal polyposis (CRSwNP).¹

MISSISSAUGA, ON, Nov. 17, 2020 /CNW/ - Sanofi Canada announced today that Health Canada approved a new indication for DUPIXENT[®] (dupilumab injection), for adults and adolescents aged 12 years and older as an addon maintenance treatment for severe asthma with a type 2 / eosinophilic phenotype or oral corticosteroiddependent asthma.²

"For Canadians struggling with severe asthma, the approval of Dupixent offers an exciting new treatment pathway," says Dr. Kenneth Chapman, Professor of Medicine at the University of Toronto and Director of the Asthma and Airway Centre of the University Health Network. "Too often, such patients must resort to oral steroids to bring their disease under control."



DUPIXENT[®] is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins³ and is not an immunosuppressant. Data from DUPIXENT[®] clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in asthma, atopic dermatitis, and CRSwNP.

"Despite advances in treatment for severe asthma, there are many Canadians whose disease is inadequately controlled with current therapies, which can have a deep impact on their quality of life," says Marissa Poole, Country Lead, Sanofi Canada and General Manager, Sanofi Genzyme Canada. "With this additional indication for DUPIXENT[®], a new treatment option is now available that addresses the physiological aspect of the disease, to ultimately help patients achieve improved control of their symptoms."

Asthma is a chronic disease caused by swelling and inflammation of the airway, lining, and tightening of the muscles around the airway, which blocks the flow of air through the lungs.⁴ People with severe asthma experience difficulty breathing, coughing, wheezing, and are at-risk for life-threatening asthma attacks that may require emergency room visits or hospitalization.^{5,6} While some people with severe asthma can manage their symptoms with oral corticosteroids, others remain uncontrolled despite available treatments.

"The daily management of asthma can be a significant burden for Canadians living with the disease. It can be even more frustrating for those patients who are compliant with their Asthma Action Plan and medication, but their debilitating symptoms persist," says Vanessa Foran, President & CEO, Asthma Canada. "With better understanding of the physiological underlying cause of the disease and the development of treatments that address that root cause, many patients are able to reduce the number of treatments they use to effectively manage their disease and improve their quality of life."

About DUPIXENT®

DUPIXENT[®] was first approved by Health Canada on November 30, 2017, and remains the only biologic medicine for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.⁷ In September 2019, Health Canada expanded this approval to include adolescents aged 12 years and older.⁸ In August 2020, Health Canada approved DUPIXENT[®] for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyposis.⁹

DUPIXENT[®] is jointly developed by Sanofi and Regeneron under a global collaboration agreement.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi entities in Canada employ approximately 2,000 people. In 2018, we invested more than \$127 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

Follow us on Twitter <u>@SanofiCanada</u> and on <u>YouTube</u>.

Sanofi, Empowering Life

References

¹ DUPIXENT[®] Canada Product Monograph. November 12, 2020.

² DUPIXENT[®] Canada Product Monograph. November 12, 2020.

³ DUPIXENT[®] Canada Product Monograph. November 12, 2020.

⁴ Asthma Canada. Asthma Facts and Statistics. Available from <u>https://asthma.ca/wp-content/uploads/2020/07/Asthma-101.pdf</u>. Accessed October 15, 2020.

⁵ Asthma Canada. Severe Asthma. Available from <u>https://asthma.ca/get-help/severe-asthma/</u>. Accessed October 15, 2020.

⁶ Asthma Canada. Asthma Facts and Statistics. Available from <u>https://asthma.ca/wp-</u>

content/uploads/2020/07/Asthma-101.pdf. Accessed October 15, 2020.

⁷ DUPIXENT[®] Canada Product Monograph. November 12, 2020.

⁸ DUPIXENT[®] Canada Product Monograph. November 12, 2020.

⁹ DUPIXENT[®] Canada Product Monograph. November 12, 2020.

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For further information: Media Relations Contact, Marissa Smith, Tel: +1 (416) 892-2158, Marissa.Smith@sanofi.com