News Releases

DUPIXENT® (dupilumab injection) now approved by Health Canada for severe chronic rhinosinusitis with nasal polyposis

- *First biologic approved in Canada for adults with severe chronic rhinosinusitis with nasal polyposis (CRSwNP)*[1]
- *Third indication for DUPIXENT® in Canada following moderate-to-severe atopic dermatitis in adults and adolescents*[2]

MISSISSAUGA, ON, Aug. 18, 2020 /CNW/ - Sanofi Canada announced today that Health Canada approved a new indication for DUPIXENT® (dupilumab injection), as an add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyposis (CRSwNP) inadequately controlled by systemic corticosteroids and/or surgery,[3] making it the first biologic for the treatment of this disease inCanada.[4]

CRSwNP is a chronic, type 2 inflammatory disease of the upper airway that obstructs the sinuses and nasal passages. It can lead to breathing difficulties, nasal congestion and discharge, reduced or loss of sense of smell and taste and facial pressure.[5]

> *"At Sanofi Genzyme, we are committed to making a difference for patients by introducing innovative therapies that address unmet needs. The approval of Dupixent® for CRSwNP provides patients with the first biologic treatment to address the type 2 inflammation that underlies this debilitating disease,"* says Marissa Poole, Country Lead, Sanofi Canada and General Manager, Sanofi Genzyme Canada.

DUPIXENT® is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins[6] 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 atopic dermatitis and CRSwNP.

> *"Current standard of care therapies for CRSwNP use combinations of intranasal and systemic corticosteroids, with endoscopic sinus surgery, or ESS, used to treat patients not controlled by medication. Unfortunately, surgery is not universally effective, and in certain instances, disease can recur in as little as six months after surgery,"* says Dr. Martin Desrosiers, Clinical Professor, Program Director, ORL-HNS, Université de Montréal.*"Until now, therapeutic options for patients with surgery-unresponsive disease has been repeat surgery, with some patients undergoing as many as 10 previous surgeries. In clinical trials, DUPIXENT® has shown the capacity to control disease in this hard to treat group of patients, without resorting to surgery. The availability of DUPIXENT® thus provides a welcome new treatment option to help Canadian patients living with the burden of uncontrolled CRSwNP."*

About the DUPIXENT® Clinical Program

The Health Canada approval is based on two pivotal Phase 3 trials (the 24-week SINUS-24 and 52-week SINUS-52) that evaluated DUPIXENT® 300 mg every two weeks plus standard-of-care intranasal corticosteroids compared to placebo plus intranasal corticosteroids.[7] In these trials, patients treated with DUPIXENT® achieved statistically significant improvements in all primary and secondary endpoints at 24 weeks.[8] Treatment effects on nasal congestion and loss of smell were observed with the first assessment at 4 weeks and showed continued improvement for the duration of the trials.[9] In the CRSwNP clinical trials, the common (at least 1%) adverse events in the DUPIXENT® group were inflammation of the eye and eyelids (conjunctivitis), high count of certain white blood cells (eosinophilia), injection site reactions and injection site swelling.[10]

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.[11] In September 2019, Health Canada expanded the approval to include adolescents aged 12 years and older.[12]

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 @SanofiCanada and on YouTube.

Sanofi, Empowering Life

References

[1] DUPIXENT® Canada Product Monograph. August 12, 2020.
[2] DUPIXENT® Canada Product Monograph. August 12, 2020.
[3] DUPIXENT® Canada Product Monograph. August 12, 2020.
[4] DUPIXENT® Canada Product Monograph. August 12, 2020.
[5] *Can Fam Physician*. 2013;59(12):1275-81, e528-34
[6] DUPIXENT® Canada Product Monograph. August 12, 2020.
[7] DUPIXENT® Canada Product Monograph. August 12, 2020.
[8] DUPIXENT® Canada Product Monograph. August 12, 2020.
[9] DUPIXENT® Canada Product Monograph. August 12, 2020.
[10] DUPIXENT® Canada Product Monograph. August 12, 2020.
[11] DUPIXENT® Canada Product Monograph. August 12, 2020.
[12] DUPIXENT® Canada Product Monograph. August 12, 2020.

SOURCE Sanofi Canada

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