News Releases

DUPIXENT® (dupilumab) receives positive recommendation from INESSS for the treatment of moderate-to-severe atopic dermatitis in adolescents

- The *Institut national d'excellence en santé et en services sociaux* (INESSS) recommends extending existing coverage in Quebec to include patients aged 12 years and older
- Recommendation was supported by multiple clinical trials that demonstrated superiority of Dupixent® over placebo in improving disease extent and severity, skin clearance and itch intensity, as well as health-related quality of life
- Only biologic approved in Canada for patients aged 12 and older with moderate-to-severe atopic dermatitis

MISSISSAUGA, ON, July 14, 2020 /CNW Telbec/ - Sanofi Canada is pleased to announce a positive recommendation from the *Institut national d'excellence en santé et en services sociaux* (INESSS) for DUPIXENT® (dupilumab) for Quebec residents aged 12 to 17 years with moderate-to-severe atopic dermatitis whose disease is not adequately managed with current therapy and when specific conditions are met. Full details on the recommendation by INESSS, including recommended criteria for reimbursement, are available on the INESSS website.

"The impact that moderate-to-severe atopic dermatitis has both physically and emotionally on patients is significant, and it can be even more devastating for adolescents during their formative years," said Marissa Poole, Country Lead, Sanofi Canada and General Manager, Sanofi Genzyme Canada. "With this recommendation from INESSS, adolescents, and their caregivers who often play an integral role in helping to manage their disease, will now have access to DUPIXENT®."

DUPIXENT® is currently reimbursed by the Régie de l'assurance maladie Québec (RAMQ)ⁱⁱ and by the Non-Insured Health Benefits (NIHB) program for patients over the age of 18 with moderate to severe atopic dermatitis. Most recently, the Canadian Agency for Drugs and Technologies in Health (CADTH) Canadian Drug Expert Committee (CDEC) issued a recommendation that DUPIXENT® (dupilumab) be reimbursed by public drug plans for Canadians aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately managed with current therapy and when specific conditions are met. DUPIXENT® is also covered by most private insurance programs in Canada for adults and adolescents with moderate-to-severe atopic dermatitis.

Atopic dermatitis, the most common form of eczema, is a chronic inflammatory disease.^{iv} 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 or darkness, crusting and oozing.^v Inadequately controlled atopic dermatitis can have a physical, emotional and psychosocial impact, causing sleep disturbance, symptoms of anxiety and depression, and feelings of isolation.^{vi}

About DUPIXENT®: Innovative Treatment for Patients with Moderate-to-Severe Atopic Dermatitis

DUPIXENT® is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins.

DUPIXENT® was first approved by Health Canada on November 30, 2017 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. In September, 2019, Health Canada expanded the approval to include adolescents aged 12 years and older.

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.

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Sanofi, Empowering Life

- i INESSS. https://www.inesss.qc.ca/thematiques/medicaments/medicaments-evaluation-aux-fins-dinscription/extrait-davis-au-ministre/dupixent-5199.html. Accessed July 10, 2020
- ii DUPIXENT® (dupilumab) Product Monograph. Page 3. September 2019.
- iii CADTH. Available at: https://cadth.ca/sites/default/files/cdr/complete/SR0636%20Dupixent%20-%20CDEC%20Final%20%20Recommendation%20April%2024%2C%202020%20for%20posting.pdf. Accessed April 24, 2020.
- Mount Sinai. Patient Care Atopic Dermatitis. Available at: http://www.mountsinai.org/patient-care/health-library/diseases-and-conditions/atopic-dermatitis#risk. Accessed August 1, 2019.
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- vi Eczema Society of Canada. (2017). Atopic Dermatitis Quality of Life Report (Moderate-to-Severe Disease 2016/2017 Survey Results). Keswick, Ontario.
- vii DUPIXENT® (dupilumab) Product Monograph. Page 3. September 2019.
- viii DUPIXENT® (dupilumab) Product Monograph. Page 3. September 2019.

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