News Releases

Dupixent® (dupilumab injection) receives marketing authorization for prurigo nodularis

- **Dupixent® reduced itch and skin lesions compared to placebo in a direct-to-Phase 3 program consisting of two pivotal trials**
- **Authorization represents the second dermatology indication for Dupixent® and the 9th indication overall in Canada**

Toronto, Canada July 17, 2023 – Sanofi-aventis Canada Inc. (Sanofi Canada) announced today that Health Canada has issued a Notice of Compliance for Dupixent® (dulipumab injection) for the treatment of 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.[1] Dupixent® can be used with or without topical corticosteroids.

Prurigo nodularis is a chronic, debilitating skin disease with underlying type 2 inflammation and its impact on quality of life is one of the highest among inflammatory skin diseases.

Dr. Chih-ho Hong, MD, FRCPC
Clinical Assistant Professor, Department of Dermatology and Skin Science at the University of British Columbia

"As a dermatologist in Canada, I have had few helpful treatment options for the treatment of prurigo nodularis. This has led to a significant care gap for this patient group. I am excited about the additional indication for Dupixent® to treat prurigo nodularis, offering my patients a potential relief from the burden of the itchy and painful skin lesions which cover their skin, which will hopefully free them from the physical and mental burden that this has on their day to day life."

James Guy
Immunology Franchise Head, Sanofi Canada

"Dupixent® has the potential to transform the standard-of-care for people in Canada living with this debilitating skin disease. This approval of Dupixent® underscores our continued commitment toimproving research, standard of care, and support for patients suffering from chronic skin diseases with underlying type 2 inflammation."

The Health Canada Notice of Compliance is based on data from two Phase 3 trials, evaluating the efficacy and safety of Dupixent® in adults with prurigo nodularis.

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.

Dupixent® was first approved in Canada in 2017 for the treatment of adults with moderate-to-severe atopic dermatitis and has since been approved for the treatment of infants and children aged 6 months to 5 years old as well as adolescents and children aged six and older with moderate-to-severe atopic dermatitis. Dupixent® has also received authorization for the treatment of adults with chronic rhinosinusitis with nasal polyposis (CRSwNP); adults, adolescents, and children aged six and older with severe asthma; patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE); and now adults living with prurigo nodularis.

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.

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

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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[1] Dupixent® Product Monograph, July, 2023.