News Releases

Sanofi denounces CADTH negative recommendation that could limit treatment options for Canadians with atopic dermatitis

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

* CADTH recommendation for Dupixent™ disregards patient input and ignores clinical value

LAVAL, QC, July 10, 2018 /CNW Telbec/ - Sanofi Genzyme is disappointed with the recent recommendation by the Canadian Agency for Drugs and Technologies in Health (CADTH) to not reimburse Dupixent™, one of the most important recent pharmacological innovations for the treatment of adult patients with moderate-to-severe atopic dermatitis (AD). This recommendation disregards patient input and ignores the product's clinical value and the potential improvement to patient and caregiver quality-of-life (QoL).

CADTH recommendation positions Canada as global outlier in AD treatment

In 2017, Health Canada, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) approved Dupixent™ based on its clinical value and benefits to patients with moderate-to-severe AD. The FDA also granted a priority review and Breakthrough Therapy designation for Dupixent™. These designations expedite the review process and are only given to products the agency deems to have a particularly significant impact on the treatment of the disease.

Moreover, the National Institute for Health Care Excellence (NICE) recently issued a positive Final Appraisal Determination for Dupixent™ for routine use on the National Health Service in England, paving the way for the first targeted biologic for adults with moderate to severe atopic dermatitis.

Within Canada, the *Institut national d'excellence en santé et en services sociaux* (INESSS), in Québec, has also recognized the clinical value of Dupixent™. Sanofi Genzyme looks forward to working with the *Ministère de la Santé et des Services sociaux* (Ministry of Health and Social Services) to achieve public reimbursement quickly for patients in need.

If the provincial, territorial and federal drug plans adopt CADTH's recommendation, Canada risks becoming a global outlier in AD treatment options as it conflicts with local and major global public reimbursement bodies.

A detrimental impact on patients with atopic dermatitis

The CADTH recommendation, made public on July 9, after consultation with the agency's Canadian Drug Expert Committee (CDEC), could have a highly detrimental effect on access to this medication for patients with moderate-to-severe AD. CADTH recommendations have an influence on reimbursement decisions by jurisdictional public drug plans, potentially leading to the therapy being rejected for public reimbursement. This would limit access to therapy for patients dependent on public drug plans, and would restrict physicians from prescribing the most appropriate treatment option. Contrary to the CADTH negative recommendation, the value of Dupixent™ has been recognized by private employer benefits plans, being covered by the majority of private payer plans across Canada.

"I am disappointed. My colleagues are disappointed. Many of my patients who suffer from this severe disease and had hope for a new medication will be devastated when I break the bad news to them", says Dr. Melinda Gooderham, Dermatologist, Peterborough Regional Health Centre and Assistant Professor, Department of

Medicine at Queen's University.

Dupixent™: innovative treatment for patients with atopic dermatitis

Dupixent™ (dupilumab), is the first biologic therapy in Canada to target the root cause of AD – a form of eczema – to treat adult patients whose moderate to severe disease is not adequately controlled with topical prescription corticosteroids or when those therapies are not advisable.[1] The therapy was approved by Health Canada on November 30, 2017 after clinical studies showed an acceptable safety profile with a significant improvement in the condition of patients' skin and reduction in itch within the first four months of biweekly treatment.[2] The medicine is jointly developed by Regeneron and Sanofi under a global collaboration agreement.

Moderate to severe AD can be debilitating and negatively impacts Quality of Life

Atopic dermatitis, a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin.[3,4,5,6] Moderate-to-severe atopic dermatitis is characterized by rashes often covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing.[7] Itch is one of the most burdensome symptoms for patients and can be debilitating.[8] In addition, people with moderate-to-severe atopic dermatitis experience impaired quality of life, including disrupted sleep, and increased anxiety and depression symptoms along with their disease.[9]

Recommendation discourages future innovation

The recommendation reached by CADTH is contrary to the Canadian government's own commitment to invest in innovation and may have detrimental effects on patients' health.

"Sanofi Genzyme is committed to helping the atopic dermatitis community, but the challenges of researching new treatment solutions cannot be overstated," says Peter Brenders, General Manager, Sanofi Genzyme Canada. "We should work collectively to break down roadblocks to innovation in the best interest of patients, so that we may find sustainable solutions that keep therapeutic decision-making in the hands of patients and their physicians, where it belongs."

As one of the largest investors in research and development, Sanofi in Canada has been investing approximately 20% of its revenues year-after-year in Canadian biopharma research, bringing new innovative health solutions to Canadians – and the world.

About Sanofi – www.sanofi.ca

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 more than 2,000 people. In 2017, we invested $123 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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1 Dupixent™ (dupilumab) Product Monograph. Page 3. November 30, 2017.
2 Dupixent™ (dupilumab) Product Monograph. November 30, 2017.
3 Eichenfield et al. Guidelines of Care for Atopic Dermatitis. AAD 2014, pp. 118.
4 Guideline to treatment, European Dermatology Forum. http://www.euroderm.org/edf/index.php/edf-guidelines/category/5-guidelines-miscellaneous?download=36:guideline-treatment-of-atopic-eczema-atopic-dermatitis. Accessed November 27, 2017.
5 Gelmetti and Wolleberg, BJD 2014, Atopic dermatitis- all you can do from the outside. Page 19.
6 National Institutes of Health (NIH). Handout on Health: Atopic Dermatitis (A type of eczema) 2013.
7 Mount Sinai. Patient Care Atopic Dermatitis. Available at: http://www.mountsinai.org/patient-care/health-library/diseases-and-conditions/atopic-dermatitis#risk. Accessed November 27, 2017.
8 Zuberbier T et al. Patient perspectives on the management of atopic dermatitis. J Allergy Clin Immunol vol. 118, pp. 226-232, 2006.
9 National Institutes of Health (NIH). Handout on Health: Atopic Dermatitis (A type of eczema) 2013.

SOURCE Sanofi Canada

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