News Releases

Health Canada approves Dupixent™ as the first biologic for the treatment of adolescents with moderate-to-severe atopic dermatitis

- Dupixent™ can significantly reduce the constant itch and improve the skin's overall condition1

TORONTO, Sept. 27, 2019 /CNW/ - Health Canada has approved Dupixent™ (dupilumab) for the treatment of moderate-to-severe atopic dermatitis (AD) in adolescent patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.2 Treatment with Dupixent™, the first targeted therapy for moderate-to-severe AD, demonstrated a significant improvement in the signs and symptoms of the condition and certain quality of life measures in adolescent patients.3

Dupixent™ was first approved by Health Canada on November 30, 2017 for the treatment of adult patients with moderate-to-severe AD.4

"Dupixent™ has been used safely and effectively to treat thousands of adults living with atopic dermatitis, here in Canada and other countries," says Dr. Perla Lansang, Dermatologist, Sunnybrook Health Sciences Centre. "It's so important that this treatment option is now available to help adolescents who suffer from this life-altering disease."

The adolescent indication for Dupixent™ is based on the findings from a pivotal Phase 3 trial presented at the 27th European Academy of Dermatology and Venereology (EADV) Congress in Paris, France in 2018.

Atopic dermatitis, the most common form of eczema, is a chronic inflammatory disease.5 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, crusting and oozing.6 Inadequately controlled atopic dermatitis can have a physical, emotional and psychosocial impact, causing sleep disturbance, symptoms of anxiety and depression, and feelings of isolation.7

"Atopic dermatitis has no cure. Patients living with this disease are in desperate need of effective medications today," says Marissa Poole, General Manager, Sanofi Genzyme Canada. "Dupixent™ is a novel treatment that can help reduce the severe itching associated with atopic dermatitis, effectively clear skin and improve quality of life for adolescent patients. This treatment offers hope for a better life for patients living with this condition."

About Dupixent™

Dupixent™ (dupilumab) – the first biologic therapy in Canada to target the root cause of atopic dermatitis (AD) was first approved by Health Canada on November 30, 2017 for the treatment of adult patients with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.8 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.9 The long-term safety profile of Dupixent™ observed in adolescents was consistent with that seen in adults with atopic dermatitis.10 The medicine is jointly developed by Regeneron and Sanofi under a global collaboration agreement.

Dupixent™ showed positive results in the pivotal Phase 3 trial presented at the 27th European Academy of Dermatology and Venereology (EADV)

The findings from the Phase 3 trial showed the potential of Dupixent™ to significantly improve the constant itch and certain quality of life measures in adolescents aged 12 years and older whose AD is inadequately controlled with topical therapies or for whom topical treatment was medically inadvisable. The data was presented at the 27th European Academy of Dermatology and Venereology (EADV) Congress in Paris, France.

This late-breaking presentation at EADV indicated the co-primary endpoint outside of the U.S. had a 75 per cent improvement in the Ezcema Area and Severity Index (EASI-75), and included the following significant improvements:11

- 41.5 per cent of patients who received Dupixent™ every two weeks and 38 per cent of patients who received Dupixent™ every four weeks achieved 75 per cent or greater improvement (EASI-75) compared to 8 per cent with placebo (p less than 0.001).12
- 24 per cent of patients who received weight-based dosing of Dupixent™ every two weeks (200 mg or 300 mg) and 18 per cent of patients who received a fixed dose of Dupixent™ every four weeks (300 mg) achieved the primary endpoint – clear or almost-clear skin (IGA; score of 0 or 1) – compared with 2 per cent with placebo (p less than 0.001).13

About Sanofi, Canada

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

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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, Empowering Life

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