SANOFI

Press Release
Australia

Dupixent® (dupilumab) Registered in Australia for Moderate to Severe Asthma with Type 2 Inflammation

Sydney, Australia, May 31, 2019 - Sanofi Genzyme, the Specialty Care global business unit of Sanofi, welcomed the registration of Dupixent® (Dupilumab) in Australia for moderate to severe asthma.

Dupixent® is indicated as add on maintenance treatment in patients aged 12 years and older with moderate to severe asthma with type 2 inflammation (elevated eosinophils or elevated fractional exhaled nitric oxide (FeNO). It is indicated as maintenance therapy for oral corticosteroid dependent asthma.

Dupixent is a human monoclonal antibody that inhibits the signalling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key cytokines that play a central role in type 2 inflammation that underlies specific types of asthma as well as several other allergic diseases. This effect is associated with the reduction of type 2 inflammatory biomarkers including FeNO, immunoglobulin E (IgE) and eotaxin-3 (CCL26).[1,6,7]

The registration of Dupixent was based on LIBERTY ASTHMA clinical development program, which included data from 2,888 patients across three pivotal trials.[6-8]

Patients with moderate to severe asthma often have uncontrolled, persistent symptoms despite standard-of-care therapy that may make them suitable for treatment with a biologic therapy. They live with coughing, wheezing and difficulty breathing, and are at risk of severe asthma attacks that may require emergency room visits or hospitalisations.[2,3] Oral corticosteroids can provide relief for severe, short-term symptoms. However, their chronic use is limited to the most severe patients due to the potential for serious side effects.[4,5]

“Patients living with inadequately controlled severe asthma on current treatment continue to struggle to breathe and suffer potentially life-threatening exacerbations. The daily disease burden can significantly impact people’s quality of life, causing missed days at school, work and social activities. New treatments are needed that facilitate better control of severe asthma and that prevent acute attacks that often require oral steroid treatment and result in hospitalisation”, said Professor Phil Bardin, a Respiratory Physician at Monash Medical Centre, Melbourne.

Sanofi’s Australia and New Zealand Country Medical Chair, Dr Paul King, said today’s announcement is an important step towards helping patients aged 12 years and older with moderate to severe asthma with type 2 inflammation to take control of their symptoms.

Dupixent is being developed jointly by Sanofi and Regeneron as part of a global collaboration agreement.

About Dupixent
Dupixent is a human monoclonal antibody that inhibits the signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key cytokines that play a central role in type 2 inflammation that underlies specific types of asthma as well as several other allergic diseases.

Dupixent is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for chronic systemic therapy. Not indicated for episodic use.

Dupixent is indicated for add on maintenance treatment in patients aged 12 years and older with moderate to severe asthma with type 2 inflammation (elevated eosinophils or elevated FeNO). It is indicated as maintenance therapy for oral corticosteroid dependent asthma.

Atopic dermatitis:
Initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites), followed by 300 mg given every other week. Refer to full PI for preparation, handling and administration.

Moderate to severe asthma:
Initial dose of 400 mg by subcutaneous injection (two 200 mg injections consecutively in different injection sites) followed by 200 mg given every other week. Refer to full PI for preparation, handling and administration.

Oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis:
Initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites) followed by 300 mg given every other week.

Dupixent is contraindicated in patients with hypersensitivity to dupilumab or any of its excipients.

Precautions for Dupixent include hypersensitivity, helminth infections, conjunctivitis and keratitis, comorbid, concomitant atopic conditions, eosinophils conditions, acute asthma or deteriorating disease, gradual corticosteroid dose reduction. There is no safety data on co-administration with other immunomodulators, or concurrent use with live vaccines.

The most common adverse reactions seen in clinical trials were Injection site reactions, conjunctivitis, conjunctivitis allergic, oral herpes, conjunctivitis bacterial, herpes simplex, eosinophilia, eye pruritus, blepharitis, dry eye, hypersensitivity, oropharyngeal pain and eosinophilia.

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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