SANOFI

Press Release
AUSTRALIA
Medical Media

Dupixent® PBS listed for uncontrolled severe asthma in adults and adolescents 12 years and older

Embargoed until 29 March 2021 – Australians with severe asthma that remains uncontrolled despite the use of high-dose steroid medication will now have subsidised access to the first biologic therapy to target two key proteins responsible for the underlying type 2 inflammation of the disease.[1]

The PBS listing of Dupixent (dupilumab) for approximately 1,700 patients[2] aged from 12 years with severe uncontrolled asthma caused by type 2 inflammation means that doctors can, for the first time, offer a treatment that specifically targets two key proteins – interleukins-4 and 13 – that drive the inflammatory response in the airways of 50-70 per cent of patients with severe asthma (allergic or eosinophilic).[1,3-4]

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways. IL-4 and IL-13 are key and central drivers of type 2 inflammation that plays a central role in allergic and eosinophilic asthma, as well as atopic dermatitis.[1]

Associate Professor David Langton, Peninsula Health Director of Thoracic Medicine said, "Traditionally, clinicians have treated a particular phenotype of asthma, but it is well accepted that most patients with severe disease have a mixture of phenotypes".[5]

"By targeting two cytokines responsible for type 2 inflammation, Dupixent makes it possible to treat patients with severe uncontrolled asthma, regardless of whether they have allergic or eosinophilic asthma, or a mixture of both,"[1] he said.

"As our understanding of the cause of severe and uncontrolled asthma increases, so too does our ability to target and counter the immune-driven inflammatory response.

"Alongside improved lung function and fewer exacerbations, Dupixent can reduce the need for oral corticosteroids – an important goal of treatment."[1,6-8]

In clinical trials, Dupixent significantly improved lung function as early as two weeks, regardless of the patient's dependence on oral corticosteroids, with lung function improvements maintained throughout the duration of the 52-week study.[1,6]

The therapy also reduced the rate of severe asthma exacerbations up to 70 per cent (compared to placebo), with greater reductions in the rate of severe exacerbations in patients with higher baseline biomarker levels of type 2 inflammation, such as eosinophils and FeNO.[1,7]

Importantly, Dupixent also reduced the dose of oral corticosteroids required by patients with steroid dependent asthma by 28.2 per cent (compared to placebo) over 24-weeks. At 24-weeks, more than half (52 per cent) of patients treated with Dupixent no longer used oral corticosteroids (compared to 29 per cent in the placebo group).[8]

Sanofi Genzyme Australia and New Zealand Head of Medical, Dr Paul King said, “Dupixent is the first and only therapy available on the PBS for patients with type 2 inflammatory asthma which blocks two key proteins (IL-4 and IL-13) responsible for the excessive immune reaction.”[1]

“This is an important milestone. Dupixent can help provide Australians with severe uncontrolled asthma the opportunity for improved lung function, reduced rates of exacerbation and less reliance on oral corticosteroids,”[1] he concluded.

Dupixent is PBS listed for the treatment of uncontrolled severe eosinophilic or allergic asthma, both with and without oral corticosteroid dependence. Refer to PBS schedule for full criteria.

About Dupixent

Dupixent is jointly developed by Sanofi and Regeneron under a global collaboration agreement.

In Australia, Dupixent is registered (AUST R 282981, 283127, 302463) for the following indications:[1]

- 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).
- Maintenance therapy for oral corticosteroid dependent asthma.
- Moderate to severe atopic dermatitis in patients aged 12 years and older who are candidates for chronic systemic therapy. Dupixent is not intended for episodic use.

The recommended dose for moderate-to-severe asthma in adults and adolescents is 200 mg subcutaneous injection once every two weeks via a pre-filled syringe after an initial 400 mg loading dose (two 200 mg injections consecutively in different injection sites). For patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis, the initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites) is followed by 300 mg given every other week.[1]

Dupixent is generally well tolerated and does not require monitoring for organ toxicity. In asthma clinical trials, the most common side effects included injection site reactions,

oropharyngeal pain and eosinophilia.[1] Care should be taken in patients with helminth (worm) infections and in patients receiving live vaccines.[1] Patients should be reminded to report any new or worsening eye symptoms.[1] Use in pregnancy or breastfeeding should be discussed with the treating clinician.[1]

Australians with moderate-to-severe asthma who do not meet PBS criteria will be able to access the medicine on private prescription.

For information about Dupixent, please contact Sanofi Medical Information on 1800 818 806.

PBS Information: This product is not listed on the PBS for Severe Asthma.

Please review full Product Information before prescribing.
Full Product Information is available from Sanofi-Aventis Australia Pty Ltd at www.guildlink.com.au/gc/ws/sw/pi.cfm?product=swpdupix or by contacting 1800 818 806.

Dupixent (dupilumab) MINIMUM PRODUCT INFORMATION.
INDICATIONS Atopic dermatitis: Treatment of moderate to severe atopic dermatitis in patients aged 12 years and older who are candidates for chronic systemic therapy. Not intended for episodic use. **Moderate to severe asthma:** 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). Indicated as maintenance therapy for oral corticosteroid dependent asthma. **DOSAGE AND ADMINISTRATION Atopic dermatitis – Adults:** 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. Treatment should be initiated and supervised by a dermatologist or immunologist. **Atopic Dermatitis – Adolescent patients aged 12-17 years Patients < 60 kg:** 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
Patients ≥ 60 kg: 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. **CONTRAINDICATIONS** Hypersensitivity to dupilumab or any of its excipients. **PRECAUTIONS** Record the tradename and the batch number to improve traceability, hypersensitivity, angioedema, helminth infections, conjunctivitis and keratitis, comorbid asthma, concomitant atopic conditions, eosinophilic conditions, acute asthma or deteriorating disease, gradual corticosteroid dose reduction. Refer to full PI.
INTERACTIONS Live vaccines, No safety data on co-administration with other immunomodulators. Refer to full PI. **ADVERSE EFFECTS Atopic dermatitis:**

Injection site reactions, conjunctivitis, conjunctivitis allergic, oral herpes, conjunctivitis bacterial, herpes simplex, eosinophilia, eye pruritus, blepharitis, dry eye, hypersensitivity – refer to full PI. **Moderate to severe asthma:** Injection site reactions, oropharyngeal pain, eosinophilia – refer to full PI. **Post marketing experience:** Angioedema, arthralgia, keratitis, ulcerative keratitis. **NAME OF SPONSOR** sanofi-aventis australia pty ltd, 12-24 Talavera Road, Macquarie Park, NSW 2113. **Please review full Product Information before prescribing.** Full Product Information is available from sanofi-aventis australia pty ltd at http://www.guildlink.com.au/gc/ws/sw/pi.cfm?product=swpdupix or by contacting 1800 818 806. Based on Full Product Information with TGA date of approval of 06 October 2020. Date of Preparation: 06 October 2020.

Issued by Ethical Strategies on behalf of Sanofi Australia

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

Media Relations Contact
Name: Amy O'Hara
Position: Communications Manager, Sanofi Australia
Tel.: 0417 861 984
Email: Amy.O-Hara@sanofi.com

Name: Fiona Beveridge
Position: Account Director, Ethical Strategies
Tel.: 0405 902 826
Email: fbeveridge@ethicalstrategies.com.au

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