SANOFI

Press Release
AUSTRALIA
Consumer Media

# New treatment era for patients with severe uncontrolled asthma

## Dupixent® (dupilumab) PBS listed for severe uncontrolled asthma in patients 12 years and older

**Sydney – 28 March 2021 –** Australians who struggle to breathe due to severe uncontrolled asthma will, for the first time, have access to Dupixent – a therapy that targets a type of inflammation in their airways called 'type 2 inflammation'.[1]

From 1 April, Dupixent will be listed on the Pharmaceutical Benefits Scheme (PBS) for approximately 1,700 Australians[2] aged from 12 years who live with severe uncontrolled asthma caused by type 2 inflammation (allergic or eosinophilic).[1]

Patients with severe asthma produce high levels of proteins called interleukin 4 and interleukin 13 (IL-4 and IL-13), triggered when the body's immune system overacts to an allergen or infection. IL-4 and IL-13 can cause the type 2 inflammation leading to disease symptoms, which occurs in 50-70 per cent of patients with severe asthma.[3,4]

Dupixent is the first and only therapy that blocks the action of IL-4 and IL-13 to relieve disease symptoms[1] in severe asthma. It is used in addition to other asthma medications.

Associate Professor David Langton, Peninsula Health Director of Thoracic Medicine said, said, "Despite treatment advances, the struggle to breathe impacts the daily life of Australians who live with uncontrolled severe asthma," he said.

"Many of these patients are already on high-dose steroid therapies but continue to wheeze, cough and have difficulty breathing because the underlying cause of inflammation remains untreated. This puts some at risk of life-threatening asthma attacks.

"It's a positive step forward to have another treatment option for some patients with uncontrolled disease."

Asthma Australia CEO Michele Goldman said severe asthma has a debilitating impact on a person's life and is often difficult to treat.

"For people with severe uncontrolled asthma, finding treatments that work can be an enduring and expensive exercise, including countless hospitalisations and serious setbacks," she said.

"We welcome the PBS listing of Dupixent. It puts an important treatment option within greater reach of many Australians."

Around one-in-ten Australians live with asthma, which causes episodes of wheezing, breathlessness, and chest tightness due to narrowing of the airways.[5]

For the majority, the condition can be managed using inhaled preventer and reliever medication. However, around 176,000 Australians live with severe asthma, which can be life-threatening.[6] Asthma is responsible for approximately 40,000 hospitalisations and approximately 400 deaths a year.[5]

Dupixent is injected once every two weeks and, with the PBS subsidy, will cost eligible patients $41.30 per prescription, or $6.60 with a concession card. Without a subsidy, patients would pay approximately $22,800 a year for treatment with Dupixent.

Sanofi Genzyme Australia and New Zealand General Manager, Fiona Clark said, "We are pleased that the Federal Government has recognised the importance of Dupixent for Australians with severe, uncontrolled asthma.

"We are committed to working with clinicians to support the use of Dupixent to treat severe, uncontrolled asthma", she said.

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

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.

**Note to Editor:** Associate Professor Langton has served on advisory boards and been involved in clinical trials sponsored by Sanofi Genzyme for which compensation was received. In relation to this Sanofi Genzyme media announcement, no compensation was provided to Associate Professor Langton and the opinions expressed are his own.

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.**

**The CMI is available at the following:**
**http://www.guildlink.com.au/gc/ws/sw/cmi.cfm?product=swcdupix**

**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

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## References:

1. Dupixent TGA Approved Product Information, 6 October 2020
2. Sanofi, Data on file.
3. Global Initiative for Asthma Difficult-to-Treat and Severe Asthma in adolescent and adult patients Diagnosis and Management. A GINA Pocket Guide for Health Professionals.

4. Peters MC, et al. Measures of gene expression in sputum cells can identify TH2-high and TH2-low subtypes of asthma. J Allergy Clin Immunol. 2014;133(2):388-394.
5. Australian Institute of Health and Welfare Asthma. Updated August 2020 https://www.aihw.gov.au/reports/chronic-respiratory-conditions/asthma/contents/asthma Accessed February 2021
6. Centre of Excellence in Severe Asthma; What is severe asthma, available at www.severeasthma.org.au/ Accessed February 2021