

## Dupixent<sup>®</sup> PBS listed for severe atopic dermatitis

*First biologic that targets underlying immune dysregulation  
PBS listed for adults and adolescents*

**Sydney – 27 February 2021** – Experts are welcoming a government announcement that a first-in-class therapy that blocks proteins responsible for type 2 inflammation in atopic dermatitis will be subsidised for eligible patients.<sup>1,2</sup>

From 1 March, Dupixent<sup>®</sup> (dupilumab) will be listed on the Pharmaceutical Benefits Scheme for the treatment of patients, 12 years and above, with severe atopic dermatitis, who have failed to respond to optimally prescribed topical treatments.<sup>1,2</sup>

Dermatologist, Associate Professor Peter Foley, Director of Research, Skin Health Institute, said, “The PBS listing of Dupixent is exciting news for many patients with severe atopic dermatitis and will provide specialists with a welcome alternative to long-term use of topical medication and immunosuppressant therapy.”

“Biologic therapy represents a new treatment paradigm for severely impacted atopic dermatitis patients,” he said.

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins, and is not an immunosuppressant. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis.<sup>2</sup>

Type 2 inflammation is the common denominator behind a range of lifelong diseases, including atopic dermatitis, asthma, and other allergic or atopic disorders, which appear to be disparate conditions but occur when the immune system overreacts to an allergen or pathogen.

Professor Connie Katelaris, from the Department of Immunology and Allergy at Campbelltown Hospital said, “As the first targeted medication for severe atopic dermatitis, Dupixent treats the underlying immune dysregulation, known as type 2 inflammation, without causing broad immunosuppression.”<sup>2</sup>

“This means that many patients will no longer need to struggle with unsightly skin rashes and unrelenting itchy skin which may disrupt sleep, impact work and relationships, require hospitalisation to treat infections, and increase the risk of anxiety and depression,” she said.

Dupixent has been studied in more than 2,500 adult patients and 250 adolescent patients with moderate-to-severe atopic dermatitis. In the pivotal studies, at least three times as many patients treated with Dupixent, compared to placebo, achieved  $\geq 75$  per cent improvement in lesion extent and severity at 16 weeks.<sup>2</sup> In the one-year CHRONOS study, which included 740 adults with moderate-to-severe atopic dermatitis, the 16-week efficacy responses were maintained at week 52.<sup>2</sup> For some patients, improvements in itch reduction were seen as early as week 2.<sup>2,3</sup>

Dupixent is also the only systemic treatment for uncontrolled moderate-to-severe atopic dermatitis that has been studied for up to three years in adults.<sup>4</sup> The long-term safety profile of Dupixent observed in adolescents was consistent with that seen in adults with atopic dermatitis.<sup>2</sup>

Welcoming the Federal Minister for Health, Greg Hunt’s announcement, Sanofi Genzyme Australia and New Zealand Head of Medical, Dr Paul King said the listing “heralds a new era in the treatment of severe atopic dermatitis.”

“Specialists have been waiting a long time for a therapy that targets type 2 inflammation to address the immune system overreaction in atopic dermatitis.”

“This PBS listing for adults and adolescents recognises the extent to which severe atopic dermatitis can impact on the mental and physical wellbeing of patients,” Dr King said.

In a recent Australian study, atopic dermatitis has been found to increase the risk of insomnia, anxiety, and depression by 79 per cent, 44 per cent and 41 per cent respectively,<sup>5</sup> while another study found suicidal thoughts and suicide attempts by 44 per cent and 36 per cent more likely, respectively,<sup>6</sup> compared to people without the condition.

Approximately 100,000 Australians are living with severe atopic dermatitis.<sup>7</sup> Recent Australian management consensus guidelines recommended Dupixent as a first-line systemic treatment option in adults with moderate-to-severe atopic dermatitis who are uncontrolled with topical therapies.<sup>8</sup>

“We are pleased that we have been able to reach agreement with the Australian Government to list Dupixent on the PBS and thank the many clinicians, patients and patient organisations who advocated for both a greater understanding of atopic dermatitis and access to new treatment options,” Dr King said.

## About Dupixent

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

In Australia, Dupixent is approved by the Therapeutic Goods Administration to treat moderate-to-severe atopic dermatitis in patients aged 12 years and over who are candidates for chronic systemic therapy. The medicine is available on the PBS for eligible patients from 1 March but will remain available on private prescription for Australians with moderate atopic dermatitis. Dupixent is not intended for episodic use.<sup>2</sup>

The recommended dose for atopic dermatitis in adults, and adolescents that weigh 60 kg or more, is 300 mg subcutaneous injection once every two weeks via a pre-filled syringe after an initial 600 mg loading dose. Adolescents under 60 kg require a 200 mg dose once every two weeks after an initial 400 mg loading dose.<sup>1</sup> Treatment must be initiated and supervised by a dermatologist or immunologist.<sup>1</sup>

Dupixent is generally well tolerated and does not require regular blood tests. In clinical trials the most common side effects included injection site reactions, conjunctivitis, blepharitis, eye pruritus, and oral herpes. Care should be taken in patients with helminth (worm) infections and in patients receiving live vaccines. Patients should be reminded to report any new or worsening eye symptoms. Use in pregnancy or breastfeeding should be discussed with the treating clinician.<sup>2</sup>

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

**PBS Information: This product is not listed on the PBS.**

**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](http://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.

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### References:

1. Federal Health Minister's announcement, 27 February 2021
2. Dupixent TGA Approved Product Information 6 October 2020
3. Silverberg, JI. et al. Dupilumab treatment results in early and sustained improvements in itch in adolescents and adults with moderate-to-severe atopic dermatitis: analysis of the randomized phase 3 studies SOLO 1 & SOLO 2, AD ADOL, and CHRONOS. *Journal of the American Academy of Dermatology* (2020).
4. Beck LA et al. Dupilumab provides favorable safety and sustained efficacy for up to 3 years in an open label study of adults with moderate-to-severe atopic dermatitis. *American Journal of Clinical Dermatology*. 2020 Aug;21(4):567-577
5. Chidwick K, et al. Prevalence, incidence and management of atopic dermatitis in Australian general practice using routinely collected data from MedicineInsight *Australasian Journal of Dermatology* 2020;61:e319-27
6. Sandhu, JK et al. Association Between Atopic Dermatitis and Suicidality: A Systematic Review and Meta-analysis *JAMA Dermatology* 2019 155(2):178-187
7. METIS Healthcare Research. Dupilumab Patient Tracker, prepared August 2019.
8. Smith S, et al. Atopic dermatitis in adults: An Australian management consensus *Australasian Journal of Dermatology* 2020, 61, 23-32

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