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Press Release
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Consumer Media

Dupixent® PBS listed for severe atopic dermatitis

First-in-class medicine subsidised for debilitating skin condition

Sydney – 27 February 2021 – Australians battling severe uncontrolled atopic dermatitis, commonly known as eczema and characterised by relentless itching and painful rashes, will now have an affordable new treatment option.[1]

From 1 March, a first-in-class biologic therapy known as Dupixent® (dupilumab) will be listed on the Pharmaceutical Benefits Scheme for the treatment of patients 12 years or older with severe atopic dermatitis, who have failed to respond to optimally prescribed topical treatments.[1]

Dermatologist, Associate Professor Peter Foley, Director of Research, Skin Health Institute, said, "Severe atopic dermatitis is more than just a skin condition. It affects every aspect of life, disrupting sleep, impacting work and relationships, and has been linked to an increased frequency of anxiety and depression."

"Many people think of eczema as a relatively mild skin condition which resolves after the early years of life, but for some people it can be debilitating and lifelong," he 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,[2] while another study found suicidal thoughts and suicide attempts by 44 per cent and 36 per cent more likely, respectively, compared to people without the condition.[3]

Approximately 100,000 Australians are living with severe atopic dermatitis[4] and can experience flare-ups that are frequent, extensive and may require hospitalisation to prevent or treat severe skin infections.[5]

Professor Connie Katelaris, from the Department of Immunology and Allergy at Campbelltown Hospital said, "Until now, atopic dermatitis treatment has focused on reducing inflammation through a combination of intensive topical treatments and through broad based systemic therapies that may have widespread effects on the body.

"While this may be effective in some patients, many others struggle with uncontrolled disease and experience a constant battle to control symptoms because the underlying type 2 inflammation remains unchecked," Professor Katelaris said.

“Dupixent is the first and only dual-acting targeted therapy that simultaneously inhibits two signaling proteins, IL-4 and IL-13, which are key culprits responsible for the type 2 inflammation that causes severe inflamed and itchy skin, often associated with atopic dermatitis,[6]” she said.

“This marks the first time that a biologic therapy has been subsidised through the PBS to treat atopic dermatitis.

“It also represents a new treatment era, as it is the first time a therapy has been available for severe atopic dermatitis that targets the underlying type 2 inflammation,” she said.

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.

The medicine is injected once every two weeks and is not intended for episodic use.[6] Without a subsidy, Dupixent will cost approximately $22,800 per year. With the PBS subsidy, eligible patients will only need to pay $41 per prescription, or $6.60 with a concession card.

Sanofi Genzyme Australia and New Zealand General Manager, Fiona Clark said the company was committed to working with clinicians to help Australians affected by atopic dermatitis.

“I would like to acknowledge the many clinicians, patients and patient organisations who advocated for both greater understanding of the impacts of severe atopic dermatitis and access to new treatment options,” she said.

“Access to new treatments on the PBS is fundamental to Australia having the best health system in the world.

“We are pleased that we have been able to reach agreement with the Australian Government to list Dupixent on the PBS,” Ms Clark said.

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.[6]

Care should be taken in patients with helminth (worm) infestation and in patients who have recently received certain types of vaccines (check with your Doctor). Patients

should be reminded to report any changes in their vision to their doctor. Use in pregnancy or breastfeeding needs to be discussed with the treating doctor.[6]

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

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

Note to Editor: Associate Professor Foley and Professor Katelaris have served on advisory boards for which compensation was received and been involved in clinical trials sponsored by Sanofi Genzyme for which institutional compensation was received. In relation to this Sanofi Genzyme media announcement, no compensation was provided to Associate Professor Foley or Professor Katelaris and the opinions expressed are their own.

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

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.

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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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References:

1. Federal Health Minister's announcement, 27 February 2021
2. 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

3. Sandhu, JK et al. Association Between Atopic Dermatitis and Suicidality: A Systematic Review and Meta-analysis JAMA Dermatology 2019 155(2):178-187
4. METIS Healthcare Research. Dupilumab Patient Tracker, prepared August 2019.
5. Smith S, et al. Atopic dermatitis in adults: An Australian management consensus Australasian Journal of Dermatology 2020, 61, 23-32
6. Dupixent TGA Approved Product Information 6 October 2020

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