SANOFI

Press Release
Australia

First in class atopic dermatitis medicine now available for adolescents[1]

Sydney – 3 February 2020 - For the first time, adolescents battling severe and uncontrolled atopic dermatitis, commonly known as eczema, can receive medication that curbs the over-reaction by the immune system responsible for the distressing skin condition.[1]

A new generation therapy, known as Dupixent® (dupilumab) and previously only indicated for adults, has been registered by the Therapeutic Goods Administration for use in adolescents aged 12-17 years with moderate-to-severe atopic dermatitis (eczema).[1]

Professor Connie Katelaris from the Department of Immunology and Allergy at Campbelltown Hospital said that while some young children outgrow episodic eczema, "when the disease continues into adolescence, sustained treatment may be required".

"Dupixent is an important treatment, especially for patients with severe disease, which significantly impacts their quality of life and for whom there are limited treatment options," she said.

"For too long eczema has been dismissed as just an itch and some rash. The reality is that the unrelenting symptoms not only cause considerable physical distress but can also lead to psychological suffering."

Australian research found that 40 per cent of adults with atopic dermatitis suffer depression and anxiety, 85 per cent of people with severe or very severe forms of the disease have trouble sleeping, and close to half report that the disease has affected their relationships.[2]

"Negotiating teenage years is hard enough, let alone when you're managing a severe and very obvious skin disease," Professor Katelaris said.

"We're acutely aware of mental health concerns in young people. New treatment options for this vulnerable patient group are absolutely vital."

Professor Katelaris explained that unlike broad-spectrum immunosuppressants, Dupixent has a targeted mode of action.[1]

“Atopic dermatitis is a disease caused by an overactive immune system. Dupixent inhibits a particular immune cell from triggering an inflammatory reaction which means the immune system is less likely to become hyperactive,”[1] she said.

Sanofi Genzyme is working with the Federal Government to obtain PBS listing for Dupixent. The therapy is reimbursed for the treatment of eligible atopic dermatitis patients in 23 countries overseas, including the United Kingdom, Germany, France, Japan, Italy and Israel.[3]

Sanofi Genzyme Australia and New Zealand Head of Medical, Dr Paul King, said the company understood the importance of a PBS listing for physicians and their patients.

“Feedback from the PBAC has been constructive and we look forward to continuing to work with the Government to obtain PBS listing for Dupixent – initially in adults and hopefully then for adolescents,” he said.

“In the meantime, we understand that some clinicians have patients who are willing and able to purchase Dupixent on private prescription ahead of a potential PBS listing, so we’re pleased to be able to provide that option.”

Dermatologists and immunologists can prescribe Dupixent on private prescription at a cost of $1,615.38 per month (2 x 300 mg injections used every two weeks).

In Australia, Dupixent is indicated to treat moderate-to-severe atopic dermatitis in adult and adolescent (12-17 years) patients who are candidates for chronic systemic therapy. Dupixent is not intended for episodic use.[1]

Dupxient must not be prescribed in patients with an allergy to any medicine containing dupilumab (the active ingredient) or any of the ingredients listed in the leaflet accompanying the product. 1

Adults and adolescents that weigh 60 kg or more can self-administer a 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 treatment with a 200 mg dose after an initial 400 mg loading dose.[1] The 200 mg dose of Dupixent is not currently available in Australia.

Dupixent is generally well tolerated and does not require monitoring for organ toxicity. In clinical trials the most common side effects included injection site reactions, conjunctivitis, blepharitis, eye pruritus, and oral herpes.[1]

Care should be taken in patients with helminth (worm) infestation and in patients who've 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". [1]

Note to Editor: Professor Katelaris 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 Professor Katelaris, and the opinions expressed are her own.

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

The Dupixent CMI is available here

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. 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, 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. **NAME OF SPONSOR** sanofi-aventis australia

pty ltd, 12-24 Talavera Road, Macquarie Park, NSW 2113. Based on Full Product Information with TGA date of approval of 25 October 2019. Date of Preparation: 05 November 2019.

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 5 November 2019
2. ICCDR. 2018. Atopic Dermatitis Australian Study. PEEK. 1:4. Available at: https://www.cc-dr.org/wp-content/uploads/2018/05/2018AUADE_FULL-REPORT.pdf
3. Data on File. Sanofi

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