

First targeted biologic for moderate-to-severe atopic dermatitis registered in Australia

- Sanofi Genzyme receives registration for Dupixent® (dupilumab) -

Sydney, Australia – 5 February, 2018 – [Sanofi Genzyme](#), the specialty care global business unit of [Sanofi](#), welcomes the registration of Dupixent® (dupilumab) in Australia.

Dupixent® is the first targeted biologic indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for chronic systemic therapy. Dupixent is not intended for episodic use.¹

Atopic dermatitis, is a chronic inflammatory disease of the skin. Moderate-to-severe atopic dermatitis is characterised by rashes often covering much of the body, and can include pain, intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing. Itching, one of the most burdensome symptoms for patients can be debilitating. People living with moderate-to-severe atopic dermatitis often experience impaired quality of life, including disrupted sleep, and increased anxiety and depression symptoms along with their disease.^{2,3}

“The physical and psychological burdens often experienced by people living with moderate-to-severe atopic dermatitis can have devastating impacts on quality of life,” said Associate Professor, Peter Foley, Department of Medicine (Dermatology), University of Melbourne and Director of Research, Skin & Cancer Foundation Inc.

“Atopic dermatitis can take control of people’s lives. Many patients struggle with their disease and with the treatment options currently available”.

Sanofi’s Australia and New Zealand Country Medical Chair, Dr Paul King, said there continues to be a high unmet medical need for patients with moderate-to-severe atopic dermatitis.

“Registration of Dupixent is an important step toward bringing effective, long-term treatment options to these patients in Australia.”

Dupixent is a fully human monoclonal antibody that inhibits interleukin-4 and interleukin-13 signalling. Interleukin-4 and interleukin-13 are key type 2 cytokines involved in atopic disease.¹ The registration of Dupixent was based on a clinical development program that included pivotal randomised, placebo-controlled, double-blind Phase III trials SOLO 1, SOLO 2 and CHRONOS. The studies examined the use of Dupixent either alone or with topical corticosteroids in patients with moderate-to-severe atopic dermatitis. Patients enrolled in the trials responded inadequately to topical corticosteroids (SOLO 1, SOLO 2 and CHRONOS) or systemic therapies (CHRONOS). Dupixent met the primary and key secondary endpoints in all studies.^{3,4}

Dupixent 300 mg is self-administered as a subcutaneous injection once every two weeks via a pre-filled syringe after an initial 600 mg loading dose. Dupixent treatment should be initiated and supervised by a dermatologist or immunologist.¹

In clinical trials the most common side effects included injection site reactions, conjunctivitis (allergic and bacterial), blepharitis, eye pruritus, and oral herpes.¹

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

About Dupixent ^{1,3}

Dupixent is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, interleukin-4 (IL-4) and interleukin-13 (IL-13), which are believed to be major biological drivers of the persistent underlying inflammation that causes atopic dermatitis.

Dupixent is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for chronic systematic therapy. Dupixent is not intended for episodic use. The recommended dose in adults is an initial dose of 600 mg by subcutaneous injection, followed by 300 mg given every other week.

Dupixent is contraindicated in patients with hypersensitivity to dupilumab or any of its excipients.

Precautions for Dupixent include hypersensitivity, helminth infections, conjunctivitis and keratitis, comorbid asthma, and concomitant atopic conditions. There is no safety data on co-administration with other immunomodulators, or concurrent use with live vaccines.

The most common adverse reactions seen in clinical trials were injection site reactions, conjunctivitis, conjunctivitis allergic, oral herpes, conjunctivitis bacterial, herpes simplex, eosinophilia, eye pruritus, blepharitis, dry eye.

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 the 100 countries. Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families.

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December

31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.'

PBS Information: DUPIXENT is not currently listed on the PBS.
The Dupixent Consumer Medicine Information accompanies this media release.

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References

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