

## **NICE recommends Sanofi's new treatment Dupixent<sup>®</sup> ▼ (dupilumab) for adults with moderate-to-severe atopic dermatitis in England<sup>1</sup>**

- \* Positive recommendation for Dupixent<sup>®</sup> (dupilumab) in final appraisal determination (FAD) paves the way for the first targeted biologic for adults with moderate to severe atopic dermatitis
- \* Atopic dermatitis is the most common type of eczema,<sup>2</sup> affecting approximately 1.5 million adults in the UK<sup>3,4</sup>
- \* Patients with inadequately controlled moderate to severe atopic dermatitis can face significant physical and psychological burdens of the disease<sup>5</sup>

**GUILDFORD, UK – JUNE 22, 2018** – The National Institute for Health and Care Excellence (NICE) has published a positive Final Appraisal Determination (FAD) recommending dupilumab, in combination with topical corticosteroids, for routine use on the National Health Service (NHS) in England for the treatment of moderate to severe atopic dermatitis in adults when they have not responded to at least one other systemic therapy (e.g. immunosuppressants) or these are contraindicated or not tolerated. Typically healthcare systems in Wales and Northern Ireland will implement NICE guidance.

*“Atopic dermatitis is a long-term, inflammatory disease which can be a debilitating condition that not only impacts the skin, but can have a detrimental effect on a patient’s mental wellbeing and quality of life,” said Professor Graham Ogg, Professor of Dermatology, University of Oxford and Consultant Dermatologist, Oxford University Hospitals NHS Trust. “NICE’s recommendation for dupilumab represents a much needed step change in the management of moderate to severe atopic dermatitis and offers an important new treatment for those living with the disease.”*

Atopic dermatitis (also known as atopic eczema) is the most common form of eczema.<sup>2</sup> In the United Kingdom, approximately 1.5 million (3%) adults have atopic dermatitis.<sup>3,4</sup> Within the general UK population, it is estimated that there are 14 adults per 100,000 with moderate atopic dermatitis and 6 adults per 100,000 with severe atopic dermatitis who may be eligible for treatment with dupilumab.<sup>6</sup>

Moderate to severe atopic dermatitis is characterised by rashes often covering much of the body, and can include intense, persistent itching and

skin dryness, cracking, redness, crusting, and oozing.<sup>2,7</sup> Itch is one of the most burdensome symptoms for patients and can be debilitating. In addition, people with moderate-to-severe atopic dermatitis experience impaired quality of life, including disrupted sleep, and increased anxiety and depression symptoms along with their disease.<sup>5</sup>

*“This decision is a great step forward for patients with moderate to severe atopic dermatitis, who will now be one step closer to accessing dupilumab through the NHS in England,” commented Andrew Proctor, Chief Executive at the National Eczema Society (NES). “Dupilumab represents a new way of treating atopic dermatitis and we are delighted that NICE has recognised the huge challenges that some patients face in successfully managing their condition. The decision gives real hope to people who desperately need more effective treatment.”*

The recommendation in the FAD is expected to form the basis for NICE’s final Technology Appraisal Guidance (TAG) on the use of dupilumab, anticipated on 1 August, 2018. When medicines introduced through the Early Access to Medicines Scheme (EAMS) scheme receive a positive NICE final guidance, the NHS is obliged to provide funding for them in England within 30 days of NICE guidance (instead of 90 days for non-EAMS commissioning).

The Medicines and Healthcare products Regulatory Agency (MHRA) acknowledged the innovative nature of Dupixent<sup>®</sup> ▼ (dupilumab) designating it as a Promising Innovative Medicine and accelerating its journey to patients through the EAMS.

*Peter Kuiper, General Manager UK & Ireland at Sanofi Genzyme added: “Throughout the development of dupilumab we have seen, spoken to and worked around the world with clinicians, patient groups, and most importantly patients, and have witnessed the profound impact that atopic dermatitis can have on individuals and their families. Seeing first-hand the difference that dupilumab can make to patients’ lives has given us the drive and determination to ensure it becomes available to those who need it as quickly as possible.”*

In Scotland, the outcome of an assessment by the Scottish Medicines Consortium (SMC) is expected towards the end of 2018.

### **About Dupixent<sup>®</sup> (dupilumab)**

Dupixent<sup>®</sup> (dupilumab) is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in atopic dermatitis.<sup>8</sup> Dupixent<sup>®</sup> (dupilumab) was granted a marketing authorisation in the European Union on 27 September 2017.<sup>9</sup>

The medicine is being jointly developed by Regeneron and Sanofi under a

global collaboration agreement.

Full summary of product characteristics for dupilumab can be accessed at:  
<https://www.medicines.org.uk/emc/product/8553/smpc>

### About Sanofi

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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

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- <sup>2</sup> NHS Choices. Atopic Eczema (Atopic Dermatitis). Available at: <https://www.nhs.uk/conditions/atopic-eczema/> (Accessed June 2018).
- <sup>3</sup> Nutten S. Atopic Dermatitis: Global Epidemiology and Risk Factors. *Ann Nutr Metab* 2015;66 (suppl 1): 8–16.
- <sup>4</sup> Office for National Statistics. 2014 UK mid-year population estimate. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections/bulletins/nationalpopulationprojections/2015-10-29> (Accessed June 2018).
- <sup>5</sup> Simpson et al. Patient burden of moderate to severe atopic dermatitis (AD): Insights from a phase 2b clinical trial of dupilumab in adults. *Am Acad Dermatol*, pp. 74(3):491-498, 2016.
- <sup>6</sup> Sanofi. Data on File. August 2016.
- <sup>7</sup> Mount Sinai. Patient Care Atopic Dermatitis. Available at: <http://www.mountsinai.org/patient-care/health-library/diseases-and-conditions/atopic-dermatitis#risk>. (Accessed June 2018).
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- <sup>9</sup> European Medicines Agency. Dupilumab. Summary of Product Characteristics. Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/004390/WC500236507.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004390/WC500236507.pdf) (Accessed June 2018).