Press Release

For UK media and investors only
Issued: 10th July 2024, Uxbridge, UK

NICE recommends Ebglyss (lebrikizumab) for use in moderate to severe Atopic Dermatitis in the NHS England in eligible adolescents and adults

- **Lebrikizumab is recommended by NICE for the use in moderate to severe Atopic Dermatitis in patients 12 years and over when their condition has not responded to at least 1 systemic immunosuppressant, or when these treatments are not suitable**
- **Following approval of the European Commission (October 2023) and the MHRA (December 2023), lebrikizumab will be available for prescription through the NHS in England and Wales**
- **Lebrikizumab is a monoclonal antibody that binds to Interleukin-13 with high affinity, selectively inhibiting its downstream signalling[1-4]**

Uxbridge, UK. 10th July 2024 – Almirall S.A. (BME: ALM), a global biopharmaceutical company dedicated to medical dermatology, announced today that the National Institute for Health and Care Excellence (NICE) has recommended Ebglyss (lebrikizumab) for use in moderate to severe Atopic Dermatitis in the NHS England.

Lebrikizumab is indicated for the treatment of adult and adolescent patients (12 years and older with a body weight of at least 40 kg) with moderate-to-severe Atopic Dermatitis (AD), who are candidates for systemic therapy. The treatment was approved by the European Commission and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) in December 2023.

In the United Kingdom, approximately 5.2 million adults (7.7%, 18-74 years) and 2.5 million children (18%, 0-17 years) have moderate or severe atopic dermatitis[10], also commonly referred to as atopic eczema.

"*Most people have heard of atopic eczema, but don't realise how it can dominate the lives of patients and their families. As well as the physical symptoms of itchy, sore, cracked, bleeding skin, eczema can affect so many decisions a patient makes – every day; from what to wear, activities they can and cannot participate in, to managing time-consuming, messy skincare regimens,*" explains **Andrew Proctor, National Eczema Society Chief Executive**. "*The National Eczema Society welcomes the NICE recommendation for lebrikizumab as an additional treatment for eligible people with moderate to severe atopic eczema. It's important we have a range of treatment options, so patients have the chance to access a treatment that works well for them*."

"*The NICE recommendation for lebrikizumab for eligible people 12 years and over suffering with moderate-to-severe AD in England is testament to the benefits this treatment can bring to patients due to its demonstrated efficacy, with 4-weekly maintenance dosing and an acceptable safety profile. This is well aligned with our company purpose to transform the patient's world by helping them realize their hopes and dreams for a healthy life."* stated **Jorgen Damsbo, General Manager at Almirall, UK.**

"*Atopic dermatitis often has a greatly underestimated psychosocial burden for the patients and their families. Both adults and children frequently face stigmatisation, loss of confidence and bullying, sleep deprivation and overwhelming itch, which may impact their performance at school and work. In severe atopic dermatitis, patients often suffer from depression, anxiety, and even suicidal ideation. The addition of this targeted biological therapy is an important step forward and most welcomed for patients and clinicians alike."* said **Prof Tony Bewley, Consultant Dermatologist, Barts Health NHS Trust, and Honorary Professor of Dermatology at QMUL**.

"*Atopic Dermatitis is a chronic, life-long condition, with no cure. It is very encouraging to witness the increase in drug development in Atopic Dermatitis, especially with biological treatments, which can have a very beneficial effect on the condition. That lebrikizumab is now reimbursed by NICE is great news for patients as it adds another much-needed targeted biologic to the treatment options already available for Atopic Dermatitis.*" said **Prof Richard Weller, Professor of Medical Dermatology at the University of Edinburgh, and Honorary Consultant Dermatologist.**

About lebrikizumab

Lebrikizumab is a monoclonal antibody that binds the cytokine IL-13 with high affinity to specifically prevent the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signalling, thus inhibiting the biological effects of IL-13. Therefore, inhibition of the IL-13 signalling is expected to be of benefit in diseases in which IL-13 is a key contributor to the disease pathogenesis. IL-13 is key in atopic dermatitis, driving the type-2 inflammatory loop in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection. Lebrikizumab represents a step forward in patients with moderate-to-severe AD not controlled with topical therapy due to its selective mechanism of action, proven efficacy, acceptable safety profile, and a 4-weekly maintenance dosing for all patients. Lebrikizumab demonstrated clinical efficacy in both, monotherapy and in combination with topical corticosteroids with 4-weekly maintenance dosing for all patients, and has been approved by the EMA in October 2023[9]. Clinical data up to one year after first dosing have been published, as well as interim clinical data up to two years after first dosing.[5-8]

About atopic dermatitis

AD, also referred to as atopic eczema, is a non-contagious chronic, inflammatory disease of the skin characterized by recurrent inflammation of the skin associated with intense pruritus or itching. Beyond the evident physical manifestations such as dryness, itchiness, redness, and inflammation, this condition can exert profound emotional effects that can significantly disrupt the academic, social, and professional lives of those affected. With an estimated prevalence of up to 4.4% among adults in the EU, the incidence of AD appears to have increased in recent decades, with approximately 20-30% of patients having moderate-to-severe disease.

About Almirall

Almirall is a global pharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We are at the forefront of science to deliver ground-breaking, differentiated medical dermatology innovations that address patients´ needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Almirall (total revenue in 2023: €898.8 MM, 1900 employees globally) has direct presence in 21 countries and marketed products in over 100.

For more information, please visit almirall.com

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