



— we help people achieve healthy skin

PRESS RELEASE

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New data show LEO Pharma's Kyntheum® (brodalumab) provides greater probability of achieving complete skin clearance for people with moderate to severe psoriasis compared with ustekinumab

Possibility of complete clearance of psoriasis symptoms can have a transformational impact on happiness, according to a new European survey of more than 7,000 people living with the disease.

Ballerup, Denmark: Data presented at the 27th European Academy of Dermatology and Venereology (EADV) in Paris, show that treatment with LEO Pharma's Kyntheum® (brodalumab) for people with moderate to severe plaque psoriasis, was associated with a more rapid reduction in absolute Psoriasis Area Severity Index (PASI) scores and a greater probability of achieving complete skin clearance in all body regions compared with ustekinumab.^{1,2} The possibility of attaining completely clear skin makes a significant difference to the lives of people with psoriasis, according to the newly published PsoClear Report.³

Outcomes of the first of two analyses of pooled data from the AMAGINE-2 and AMAGINE-3 studies showed a greater proportion of those taking Kyntheum® achieved (absolute) PASI 0, meaning complete skin clearance without any symptoms of psoriasis, over time compared with ustekinumab (75% versus 52%, respectively at 52 weeks).¹ Absolute PASI scores measure the severity of redness, thickness and scaling of skin on different parts of the body, whereby a score of less than three is indicative of treatment success.⁴ Results of the second analysis found that the time it took for 50% of patients to achieve complete clearance across all body regions – head and neck, trunk, upper limbs and lower limbs – was shorter with Kyntheum® than ustekinumab. Over the course of the 52-week analysis, superior rates of complete clearance were seen as early as week two for Kyntheum® treated patients.²

Professor Marc Radtke, Institute for Health Care Research in Dermatology and Nursing, Hamburg, Germany, commented, *“Even when a relatively small proportion of body surface is affected by psoriasis, it can still impose a substantial burden. The latest Kyntheum® data are of interest to clinicians and patients, because they show what the treatment can achieve overall*

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and on specific body regions. This gives reassurance that high levels of skin clearance are increasingly possible with newer treatments.”

2/7

Achieving complete skin clearance is a significant milestone for people with psoriasis and one which has a direct correlation to their quality of life, including their happiness levels.^{3,5,6} The recent PsoClear Report of 7,644 Europeans, showed those living with disease would be, on average, 49% happier if they achieved clear skin, defined as skin that is completely free of lesions and symptoms like itchiness and scaling.³ Nearly one in four (24%) felt achieving skin clearance would allow them to live their best possible life, giving their potential happiness level a top ranking on a 10 point happiness scale.³ However, not all of those surveyed felt so optimistic. Nearly two-thirds (63%) of people living with psoriasis believe achieving clear skin is impossible or very unlikely.³

“With treatments, like Kyntheum[®], that can offer more people a chance for complete skin clearance, it’s time to better understand and appreciate the importance and impact this improvement can have on a person’s life,” said Gitte Aabo, President & CEO, LEO Pharma. *“At LEO Pharma, helping people achieve healthy skin is at the heart of all we do and we want all people with psoriasis to have the chance to experience the transformative difference complete clearance makes.”*

A total of 13 abstracts on brodalumab and complete skin clearance in psoriasis are being presented at the 2018 EADV annual congress.

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About Kyntheum®

Kyntheum® (brodalumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults within the European Union who are candidates for systemic therapy.⁷ It is the first and only biologic treatment for psoriasis that selectively targets the interleukin-17 (IL-17) receptor subunit A.^{8,9} These receptors are the ones through which the IL-17 cytokines – a family of proteins involved in immune responses – signal, causing the inflammation associated with psoriasis. Other anti-IL-17 biologics target the IL-17A cytokine alone.^{8,10,11,12} This mechanism of action is different to all other psoriasis biologics currently available.^{8,9}

The efficacy and safety of brodalumab was evaluated in three clinical trials: AMAGINE-1, AMAGINE-2 and AMAGINE-3.¹⁰ In total, the trials included 4,373 patients with moderate to severe psoriasis,¹⁰ the largest study population in the development programme of any new biologic treatment in psoriasis to date.^{11,12,13,14,15,16,17} Results indicated brodalumab provided rapid,^{18,19} and sustained response,²⁰ as well as high levels of skin clearance^{10,21} and improved health-related quality of life.²¹

Data from clinical trials found Kyntheum® to be well tolerated, with an acceptable safety profile.^{22,23} The most common adverse events were arthralgia (joint pain), headache, fatigue, diarrhoea and oropharyngeal (mouth and throat) pain.¹⁰

LEO Pharma has a partnership agreement with AstraZeneca, granting LEO Pharma exclusive licence to develop and commercialise Kyntheum® in Europe. Outside of Europe, Valeant Pharmaceuticals has global commercial rights for brodalumab except in Japan and certain other Asian countries, where the rights are held by Kyowa Hakko Kirin Co. Ltd.

Kyntheum® was granted marketing authorisation by the European Commission in July 2017.^{10,21}

About psoriasis

Psoriasis is a common, chronic, immune-mediated, inflammatory disease that primarily involves the skin.²⁴ The most frequently reported symptoms include thickening and scaling of the skin, itching and erythema (superficial reddening of the skin, usually in patches).²⁴

An estimated 125 million people worldwide live with psoriasis,²⁵ including nearly 14 million Europeans.²⁶

4/7

Psoriasis can be a painful, disabling and stigmatising condition with substantial social and psychological impact on a person's life.²⁴ People with psoriasis, especially those with more severe symptoms, are also at increased risk of developing other serious associated conditions,²⁷ including heart disease^{28,29,30} and metabolic diseases (a combination of diabetes, high blood pressure and obesity).³¹ Mental health complications, such as depression and anxiety, are also more common in people with psoriasis.³²

According to the World Health Organization, the burden of living with psoriasis is underestimated and it urges for action to fight stigma and improve treatment.²⁴

About the PsoClear Report

The goal of the survey was to explore the perspectives of people living with psoriasis with regard to what it meant to achieve clear skin, defined as 'skin that is completely free of lesions and symptoms like itchiness and scaling'.

The PsoClear Report data were collected through PsoHappy, an advocacy online platform aiming to explore and promote the wellbeing of people living with psoriasis. In collaboration with the Happiness Research Institute, PsoHappy analysed surveys from 120,000 people from 184 countries to form the basis of the first World Psoriasis Happiness Report, published in October 2017.³³

The survey combined validated survey models that explore mental wellbeing aspects, original methodologies and open-ended questions that capture the experiences and emotions of respondents. It ran between April and May 2018, gathering responses from 7,644 respondents between the ages of 15 and 80 years old in 12 European countries: Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Italy, Norway, Portugal, Spain and the United Kingdom.³

About LEO Pharma

LEO Pharma helps people achieve healthy skin. By offering care solutions to patients in more than 130 countries globally, LEO Pharma supports people in managing their skin conditions. Founded in 1908 and owned by the LEO Foundation, the healthcare company has devoted decades of

research and development to delivering products and solutions to people with skin conditions. LEO Pharma is headquartered in Denmark and employs approximately 5,200 people worldwide.

5/7

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6/7

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