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**New data show that LEO Pharma’s Kyntheum® (brodalumab) sustains PASI 100 scores longer than ustekinumab for people with moderate-to-severe plaque psoriasis**

Ballerup, Denmark, April 25, 2019: LEO Pharma A/S, a global leader in medical dermatology, today announced that new data presented this week at the 6th Congress of the Skin Inflammation and Psoriasis International Network (SPIN) in Paris demonstrate that more patients with moderate-to-severe psoriasis who received treatment with brodalumab maintained a PASI (Psoriasis Area Severity Index) 100 score for longer than those who were treated with ustekinumab over 52 weeks.[[1]](#endnote-1)

The post-hoc analysis of the AMAGINE-2 and AMAGINE-3 studies – which included 3,712 people with moderate-to-severe psoriasis – shows that 90% of patients treated with brodalumab who achieved PASI 100 also experienced sustained PASI 100. In the same analysis, only 77% of patients treated with ustekinumab who achieved PASI 100 also experienced sustained PASI 100.1 Study authors measured ‘sustained PASI 100’ as the time to inadequate response, based on a static physician’s global assessment (sPGA) of ≥3 or persistent values of 2 over at least a 4-week period at or after week 16.1

Because the sub-populations of patients treated with brodalumab and ustekinumab in these studies had different baseline characteristics, the study authors did not apply statistical comparisons.1

*“*Newer treatments for moderate-to-severe psoriasis have made it possible for patients to completely clear their skin, but the disease fluctuates over time, so we wanted to explore how fast and for how long patients can count on having complete skin clearance,” saidProfessor Lluís Puig, Director, Department of Dermatology, Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona. “These results show that brodalumab can offer more patients a longer, more sustained period of complete skin clearance than ustekinumab. That difference can have a big impact on patients’ quality of life.”

PASI scores are used in clinical trials for psoriasis treatments to measure a change in disease severity. Most psoriasis trials have used PASI 75 (75% clearing of skin lesions) as a primary endpoint,[[2]](#endnote-2) however PASI 100 (100% clearing of skin lesions) has become commonly used in more recent studies.[[3]](#endnote-3) In its phase 3 clinical trial program, which was the largest for a biologic treatment for psoriasis at the time it was conducted, brodalumab was the first biologic that investigators evaluated using PASI 90/100 scores as a primary endpoint for patients with moderate-to-severe plaque psoriasis.

A 2018 report of 7,644 people living with psoriasis in twelve European countries found that an average of 49% would be happier if their skin was completely free of lesions and symptoms like itchiness and scaling.[[4]](#endnote-4) Nearly one in four (24%) felt achieving skin clearance would allow them to live their best possible life and gave their potential happiness level a top ranking on a 10-point happiness scale. However, nearly two-thirds (63%) of respondents believed achieving clear skin is impossible or very unlikely.4

#ENDS#

**NOTES TO EDITORS**

**About brodalumab**

Brodalumab (marketed as Kyntheum® in the European Union) is indicated for the treatment of moderate-to-severe plaque psoriasis in adults within the European Union who are candidates for systemic therapy.[[5]](#endnote-5) It is the first and only biologic treatment for psoriasis that selectively targets the interleukin-17 (IL-17) receptor subunit A.[[6]](#endnote-6),[[7]](#endnote-7) The IL-17 cytokines – a family of proteins involved in immune responses– send signals through the IL-17 receptors, which cause the inflammation associated with psoriasis. Other anti-IL-17 biologics target the IL-17A cytokine alone and not the IL-17 receptor.6,[[8]](#endnote-8),[[9]](#endnote-9),[[10]](#endnote-10)

LEO Pharma has a partnership agreement with AstraZeneca, granting LEO Pharma exclusive licence to develop and commercialise brodalumab in Europe. Outside of Europe, Bausch Health Companies Inc. (formerly Valeant Pharmaceuticals) has the global commercial rights for brodalumab except in Japan and other Asian countries, where the rights are held by Kyowa Hakko Kirin Co. Ltd. Brodalumab was granted marketing authorisation by the European Commission in July 2017.8

**About psoriasis**

An estimated 125 million people worldwide live with psoriasis,[[11]](#endnote-11) including nearly 14 million Europeans.[[12]](#endnote-12) It is a common, chronic, immune-mediated, inflammatory disease that primarily involves the skin.[[13]](#endnote-13) The most frequently reported symptoms include thickening and scaling of the skin, itching and erythema (superficial reddening of the skin, usually in patches).13

Psoriasis can be a painful, disabling and stigmatising condition with substantial social and psychological impact on a person’s life.13 People with psoriasis, especially those with more severe symptoms, are also at increased risk of developing other serious associated conditions,[[14]](#endnote-14) including heart disease[[15]](#endnote-15),[[16]](#endnote-16),[[17]](#endnote-17) and metabolic diseases (a combination of diabetes, high blood pressure and obesity).[[18]](#endnote-18) Mental health complications, such as depression and anxiety, are also more common in people with psoriasis.[[19]](#endnote-19) 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.13

**About LEO Pharma**

LEO Pharma helps people achieve healthy skin. The company is a leader in medical dermatology with a robust R&D pipeline, a wide range of therapies and a pioneering spirit. Founded in 1908 and owned by the LEO Foundation, LEO Pharma has devoted decades of research and development to advance the science of dermatology, setting new standards of care for people with skin conditions. LEO Pharma is headquartered in Denmark with a global team of 5,500 people, serving 76 million patients in 130 countries. In 2018, the company generated net sales of DKK 10,410 million.

For more information about LEO Pharma, visit [www.leo-pharma.com](http://www.leo-pharma.com).

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