

PRESS RELEASE

EMBARGO: 08:00 AM CET, 12 SEPTEMBER 2018

\*\*\* THIS MATERIAL IS NOT INTENDED FOR FRENCH JOURNALISTS \*\*\*

# LEO Pharma to showcase two dozen data presentations at 27<sup>th</sup> annual European Academy of Dermatology and Venerology Congress in Paris

BALLERUP, Denmark, 12 September 2018 – LEO Pharma A/S, a global leader in medical dermatology, today announced that 24 key data abstracts will be presented during the 27<sup>th</sup> annual European Academy of Dermatology and Venerology (EADV) Congress in Paris this week.

"Atopic dermatitis and psoriasis are two of the most common yet debilitating skin diseases that can have a profound impact on the quality of lives of people around the world, so there is still a huge unmet need for more and better treatment options," said Kim Domela Kjøller, EVP of Global R&D at LEO Pharma A/S. "We're excited about the scientific data being presented this week at the EADV as we continue our mission to develop new, innovative therapies to help patients achieve healthy skin."

All abstracts will be accessible via computers in the EADV Congress's E-Poster Hall during congress hours from today until noon on Sunday, 16 September:

Brodalumab abstracts in psoriasis			
Title	Lead Author	ID	
Absolute Psoriasis Area and Severity Index from baseline to Week 52 in patients with moderate-to-severe plaque psoriasis treated with brodalumab or ustekinumab in the AMAGINE 2 and AMAGINE 3 studies.	C. Zachariae	E-Poster P0453	
Correlation between Psoriasis Area and Severity Index and Dermatology Life Quality Index in patients with moderate-to-severe psoriasis treated with brodalumab in the AMAGINE studies	J. Lambert	Abstract ID: 3327	
Multiple IL-17 cytokines, signalling through IL- 17 receptor A, drive inflammatory pathways in psoriasis	H. Norsgaard	E-Poster P1974	
Efficacy of brodalumab, an interleukin-17 receptor antibody, on clinical signs of moderate-to-severe plaque psoriasis in different body regions	S. Segaert	E-Poster P0457; Abstract ID: 3448	

LEO Pharma A/S

Industriparken 55 2750 Ballerup Denmark

Phone +45 4494 5888 Fax +45 7226 3321

www.leo-pharma.com VAT no. 56 75 95 14





Achieving complete clearance in the AMAGINE-2 and -3 studies: Complete clearance over time in patients with moderate to severe plaque psoriasis treated with brodalumab up to 52 weeks	K. Reich	Abstract ID: 3530
Consistency of response with brodalumab treatment of moderate-to-severe psoriasis with scalp involvement across clinical subgroups: results from the AMAGINE-1 study	S. Philipp	Abstract ID: 3440
Complete Clearance is Associated with Fewer Patient-Reported Plaque Psoriasis Symptoms Compared to Almost Complete Clearance in Real Life (PSO-BIO-REAL)	G. Pellacani	E-Poster P2087
Complete Clearance is Significantly Associated with Improved Health-Related Quality-of-Life Compared to Almost Complete Clearance in Patients with Moderate to Severe Plaque Psoriasis (PSO-BIO-REAL)	A. Bewley	E-Poster P2085
The Association Between Patient-Reported Outcomes and Physician-reported Measures for Patients with Moderate to Severe Psoriasis in Real Life (PSO-BIO-REAL)	M. Augustin	E-Poster P2082
Predictors of Complete Clearance in Moderate to Severe Plaque Psoriasis (PSO- BIO-REAL)	J. Seneschal	E-Poster P2080
More Patients with Complete Clearance compared to Almost Complete Clearance Report no Psoriasis Symptoms as Measured by the Psoriasis Symptom Inventory PSI	J.P. Lacour	E-Poster P2075
Interleukin-17 and interleukin-23 targeted treatments for moderate to severe plaque psoriasis: a systematic review and network meta-analysis of PASI response	L. Sawyer	E-Poster P1901

Calcipotriol/betamethasone dipropionate abstracts in psoriasis			
Title	Lead Author	ID	
Rapid and effective itch relief from calcipotriol plus betamethasone dipropionate foam in patients with psoriasis	A. Jalili	E-Poster P2016	
Rapid onset of action with topical fixed-dose combination calcipotriol plus betamethasone dipropionate cutaneous foam in patients with psoriasis, irrespective of baseline disease severity	A. Pink	E-Poster P1852	
Pruritus correlates best with quality of life in plaque-psoriasis – analysis of a real-world	S. Gerdes	E-Poster P1845	



evidence study on calcipotriol/ betamethasone cutaneous foam (Enstilar®) in Germany		
Calcipotriol plus betamethasone dipropionate aerosol foam versus apremilast, methotrexate, acitretin, or fumaric acid esters: a matchingadjusted indirect comparison	A. Bewley	E-Poster P1927
Patients' adherence and satisfaction to the treatment of scalp psoriasis with betamethasone dipropionate/calcipotriol Gel Applicator (ASAP PSO study)	M. Kemula	E-Poster P1888
Assessing the safety and efficacy of fixed- dose combination calcipotriol 50 ug/g plus betamethasone 0.5 mg/g (as dipropionate) gel in adolescent patients with psoriasis	L.F. Eichenfield	E-Poster P2043
A 3-years longitudinal study examining switching between topical and systemic therapies in French patients with plaque psoriasis	M. Foist	E-Poster P2021

Tralokinumab in atopic dermatitis/eczema and atopic dermatitis abstracts			
Title	Lead Author	ID	
Risk of anaphylaxis and conjunctivitis with tralokinumab in atopic dermatitis	A. Wollenberg	E- Poster P0279	
Tralokinumab significantly reduces Staphylococcus aureus colonization in adult patients with moderate to severe atopic dermatitis: results from a Phase 2b, randomized, double-blind, placebo-controlled study	E. Guttman- Yassky	E- Poster P0283	
Treatment with tralokinumab improves health- related quality of life in adult patients with moderate to severe atopic dermatitis: results from a Phase 2b, randomized, double-blind, placebo-controlled study	J. Silverberg	E- Poster P0281	
Memory buttons, a supportive mobile application and topical treatment induced additive improvements in atopic dermatitis	J.R. Zibert	E- Poster P0304	
Eczema happiness study: Subjective well- being as a measure for happiness in people with eczema	J.R. Zibert	E- Poster P2136	

For more information about the 27<sup>th</sup> EADV Congress in Paris, please visit <a href="https://eadvparis2018.org/">https://eadvparis2018.org/</a>.

# ENDS #



#### **NOTES TO EDITORS**

#### **About brodalumab**

Brodalumab is indicated for the treatment of moderate to severe plaque psoriasis in adults within the European Union who are candidates for systemic therapy. It is the first and only biologic treatment for psoriasis that selectively targets the interleukin-17 (IL-17) receptor subunit A.<sup>2,3</sup> 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.

LEO Pharma has a partnership agreement with AstraZeneca, granting LEO Pharma exclusive licence to develop and commercialise brodalumab 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.

# About calcipotriol/betamethasone dipropionate

The fixed-dose combination of calcipotriol and betamethasone is a well-established treatment option for psoriasis in several guidelines across Europe. 4,5,6,7 The product is available in topical gel, ointment and foam spray formulations. Calcipotriol/betamethasone dipropionate is the first and only topical foam spray treatment for all severities of plaque psoriasis in patients who are 18 years or older,8 and was introduced in Europe and the United States in 2016 after a large clinical study program,9,10,11 with other markets beginning to launch this year.

# About tralokinumab

Tralokinumab is a fully human, immunoglobulin (Ig)G4 monoclonal antibody (mAb) that specifically and directly blocks the type 2 cytokine IL-13 and its detrimental effects. IL-13 plays a central role in the pathophysiology of AD, including inflammation, epidermal barrier dysfunction, and itch.<sup>12</sup> The importance of neutralizing IL-13-mediated inflammation, epidermal barrier dysfunction, and itch is supported by the recently published results of a 12-week phase 2b study in 204 adults with moderate-to-severe atopic dermatitis.<sup>13</sup> Tralokinumab is an investigational agent under clinical development and its safety and efficacy have not been evaluated by any regulatory authority.

#### **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.

LinkedIn: <a href="https://www.linkedin.com/company/leo-pharma">www.linkedin.com/company/leo-pharma</a>
YouTube: <a href="https://www.youtube.com/leopharmaglobal">www.youtube.com/leopharmaglobal</a>



### References

- <sup>1</sup> European Commission, Community register of medicinal products for human use, Kyntheum® (brodalumab). Available at: <a href="http://ec.europa.eu/health/documents/community-register/html/h1155.htm">http://ec.europa.eu/health/documents/community-register/html/h1155.htm</a> (Accessed July 2018).
- <sup>2</sup> Campa M, et al. Dermatol Ther 2016;6:1-12.
- <sup>3</sup> Coimbra S, et al. Core Evidence 2014;9:89–97.
- 4 Nast A, et al. Guidelines for the treatment of psoriasis vulgaris, 2017 Update, Appendix A. [cited June 2018] Available from URL: https://www.awmf.org/en/clinical-practice-guidelines/detail/ll/013-001.html.
- 5 National Institute for Health and Care Excellence (2017). Psoriasis: Assessment and management (CG153).
- 6 Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. Edinburgh: SIGN; 2010. (SIGN publication no. 121). [cited June 2018]. Available from URL: http://www.sign.ac.uk.
- 7 Carrascosa J.M. et al. Actas Dermosifilogr 2009. 190-200 [Spanish]
- 8 EnstilarR (Calcipotriol/ Betamethasone Dipropionate) EU SmPC. May 2016.
- 9 Lebwohl M et al. Fixed Combination Aerosol Foam Calcipotriene 0.005% (Cal) Plus Betamethasone Dipropionate 0.064% (BD) is More Efficacious than Cal or BD Aerosol Foam Alone for Psoriasis Vulgaris. J Clin Aesthet Dermatol 2016; 9(2): 34–41.
- 10 Leonardi C, Bagel J, Yamauchi P, Pariser D, Xu Z, Olesen M. Efficacy and Safety of Calcipotriene Plus Betamethasone Dipropionate Aerosol Foam in Patients With Psoriasis Vulgaris – a Randomized Phase III Study (PSO-FAST). J Drugs Dermatol. 2015;14(12):1468-1477.
- 11 Koo J, Tyring S, Werschler WP, et al. Superior Efficacy of Calcipotriene and Betamethasone Dipropionate Aerosol Foam Versus Ointment in Patients with Psoriasis Vulgaris A Randomized Phase II Study. J Dermatolog Treat. 2016;27:120–127.
- <sup>12</sup> Silverberg J, Kantor R. The role of interleukins 4 and/or 13 in the pathophysiology and treatment of atopic dermatitis. Dermatol Clinics 2017; 35:327–334.
- <sup>13</sup> Wollenberg A, et al. Treatment of atopic dermatitis with tralokinumab, an anti–IL-13 monoclonal antibody. J Allergy Clin Immunol 2018. https://doi.org/10.1016/j.jaci.2018.05.029 (Article in press).

