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News Release

LEO Pharma Inc.

1 Sylvan Way
Parsippany
New Jersey 07054
United States of America

Phone +1 973 637 1690
Fax +1 973 637 1682

www.leo-pharma.us

LEO Pharma Supports the FDA's Selection of Psoriasis as a Priority Disease

PARSIPPANY, NJ (August 3, 2015) – LEO Pharma supports the recent decision by the U.S. Food and Drug Administration (FDA) to include psoriasis as one of eight priority disease areas in its 2016-2017 Patient Focused Drug Development Initiativeⁱ. Psoriasis is an autoimmune disease that has a major impact on patients' lives and subsequent comorbidities, affecting 7.5 million people in the US alone.ⁱⁱ

As part of LEO Pharma's ongoing commitment to supporting patients living with psoriasis, LEO Pharma along with the National Psoriasis Foundation (NPF) and other stakeholders, worked through the FDA's commenting process to ensure psoriasis was included in the Patient Focused Drug Development Initiative.ⁱⁱⁱ

"We applaud the FDA for including psoriasis in the priority disease area and believe it is a major milestone for psoriasis patients in the United States as it will raise awareness regarding patient needs," said Barbara Osborne, President and CEO of LEO Pharma Inc. in the U.S. *"As a company dedicated to improving the lives of patients living with skin diseases, including psoriasis, we are proud to have been a valuable partner throughout the information gathering process."*

In October 2014, the FDA published a preliminary list^{iv} of 16 disease areas for consideration for the initiative, and asked the public to determine the disease areas of greatest priority. As a patient-centric dermatological company, LEO Pharma participated in this commenting process in raising the awareness of psoriasis – a disease which was not originally part of the FDA's list.

LEO Pharma will attend a future public meeting hosted by the FDA to discuss psoriasis, its impact on patients' daily lives, the types of treatments available for patients, and patients' perspectives on the acceptability of available therapies. The public meeting is also a unique opportunity for psoriasis patients to have their voices heard concerning their experiences and perspectives of living with and treatment of a chronic remitting and relapsing disease.



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About Psoriasis^v

Psoriasis is a chronic, inflammatory disease, which is frequently accompanied by multiple physical and/or psychological comorbidities, such as metabolic syndrome and psoriatic arthritis.

Plaque psoriasis is estimated to affect about 2-4% of the population in the US. Eighty percent (80%) of patients are affected by plaque psoriasis – the most common clinical form of psoriasis.

Topical treatments are first-line therapies for the majority of patients since approximately 80% of the affected patients have mild or moderate plaque psoriasis.

About LEO Pharma

LEO Pharma Inc. is a wholly owned subsidiary of LEO Pharma A/S. Founded in 1908, LEO Pharma A/S is an independent, research-based pharmaceutical company. LEO Pharma A/S develops, manufactures and markets pharmaceutical drugs in more than 100 countries globally. The company has its own sales forces in 61 countries and employs more than 4,800 employees worldwide. LEO Pharma A/S is headquartered in Denmark and is wholly owned by the LEO Foundation.

Media Contacts:

Elizabeth Maria Rosenkrands-Lange
Regulatory Policy and Intelligence Manager
elizabeth.rosenkrands-lange@leo-pharma.com
(973) 637-1654

Nora Masin
Specialist, Communications
nora.masin@leo-pharma.com
(973) 637-1611

ⁱ <https://www.federalregister.gov/articles/2015/07/02/2015-16359/prescription-drug-user-fee-act-patient-focused-drug-development-announcement-of-disease-areas-for>

ⁱⁱ https://www.psoriasis.org/cure_known_statistics

ⁱⁱⁱ <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm>

^{iv} <https://www.federalregister.gov/articles/2014/10/08/2014-23965/prescription-drug-user-fee-act-patient-focused-drug-development-request-for-comments>

^v Parisi R, *et al.* Global Epidemiology of Psoriasis: A Systematic Review of Incidence and Prevalence. The Society for Investigative Dermatology. *J Invest Dermatol* 2013;**133**(2):377-85