LEO Pharma initiates phase 2b clinical studies of topical delgocitinib cream in adults for the treatment of both atopic dermatitis and chronic hand eczema

BALLERUP, Denmark, 29 November 2018 – LEO Pharma A/S, a global leader in medical dermatology, announces today that it has enrolled the first patients in two new phase 2b clinical studies to investigate delgocitinib, a novel topical pan-Janus kinase inhibitor (JAKi), as a monotherapy for adults with mild-to-severe atopic dermatitis (AD) as well as mild-to-severe chronic hand eczema (CHE).

Both phase 2b trials are double-blind, randomized, vehicle-controlled, dose-ranging trials to evaluate the efficacy and safety of twice-daily topical application of delgocitinib cream. Both investigator- and patient-assessed outcomes will be measured in the clinical trials.

“Atopic dermatitis and chronic hand eczema are highly symptomatic and can have a profoundly negative impact on the lives of the people who suffer from them. There are still many unmet therapeutic needs for both disorders, including a need for new, highly efficacious treatments with fewer side effects,” said Jonathan Silverberg, MD, PhD, Associate Professor of Dermatology at Northwestern University Feinberg School of Medicine, Chicago, Illinois, and lead investigator in the AD trial. “Delgocitinib has a novel mechanism of action and the potential to offer both excellent efficacy and safety in atopic dermatitis and chronic hand eczema.”

Further information about trials with topical delgocitinib cream can be accessed via https://clinicaltrials.gov.

# ENDS #

NOTES TO EDITORS

About atopic dermatitis (AD)
AD is a common type of eczema that affects up to five percent of adults across the United States, Canada, Europe and Japan.1 It is a chronic, relapsing skin disease, characterized by severe itch, dry skin, persistent immune-mediated inflammation, and skin barrier defects.2 AD has a significant, negative impact on patients’ well-being, primarily due to the intense itch which leads to disrupted sleep and other negative consequences.2 There is currently a high unmet need for long-term efficacious and well-tolerated treatment options in atopic dermatitis.3
About chronic hand eczema (CHE)
Hand eczema (HE) is a heterogeneous disease with many different causes, and ranges in severity from very mild to severe. Clinically, HE is characterized by lesioned skin on the hands that may be red, patchy, swollen, scaly, cracked, or thickened, with symptoms of itch and pain. HE is considered chronic (CHE) when it lasts for more than three months or relapses twice or more per year. Painful fissures and blisters affect a person’s daily life and well-being, and can prevent manual labor, leading to significant economic loss to both individuals and society.⁴,⁵

About delgocitinib
Elevated levels of various cytokines are involved in the disease process of inflammatory diseases.⁶ Topical delgocitinib is a pan-JAK inhibitor, which blocks various cytokine signaling pathways and widely suppresses the activation of immune and inflammatory cells such as T cells, B cells, mast cells and monocytes.

In 2014, LEO Pharma and Japan Tobacco Inc. (JT) entered into a license agreement in which LEO Pharma gained exclusive rights to develop and commercialize delgocitinib for topical use in dermatological indications worldwide, excluding Japan, where JT retains rights. Delgocitinib is part of LEO Pharma’s robust pipeline of eczema products: http://www.leo-pharma.com/Home/Research-and-Development/Pipeline-1.aspx. Delgocitinib is not currently approved by a regulatory authority in any country for any indication.

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.

Facebook: www.facebook.com/LEOPharmaAS
LinkedIn: www.linkedin.com/company/leo-pharma
Twitter: www.twitter.com/leohealthyskin
YouTube: www.youtube.com/leopharmaglobal
References

3 Q&A with Dr. Silverberg. Ask the Presenter - Conference Report. AJMC 2016.