Helsinn announces abstract accepted for oral presentation at the EORTC Cutaneous Lymphoma Meeting 2019

Lugano, Switzerland, September 26, 2019 – Helsinn, the Swiss pharmaceutical group focused on building quality cancer care products, today announces an abstract has been accepted for oral presentation at the European Organization for Research and Treatment of Cancer (EORTC) Cutaneous Lymphoma Meeting 2019 taking place from September 26-28, 2019 in Athens, Greece.

The abstract entitled “Efficacy and quality of life (QoL) in patients with mycosis fungoides cutaneous T-cell lymphoma (MF-CTCL) treated with chlormethine¹ gel and other therapies: Results from the PROVe study” was a real-world study assessing 298 adult patients with any stage MF-CTCL. New users, or continuing users, of chlormethine gel were enrolled in this multi-center, observational study and were followed for a period of 24 months. The study demonstrated that responding patients adding chlormethine gel to their MF-CTCL therapeutic armamentarium had a significant improvement in their quality of life, as assessed by the SkinDex-29 questionnaire. It also highlighted the importance of continuing treatment to achieve the peak clinical response.

Dr. Silvia Sebastiani, Head of Medical Affairs at Helsinn, commented: “At Helsinn our focus is the quality of life and well-being of patients. We are therefore pleased to present these recent findings that demonstrate how clinicians can potentially improve the treatment and care of MF-CTCL patients by using Valchlor®/Ledaga® into their treatment options. We look forward to presenting the top line data of this real-world study at the EORTC this year, with the aim of expanding our collective knowledge and continuing to improve treatment for this patient group.”

In a randomised-controlled trial (n=128 exposed to Ledaga® for a median duration of 52 weeks), the most frequent adverse reactions to Ledaga® were skin related: dermatitis (54.7%; e.g., skin irritation, erythema, rash, urticaria, skin-burning sensation, pain of the skin), pruritus (20.3%), skin

¹ Chlormethine gel, also referred as mechloretamine, is approved in the US and Israel under the tradename Valchlor® and in the EU under the tradename Ledaga®.
infections (11.7%), skin ulceration and blistering (6.3%), and skin hyperpigmentation (5.5%). Cutaneous hypersensitivity reactions were reported in 2.3% of the treated patients.

Dr. Ellen J. Kim, UPENN, Professor of Dermatology, Penn Cutaneous Lymphoma Program, PROVe principal investigator, said: “The rarity of MF-CTCL has resulted in there being limited knowledge available for those affected by this disease, as well as many clinicians. We are pleased to have conducted the PROVe study and to further highlight our findings at the EORTC, as we set out to further expand our knowledge concerning the field of MF and current treatment options. The observational study assessed nearly 300 patients and verified that continued treatment of MF-CTCL patients with chlormethine gel is important and associated with improved patients' health-related quality of life.”

Presentation Details:

**Title:** Efficacy and quality of life (QoL) in patients with mycosis fungoides cutaneous T-cell lymphoma (MF-CTCL) treated with chlormethine gel and other therapies: Results from the PROVe study

**Session:** Quality of life

**Date:** September 27, 2019

**Time:** 3:30pm-4:15pm

**Presenter:** Dr Ellen Kim

About Ledaga®

Ledaga® gel is an alkylating drug indicated for the topical treatment of MF-CTCL in adult patients. Ledaga® is a gel which is applied topically once a day. The drug has been approved by the European Commission (for the treatment of MF-CTCL in adult patients). Since June 2019, Ledaga® is commercialized in Germany, The Netherlands, France and Italy.

For additional information please see the EU Summary of Product Characteristics.
About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

For more information:

Helsinn Group Media Contact:

Paola Bonvicini
Group Head of Communication
Lugano, Switzerland
Tel: +41 (0) 91 985 21 21
Email: Info-hhc@helsinn.com

For more information, please visit www.helsinn.com and follow us on Twitter, LinkedIn and Vimeo