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Building quality cancer care together

Helsinn demonstrates commitment to MF CTCL with multiple scientific sessions 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 two further abstracts have been accepted for oral presentations at the European Organization for Research and Treatment of Cancer (EORTC) Cutaneous Lymphoma Meeting 2019. Helsinn has also announced the acceptance of an abstract for the first real-world study of Valchlor®/Ledaga® at this same meeting. The EORTC Cutaneous Lymphoma meeting is taking place from September 26-28, 2019 in Athens, Greece. In addition to presenting new scientific data on Valchlor®/Ledaga®, Helsinn supported an educational satellite symposium on experiences in treating MF-CTCL.

Helsinn's oral presentation, entitled: **Efficacy of chlormethine gel in patients with stage I–IIA mycosis fungoides cutaneous T-cell lymphoma (MF-CTCL): Re-analysis of a randomized Phase 2 study**, will take place on Friday September 27, 2019, 4.45pm - 6.00pm.

The presentation reports the results of the re-analysis on the response of early-stage MF-CTCL patients to chlormethine[1] gel treatment in a randomized, controlled, observer-blinded, multi-center Phase 2 study. Early stage patients who had been previously treated with more than one skin-directed therapy were enrolled into the study and their response rate to treatment was monitored at each physician visit. Results showed that the percentage of patients with more than 50% improvement from the baseline was 46.9% at 4 months, 72.2% at 8 months and 78.9% at 10 months by the Composite Assessment of Index Lesion Severity (CAILS), 37.8% at 4 months, 4 54.4% at 8 months and 54.4% at 10 months by Severity Weighted Assessment Tool (SWAT), and 32.7% at 4 months, 52.2% at months 8 and 51.1% at 10 months by Body Surface Area (BSA).

A second oral presentation, entitled: **Clinician-level variation in mechlorethamine treatment duration in mycosis fungoides cutaneous T-cell lymphoma (MF-CTCL) / Biologic Insights III,** will take place on **Friday September 27, 2019, from 09.00am – 10:30am**. The presentation

1 Chlormethine gel, also referred as mechlorethamine, is approved in the US and Israel under the tradename Valchlor® and in the EU under the tradename Ledaga®.

will discuss research into the use of mechlorethamine in the treatment of mycosis fungoides cutaneous T-cell lymphoma (MF-CTCL). The study evaluated the association of patient volume with early discontinuation and overall treatment duration for clinicians prescribing standardized 0.016% gel formulation mechlorethamine. Clinicians with higher patient volume consistently sustained longer treatment duration and, importantly, avoided early discontinuation, perhaps attributable to experience managing the condition and dermatitis, and setting patient expectations for treatment adherence and toxicity.

As previously announced, Helsinn is also presenting a separate abstract on a significant real-world study assessing the use of chlormethine gel in 298 adult patients with any stage MF-CTCL. Full details can be found in the herewith press release link.

Helsinn has also supported an educational symposium, entitled **Tried and applied: experiences with chlormethine gel in MF-CTCL**, which took place on **Thursday September 26.** It brought together a panel of leading experts from the field of Cutaneous Lymphoma, to discuss the current treatment options of Mycosis Fungoides Cutaneous T-cell lymphoma (MF-CTCL), in particular the use of chlormethine gel in treating MF-CTCL. The full programme for the event can be viewed on the EORTC Congress website:
https://www.eortccltf2019.com/articlefiles/program/Eortc_2019_Scientific_programme_5.pdf

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 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.

Evangelia Papadavid, MD, PhD Associate Professor of Dermatology National and Kapodistrian University of Athens, Greece, Chair of the Symposium and Chair of EORTC 2019, commented: “There is currently no cure for patients living with MF-CTCL and current treatment goals are mainly aimed at reducing the abnormal appearance of the skin and to control any itching or other symptoms. This symposium specifically discussed the use of chlormethine gel in treating MF-CTCL, including where we are now and other new treatment approaches that are being explored to help patients suffering from this disease.”

Silvia Sebastiani, PhD, Head of Medical Affairs, commented: "MF-CTCL patients currently have limited treatment options mainly aimed at reducing symptom burden. At EORTC, we will be presenting significant data and outcomes of real world studies that demonstrate how chlormethine gel can help these patients managing the disease in their day to day lives. We are delighted to be among the leaders in transforming treatment of MF-CTCL and to support clinical and educational programs that brings together leading experts to share ideas on how to improve care for these patients. We thank all our partners, presenters and the Chair of the EORTC and the Symposium, Evangelia Papadavid."

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.

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