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New Insights on Mechlorethamine/Chlormethine gel presented at 4th World Congress of Cutaneous Lymphomas

Lugano, Switzerland, February 14, 2020 – Helsinn, the Swiss pharmaceutical group focused on building quality cancer care products, today announces that scientific abstracts have been accepted for oral presentation and one abstract for poster presentation at the World Congress of Cutaneous Lymphomas (WCCL) taking place from 12-14th February 2020 in Barcelona, Spain.

The first oral presentation, entitled "*The PROVe study: real-world experience with chlormethine gel[1] and other therapies in the treatment of mycosis-fungoides cutaneous T-cell lymphoma patients,*" outlines results from the largest prospective, open label, single arm, multicenter observational study (NCT02296164), assessing treatment patterns and efficacy, safety, and health-related quality of life (HR-QoL) outcomes in 298 MF-CTCL patients treated with chlormethine gel and other therapies in a real-world setting in the US.

Two additional presentations, one oral presentation and one poster, explore preliminary data from the Mechlorethamine Induced Contact Dermatitis Avoidance Study (MIDAS), an ongoing, open-label investigator-initiated study (IIS) investigating the incidence and types of contact dermatitis (CD) following treatment with mechlorethamine/chlormethine gel in patients with MF-CTCL.

One last presentation reports outcomes of a retrospective analysis evaluating the association of patient volume with early discontinuation and overall treatment duration for clinicians prescribing standardized 0.016% gel formulation mechlorethamine.

In the EU clinical study for LEDAGA: a randomized-controlled trial (n=128 exposed to Ledaga for a median duration of 52 weeks), the most frequent adverse reactions 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

[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.

hyperpigmentation (5.5%). Cutaneous hypersensitivity reactions were reported in 2.3% of the treated patients."

Dr. Silvia Sebastiani, Head of Medical Affairs at Helsinn, commented: "*As further information emerges from the PROVe and MIDAS studies, we continue exploring the potential of Valchlor®/Ledaga® for the treatment of this rare skin disease. We remain committed to offering the highest quality in care for patients."*

Dr. Ellen J. Kim, University of Pennsylvania, Professor of Dermatology, Penn Cutaneous Lymphoma Program, PROVe principal investigator, said: *"There remains a distinct lack of knowledge regarding this rare disease thus our observational PROVe study of nearly 300 patients provides valuable information to the medical community. The PROVe results confirm that mechlorethamine/chlormethine gel treatment is effective in the management of MF-CTCL."*

In the EU

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.

In the US:

About Valchlor®

INDICATION

VALCHLOR® (mechlorethamine) gel is indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in patients who have received prior skin-directed therapy.

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VALCHLOR is contraindicated in patients with known severe hypersensitivity to mechlorethamine. Hypersensitivity reactions, including anaphylaxis, have occurred with topical formulations of mechlorethamine.

WARNINGS AND PRECAUTIONS

- **Mucosal or eye injury**: Exposure of mucous membranes to mechlorethamine such as the oral mucosa or nasal mucosa causes pain, redness, and ulceration, which may be severe. Exposure of the eyes causes pain, burns, inflammation, photophobia, and blurred vision. Blindness and severe irreversible anterior eye injury may occur. Should eye exposure or mucosal contact occur, immediately irrigate for at least 15 minutes with copious amounts of water, followed by immediate medical consultation
- **Secondary exposure**: Avoid direct skin contact with VALCHLOR in individuals other than the patients due to risk of dermatitis, mucosal injury, and secondary cancers
- **Dermatitis**: Dermatitis may be moderately severe or severe. Monitor patients for redness, swelling, inflammation, itchiness, blisters, ulceration, and secondary skin infections. Stop treatment with VALCHLOR or reduce dose frequency
- **Non-melanoma skin cancer**: Monitor patients during and after treatment with VALCHLOR
- **Embryo-fetal toxicity**: May cause fetal harm. Women should avoid becoming pregnant while using VALCHLOR due to the potential hazard to the fetus. For nursing mothers, do not breastfeed during treatment with VALCHLOR
- **Flammable gel**: VALCHLOR is an alcohol-based gel. Avoid fire, flame, and smoking until the gel has dried

ADVERSE REACTIONS

The most common adverse reactions (≥5%) were dermatitis (56%), pruritus (20%), bacterial skin infection (11%), skin ulceration or blistering (6%), and hyperpigmentation (5%). These reactions

may be moderately severe or severe. Elderly patients aged 65 and older may be more susceptible. Depending on severity, treatment reduction, suspension, or discontinuation may be required.

USE IN SPECIFIC POPULATIONS

- **Contraception**: Females who are able to become pregnant, and males with female partners who are able to become pregnant, should use a barrier method of contraception to avoid direct exposure of reproductive organs to VALCHLOR
- **Infertility**: The reproductive effects of VALCHLOR have not been studied: however systemically administered mechlorethamine may impair fertility. The reversibility of the effect on fertility is unknown.

DOSING AND APPLICATION

VALCHLOR is for topical dermatologic use only. Apply a thin film of gel once daily to affected areas of the skin. VALCHLOR is a cytotoxic drug and special handling and disposal procedures should be followed during use. Caregivers must wear disposable nitrile gloves when applying VALCHLOR. Patients and caregivers must thoroughly wash hands after handling or applying VALCHLOR.

To report SUSPECTED ADVERSE REACTIONS, contact Helsinn Therapeutics (U.S.), Inc. at 1-855-482-5245 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see the VALCHLOR full Prescribing Information and Medication Guide.

About Mycosis Fungoides

Mycosis fungoides (MF) accounts for almost 50% of all primary cutaneous lymphomas, a form of non-Hodgkin's lymphoma. The cause of MF remains unknown and there are no curative treatments. MF has an indolent clinical course, slowly progressing from patches to thicker plaques and eventually to tumours over years or decades. Signs include rash, patch and plaques with severe itch. MF typically affects older adults (median age at diagnosis: 55-60 years) with male predominance.

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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.

To learn more about Helsinn Group please visit www.helsinn.com

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