Helsinn presents novel data on Chlormethine gel at EORTC cutaneous lymphomas tumors group annual meeting

- Data on chlormethine in both clinical trials and real-world settings will be presented
- Helsinn sponsoring a symposium chaired by Prof. Pablo Ortiz-Romero to discuss chlormethine's mechanism of action

Lugano, Switzerland, 21 September 2022 – Helsinn Group ("Helsinn"), a fully integrated, global biopharma company with a diversified pipeline of innovative oncology assets, announces that two scientific abstracts have been accepted for oral presentation at the upcoming EORTC CLTG (European Organisation for Research and Treatment of Cancer Cutaneous Lymphoma Tumors Group) Annual Meeting 2022, taking place in Madrid, Spain from the 22-24 September.

Details on the presentations are below:

Presentations:

Title: A Post-hoc Analysis of Clinical Trial Data Shows that Prior Phototherapy Does Not Affect Response to Chlormethine Gel in Patients with Mycosis Fungoides

Authors: Chalid Assaf, Christiane Querfeld, Marta Scandurra, Marco Turini, Julia J. Scarisbrick

Date/Time: 23 September, 6:36pm CET

Presenter: Chalid Assaf, Prof. Dr. med., Chief Physician of the Clinic for Dermatology and Venerology, Helios Klinikum Krefeld, Germany

Title: Combination Therapy with Chlormethine Gel and Narrow-Band Ultraviolet B for Patients with Mycosis Fungoides: a Case Series

Authors: Laura Gleason, Daniel Joffe, Neda Nikbakht MD, PhD

Date/Time: 23 September, 5:12pm CET

Presenter: Laura Gleason, MD, Thomas Jefferson University, Department of Dermatology and Cutaneous Biology, Philadelphia, US

During the conference Helsinn will also be sponsoring a satellite symposium which will focus on chlormethine's mechanism of action. The symposium, entitled "A multi-level analysis of chlormethine: from skin cells to clinical cases", will involve experts in the field of mycosis fungoides, including Prof. Pablo Ortiz-Romero, Head of Dermatology at University Hospital 12 de Octubre in Madrid, Spain and Prof. Emmanuella Guenova, Dermatologist at the Lausanne University Hospital, Switzerland and one of the leading researchers of the chlormethine molecule.

Satellite symposium

Title: A multi-level analysis of chlormethine: from skin cells to clinical cases

Date/Time: Thursday 22 September/1:30-2:30pm CET

Presenters: Emmanuella Guenova and Pablo Ortiz-Romero

Dr. Silvia Sebastiani, Group Head of Medical Affairs, commented: "It's fantastic to see the growing body of data emerging from *in vitro*, clinical and case studies of LEDAGA®/VALCHLOR® for the treatment of this rare skin lymphoma. We're pleased to be taking part in EORTC CLTG, sharing our own findings, as well as hearing the latest insights from across the cutaneous lymphoma research landscape. We remain committed to support the global MF-CTCL patient population."

Prof. Pablo Ortiz-Romero Head of Dermatology at University Hospital 12 de Octubre, added: "There is currently no cure for patients living with MF-CTCL and treatment goals are mainly aimed at reducing the abnormal appearance of the skin and to control any itching or other symptoms. I am delighted to Chair the Helsinn satellite symposium where emerging new data regarding chlormethine's mode of action will be discussed, as well as interesting insights from Professor Guenova's clinical experience. The latest research further delineates the mechanism of LEDAGA®/VALCHLOR® in the treatment of this rare skin cancer."

Chlormethine gel 0.016%, also known as mechlorethamine gel, is approved in multiple countries, including the EU and US, and is marketed under the trade names LEDAGA® and VALCHLOR®. The authorized use for each country varies based on the design of the registrational trial and the individual health authority requirements. For more details, please refer to the approved product information for each respective jurisdiction.

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 tumors 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.

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 almost 30 countries including Europe, Canada, Latin America.

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

About VALCHLOR® in the US

INDICATION

VALCHLOR® (mechlorethamine) gel 0.016% 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.

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
- 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®
- Non-melanoma skin cancer: Monitor patients during and after 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

HELSINN
Building quality cancer care together

About Helsinn

Helsinn is a fully integrated, global biopharma company headquartered in Lugano, Switzerland. It is focused on improving the lives of cancer patients all over the world with a leading position in cancer supportive care and an innovative pipeline of cancer therapeutics.

Helsinn is a third-generation family-owned company, that since 1976 has been focused on improving the lives of patients, guided by core values of respect, integrity and quality. It operates a unique licensing business model with integrated drug development and manufacturing capabilities. Helsinn has a commercial presence in 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-standing trusted partners. Helsinn also has a fully integrated supply chain and product development through its subsidiary in Ireland, Helsinn Birex Pharmaceuticals Ltd.

Helsinn plays an active and central role in promoting social transformation in favor of people and the environment. Corporate social responsibility is at the heart of everything we do, which is reinforced in the company's strategic plan by a commitment to sustainable growth.

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

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