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Building quality cancer care together

Helsinn Therapeutics (U.S.), Inc. waives copay fees for cancer-treating drug VALCHLOR® (mechlorethamine) gel to ensure eligible patients have access to treatment during the COVID-19 crisis

Iselin, New Jersey, April 20, 2020 – Helsinn Therapeutics (U.S.), Inc., the US subsidiary of the Swiss pharmaceutical group focused on building quality cancer care products, today announces a change to the financial assistance program for VALCHLOR® (mechlorethamine) gel 0.016% to ensure that commercially insured patients have access to treatment during the COVID-19 crisis. Starting today, eligible patients' prescription copays will be waived in full until at least **June 30, 2020**. Helsinn will continue to monitor the crisis and reassess the June 30th end date if necessary.

In addition, Helsinn will ensure VALCHLOR remains available to all patients through direct shipping via a dedicated specialty pharmacy. By providing delivery direct to patients, Helsinn is helping ensure patients are able to receive treatment from the comfort and safety of their home. VALCHLOR is indicated for the topical treatment of Stage IA/IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in patients who have received prior skin-directed therapy.[1]

Paul Rittman, Helsinn Therapeutics (U.S.), Inc. CEO, said: "We are absolutely committed to the MF-CTCL patient community and will continue to do what we can to ensure our patients and healthcare professionals are supported during these challenging times."

The VALCHLOR copay program is only available for US and Puerto Rico residents who are 18 or older and have commercial health insurance. Patients ineligible for the VALCHLOR copay/coinsurance program include those enrolled in Medicare, Medicaid, VA/DoD (Tricare), the Indian Health Service, or any other federal- or state-funded healthcare program, or where prohibited by law. The VALCHLOR copay program is not prescription drug coverage or insurance. Helsinn Therapeutics (U.S.), Inc. reserves the right to terminate or modify this program at any time without notice. Other terms and conditions apply.

Please contact your healthcare professional for more details on how to apply for the financial

[1] *VALCHLOR [package insert]. Iselin, NJ: Helsinn Therapeutics US, Inc; January 2020.*

assistance program.

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.

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. In the U.S., approximately 15,000 patients are affected by stage IA-IB MF-CTCL. Epidemiologic studies based on the Surveillance, Epidemiology, and End Results (SEER) databases have shown a ~threefold increase in CTCL incidence in the US during the last 25–30 years.[2]

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

[2] *https://www.ncbi.nlm.nih.gov/pubmed/23040434*

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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MECH-US-0016