Kyowa Kirin Asia Pacific and Helsinn sign exclusive license and distribution agreement to strengthen their presence in Asia Pacific's rare disease therapy area

Lugano, Switzerland, and Singapore, December 1, 2020 - Kyowa Kirin Asia Pacific ("Kyowa Kirin"), part of Japan-based global specialty pharmaceutical company, Kyowa Kirin Co Ltd, and Helsinn Group ("Helsinn"), a Swiss pharmaceutical group focused on building quality cancer care rare diseases products, and announced today the signing of an exclusive license and distribution agreement in China for VALCHLOR® (chlormethine, also known as mechlorethamine) gel 0.016%, a topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma ("MF-CTCL"), which is currently under review by the China National Medical Products Administration ("NMPA").

Under the terms of the licensing and distribution agreement, Helsinn will grant Kyowa Kirin an exclusive license to distribute, promote, market, and sell VALCHLOR® in China. Helsinn will be responsible for clinical development, regulatory activities, and the supply of VALCHLOR® for commercial use in China.

About the Disease MF-CTCL

Mycosis fungoides is the most common form of cutaneous T-cell lymphoma. It is a rare disease with about 30,000 diagnosed patients in the world and accounts for approximately 45% of primary cutaneous lymphomas[1]. According to a large population-based cohort study and a retrospective 5-year review[2,3] the MF-CTCL annual incidence rate in Asia Pacific ranges between 0.62-0.65/100,000 suggesting that MF-CTCL is generally a rare disease among Asians and Caucasians alike.

Dr. Tan Boon Heon, Kyowa Kirin's President in the Asia Pacific, commented: "Kyowa Kirin is committed to delivering life-changing value to people living with severe diseases. VALCHLOR® joins a growing portfolio of innovative products that we are introducing in the rare disease, nephrology and hemato-oncology space in Asia. In this respect, we are proud to partner with

[1] Journal of Dermatology; 2014; 41: 43–49; doi: 10.1111/1346-8138.12346; https://onlinelibrary.wiley.com/doi/pdf/10.1111/1346-8138.12346
[2] International Journal of Stroke; 2016; 0(0): 1–2; doi: 10.1177/1747493016633302
[3] Australasian Journal of Dermatology; 2006; 47: 248–252; doi: 10.1111/j.1440-0960.2006.00290.x

Helsinn, a leader in the development of innovative cancer and rare disease therapies, in our very first partnership specific to the Asia Pacific region, to bring an important treatment to MF-CTCL patients in China."

"By having the commercial rights of VALCHLOR® (mechlorethamine) in China, Kyowa Kirin has shown that it is serious about meeting patients' unmet needs in the rare disease therapeutic areas" **added Kazunobu Mikawa, General Manager in China (KKCN)**, "VALCHLOR® will be one of our strategic products for our dermatology and hemato-oncology franchise. We are delighted to promote VALCHLOR® as an additional therapeutic option for MF-CTCL patients in China."

Dr. Riccardo Braglia, Helsinn Group CEO and Vice President, commented, "We are very pleased to have signed this license agreement with Kyowa Kirin for the distribution of VALCHLOR® in China, which is an important milestone for us and for MF-CTCL patients globally. Kyowa Kirin has a strong and established presence in this important market, which coupled with our shared vision and commitment to improving the lives of cancer patients, makes it the ideal partnership for Helsinn. We are looking forward to working closely in partnership with Kyowa Kirin in order to make VALCHLOR® available to patients in China as soon as possible."

Enrico Magnani, Local General Manager, Helsinn Pharmaceuticals (Beijing) Co., Ltd., P.R.C., commented: "We are pleased to have secured this important partnership with Kyowa Kirin, a strategic player in the pharmaceutical space in Asia. With this licensing deal, VALCHLOR® is expanding our cancer care product portfolio in China, strengthening our position in the region and allowing us to deliver treatments to an even greater number of patients."

Global Overview

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

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.

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.

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). Ledaga® gel is commercialized in the EU since June 2019.

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

About Kyowa Kirin

Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. The company focuses on creating new values in the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, the employees from 40 group companies across North America, EMEA, and Asia/Oceania unite to champion the interests of patients and their caregivers in discovering solutions wherever there are unmet medical needs. You can learn more about the business of Kyowa Kirin at: **https://www.kyowakirin.com**

About the Helsinn Group

Helsinn is a privately-owned Swiss Pharma Company which, since 1976, has been improving the lives of patients, guided by core family values of respect, integrity and quality. The Group has an extensive portfolio of marketed innovative cancer and rare disease therapies, a robust drug development pipeline and ambitions to further accelerate its growth through in-licensing and acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with over 80 long-standing partners in 190 countries, who share our values. The Group's pharmaceutical business (Helsinn Healthcare) is headquartered

in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics US) and China (Helsinn Pharmaceuticals China) which market the Group's products directly in these countries. The Group has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis, an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals, a drug product manufacturer). Helsinn Investment Fund was created to enhance the future of healthcare by providing funding and strategic support to innovative companies.

Helsinn Group 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 Group please visit **www.helsinn.com**

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

Kyowa Kirin Asia Pacific Media Contact:

Jasminder Kaur
Corporate Communications, APAC
Singapore
Tel: +65 8725 2790
Email: jasminder.kaur.5r@1kyowakirin.com

For more information, please visit www.kyowakirin.com and follow us on LinkedIn

HELS--0007