Verity Pharmaceuticals™ and Helsinn Therapeutics sign exclusive agreement for the promotion of Akynzeo® and Valchlor® in Puerto Rico

Toronto, Ontario and Lugano, Switzerland, February 16, 2022

Verity Pharmaceuticals International Ltd. ("**Verity Pharma**"), and Helsinn Therapeutics (U.S.), Inc. **("Helsinn"**), today announced the signing of an agreement between the two parties for the exclusive rights to promote AKYNZEO® IV/Oral and VALCHLOR® in Puerto Rico.

Under the terms of the agreement, Verity Pharma will promote the following products across the island of Puerto Rico, leveraging its existing commercial footprint and health care network:

- AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsule and AKYNZEO® (fosenetupitant 235mg/palonosetron 0.25mg) Injection.
- VALCHLOR® (mechlorethamine) gel 0.016%

Helsinn will maintain control of distribution, market access, and regulatory activities in Puerto Rico.

"This suite of cancer supportive and therapeutic products has significant value to patients, in cancer treatment and effectively managing its side effects" **said Howard Glase, CEO of Verity Pharma.** "Verity Pharma is delighted to be working with Helsinn in Puerto Rico to facilitate the commercialization of Akynzeo and Valchlor."

"Verity Pharma's established salesforce and customer network in Puerto Rico will help expand patient access to our oncology portfolio," **said Paul Rittman, Chief Executive Officer of Helsinn Therapeutics**. "Helsinn is pleased to be working with Verity Pharma in order to bring much needed supportive and therapeutic care to cancer patients in need of these important products in Puerto Rico."

About AKYNZEO®

AKYNZEO® is the first and only 5-HT_3 and NK_1 receptor antagonists fixed combination approved for the prevention of chemotherapy-induced acute and delayed nausea and vomiting. A single dose of AKYNZEO® given with dexamethasone has been shown to prevent chemotherapy-induced nausea and vomiting for up to 5 days.

INDICATION

AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsules was approved in October 2014 in the United States and is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

AKYNZEO® (fosnetupitant 235mg/palonosetron 0.25) for injection was approved in April 2018 and AKYNZEO® injection was approved in May 2020 in the United States. Each is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

Limitations of Use:

- AKYNZEO® for injection and AKYNZEO® injection have not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.

AKYNZEO® is a combination of palonosetron, a serotonin-3 (5-HT3) receptor antagonist, and netupitant or fosnetupitant, substance P/neurokinin-1 (NK-1) receptor antagonists: palonosetron prevents nausea and vomiting mainly during the acute phase and netupitant/fosnetupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving

palonosetron, one of the components of AKYNZEO®, with or without known hypersensitivity to other 5-HT3 receptor antagonists.

- Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs. Serotonin syndrome can be life threatening. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes, autonomic instability, neuromuscular symptoms, seizures, and gastrointestinal symptoms. Patients should be monitored for the emergence of serotonin syndrome, and if symptoms occur, discontinue AKYNZEO® and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if AKYNZEO® is used concomitantly with other serotonergic drugs.

Adverse Reactions:

- Most common adverse reactions for AKYNZEO®: headache, asthenia, dyspepsia, fatigue, constipation and erythema.

Drug-drug Interactions:

- Use with caution in patients receiving concomitant medications primarily metabolized by CYP3A4 isoenzyme. The plasma concentrations of CYP3A4 substrates can increase when co-administered with AKYNZEO®. The inhibitory effect on CYP3A4 can last for multiple days

    - Dexamethasone doses should be reduced when given with AKYNZEO®. A more than two-fold increase in the systemic exposure of dexamethasone was observed 4 days after a single dose of netupitant or a single infusion of fosnetupitant.

    - Consider the potential effects of increased plasma concentrations of midazolam or other benzodiazepines metabolized via CYP3A4 (alprazolam, triazolam) when administering with AKYNZEO®. When administered with netupitant, the systemic exposure to midazolam was significantly increased.

- Avoid concomitant use of AKYNZEO® in patients on chronic use of a strong CYP3A4 inducer such as rifampin as this may decrease the efficacy of AKYNZEO®.

Use in Specific Populations:

- Avoid use of AKYNZEO® in patients with severe hepatic impairment, severe renal impairment, or end-stage renal disease.
- Avoid use in pregnancy, limited data is available, may cause fetal harm.

For more information about AKYNZEO® please see the full US Prescribing Information

In the US:

About VALCHLOR®

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 FOR VALCHLOR

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 US full Prescribing Information and Medication Guide for VALCHLOR®.

About the Helsinn Group

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 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

About Verity Pharmaceuticals

Verity Pharmaceuticals International Ltd. is a specialty pharmaceutical company with a primary focus on therapeutic solutions for genitourinary (GU) diseases.

Verity Pharmaceuticals works with best-in-class global pharmaceutical manufacturing partners to ensure that product quality and availability is a constant deliverable. The company is also committed to supporting programs, initiatives, and organizations that help improve health, expand research opportunities and promote education within the healthcare community. Learn more at www.veritypharma-usa.com.

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