Helsinn to present two posters at the San Antonio Breast Cancer Symposium (SABCS) 2020 evaluating high CINV recurrence in breast cancer patients and CINV duration as its predictor

Lugano, Switzerland, December 7, 2020 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare disease products, today announces that two scientific posters reviewing chemotherapy-induced nausea and vomiting (CINV) recurrence and an assessment of recurrence in later chemotherapy cycles, will be presented at the San Antonio Breast Cancer Symposium (SABCS). The symposium is taking place online from 8-11 December 2020.

- The first abstract presents findings from an evaluation of individual patients' risk of repeat CINV in each subsequent chemotherapy cycle in breast cancer patients. A post hoc analysis was made of 402 female patients in a NEPA [AKYNZEO® (netupitant/palonosetron)] clinical trial with additional analysis of a similar 2005 study of 433 breast cancer patients receiving ondansetron and aprepitant. Occurrence of CINV for cycles 2-4 of chemotherapy was compared to cycle 1 outcomes.
- The second abstract outlines findings of an evaluation of the number of days of breakthrough CINV in cycle 1 of chemotherapy treatment, and its association with individual patients' repeat breakthrough CINV in subsequent cycles, based on a post hoc analysis of the clinical trial of NEPA.

Dr Rudolph M. Navari, of the World Health Organization, and lead investigator of both studies: "The first abstract reports that success in cycle 1 prophylaxis led to high success across subsequent cycles, while conversely cycle 1 failure led to high repeat failure for aprepitant, and to a lesser degree for NEPA. One possible explanation for the differential risks seen after the first cycle may be in the duration of CINV treatment failure, as shown in our second study presented at this conference.

In clinical practice, we see considerable heterogeneity in the duration of CINV. Our second abstract demonstrated that CINV duration (short vs extended) in cycle 1 strongly predicted CINV recurrence in subsequent cycles. This suggests a simple yet important new step for oncology

practices: clinicians should monitor breakthrough CINV duration and follow guideline recommendations to change antiemetic prophylaxis when extended CINV does occur."

William L. Bailey, Helsinn Therapeutics (U.S.) Vice President of Medical & Scientific Affairs: "Helsinn is committed to preventing CINV and reducing the burden of extended CINV events in all cycles of chemotherapy. These data in breast cancer patients presented at the SABCS 2020 highlight the need for close CINV monitoring and demonstrate our strong commitment to improving the lives of people with cancer."

Presentation Details

Abstract 1 Title: Chemotherapy-induced nausea and vomiting (CINV) risk after prior breakthrough CINV: unmasking the false average

Date: December 9, 2020

Session Name: Poster Session 13 Poster 13-09

Time, Location: The full abstract can be viewed now on the SABCS website: https://www.sabcs.org/

Abstract 2 Title: Duration of chemotherapy-induced nausea and vomiting (CINV) as a predictor of later-cycle CINV

Date: December 9, 2020

Session Name: Poster Session 13 Poster 13-27

Time, Location: The full abstract can be viewed now on the SABCS website: https://www.sabcs.org/

About NEPA (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 5 full 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-HT_3) 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-HT_3 receptor antagonists.

- Serotonin syndrome has been reported with 5-HT_3 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® capsules and injection: 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

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

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