

Helsinn announces poster presentation at Academy of Managed Care Pharmacy (AMCP) 2021 Virtual Meeting evaluating healthcare resource utilization in CINV

Lugano, Switzerland, April 13, 2021 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare disease products, is pleased to announce that a poster entitled “Avoiding Acute Care and Unplanned Hydrations from Chemotherapy-Induced Nausea and Vomiting (CINV) in Real World Practice” will be presented at this year’s Academy of Managed Care Pharmacy (AMCP) National Meeting taking place virtually on 12-16 April.

CINV is included among the toxicities tracked by Medicare’s OP-35 oncology outcome measure and was shown as one of the main drivers of acute care events during chemotherapy, representing one in nine acute care events. Reducing avoidable acute care utilization has the potential to improve cancer care and reduce costs. In this analysis Medicare data on resource use were collected and combined with patient records from 17 oncology practices in IntegraConnect’s database from January 2017 through August 2020. CINV acute care utilization and unplanned hydrations after highly or moderately emetogenic chemotherapy (HEC/MEC) with netupitant and palonosetron (NEPA) plus dexamethasone or other triple prophylaxis treatment were evaluated.

The poster presentation will take place on Tuesday, April 13 and Wednesday, April 14, from 1-2:30pm ET

Details of the abstract are as follows:

Abstract ID: 975896

Title: Avoiding Acute Care and Unplanned Hydrations from Chemotherapy-Induced Nausea and Vomiting (CINV) in Real World Practice.

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William L. Bailey, Helsinn Therapeutics (U.S.) Vice President of Medical & Scientific Affairs,

commented: “CINV is an avoidable toxicity and its prevention remains suboptimal, directly affecting patient care, healthcare resource utilization and impacting total cost of care. These data provide useful information about lowering the risk of CINV-related acute care and unplanned hydrations, an important consideration in assessing the overall value and cost-effectiveness that NEPA may bring to patients and practices.”

About NEPA (AKYNZEO®)

In the EU:

AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsules for oral use was approved in May 2015 in the EU. A line extension to introduce the IV formulation AKYNZEO® (fosnetupitant 235mg/palonosetron 0.25mg) powder for concentrate for solution for infusion was approved in March 2020 in the EU. Fosnetupitant is a netupitant prodrug, which converts into netupitant once administered intravenously. Akynzeo® (oral and IV) is indicated in the EU for adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

For additional information please see the [EU Summary of Product Characteristics](#).

In the US:

AKYNZEO® is the first and only 5-HT₃ and NK₁ receptor antagonist 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-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](#)

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 acquisitions to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with 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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