Helsinn announces publication of new data evaluating impact of NEPA (netupitant/palonosetron) on hospital costs

LUGANO, Switzerland - February 3, 2023 - Helsinn Group ("Helsinn"), a fully integrated global biopharma company with a track record of over forty years of commercial execution and a strong focus in oncology and rare diseases, announces that research from a real-world study of netupitant or fosnetupitant with palonosetron (NEPA) has been published in the journal *Future Oncology*.

The article, "Antiemetic Use and Chemotherapy Induced Nausea and Vomiting related Hospitalization Costs After Highly or Moderately Emetogenic Chemotherapy", evaluates the effect of NEPA on chemotherapy-induced nausea and vomiting (CINV)-related hospitalization costs. NEPA was compared to aprepitant/fosaprepitant-containing regimens among patients who received highly or moderately emetogenic chemotherapy in the US. The company collaborated with Integra Connect, a leading provider of value-based, precision medicine solutions, to analyze real-world oncology data from its PrecisionQ database from approximately 1,200 providers in the US within 13 community oncology networks.

Results from the study indicate that CINV-related hospitalization costs were significantly lower in patients who received NEPA compared to aprepitant/fosaprepitant with ondansetron (APON) or aprepitant/fosaprepitant with palonosetron (APPA) ($P < .0001$ for both comparisons). The cost differences may be driven by the higher average cost per hospitalized patient and higher number of repeat hospitalizations in the APON and APPA groups. The study findings suggest that the downstream economic impact of antiemetic choice may differ depending on the combination of treatments.

Details of the publication:

- Title: Antiemetic Use and Chemotherapy Induced Nausea and Vomiting related Hospitalization Costs After Highly or Moderately Emetogenic Chemotherapy
- Authors: Winnie W. Nelson, Varun Vaidya, Jeffery A. Scott, Brandon Wang, Hunter Lambert, Benjamin Holmes, and William L. Bailey

- Link: https://www.futuremedicine.com/doi/10.2217/FON-2022-0972

The study retrospectively analyzed electronic medical records and Medicare claims data from 15,583 patients (807 NEPA, 2023 APON, 12,753 APPA) who received the antiemetic regimens between 1 January 2018 and 31 October 2020. Hospitalizations with CINV as the primary reason for admission were identified and all incurred costs for these hospital stays were used in the cost accounting. Costs of CINV-related hospitalization were compared between the study groups using a generalized linear model with gamma distribution and log link and adjusted for demographic and clinical variables.

Dr. Winnie Nelson, Senior Director, Health Economics and Outcomes Research, Helsinn Therapeutics (U.S.), and Lead Author commented: "There are multiple published studies showing the cost-effectiveness of NEPA based on clinical trial data. This real-world study has enabled us to further establish that NEPA has specific cost benefits in terms of CINV-related hospitalization, as compared to patients who receive aprepitant-containing combinations."

"CINV-related hospitalizations are the costliest type of medical care that can be avoided with appropriate antiemetic strategy," **commented Dr. Jeffrey Scott, Chief Medical Officer and President of Population Health Solutions at Integra Connect**. "It's exciting to see leading life sciences organizations such as Helsinn leverage our real-world dataset and identify tangible actions providers can take to advance value-based care. Results from this study can help create a blueprint to support health care decision makers' efforts to develop policies and enhance both patient care and economic outcomes."

About AKYNZEO® in the US

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.

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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 ($5\text{-}HT_3$) receptor antagonist, and netupitant or fosnetupitant, substance P/neurokinin-1 (NK_1) receptor antagonists: palonosetron prevents nausea and vomiting 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 Helsinn

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 a focus on cancer therapeutics and rare diseases.

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. Helsinn's unique business model enables it to in-license or acquire assets at a late stage of development.

It 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 plays an active and central role in promoting social transformation in favor of people and the environment. Sustainability 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 please visit: www.helsinn.com

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