Helsinn announces publication of data evaluating impact of AKYNZEO® (fosnetupitant/palonosetron) on treatment outcomes and healthcare costs

Lugano, Switzerland, June, 12, 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 the publication of real-world evidence of AKYNZEO® (fosnetupitant with palonosetron) injection/for injection in the journal *Advances in Therapy*.

The article, "Real-world Treatment Outcomes, Healthcare Resource Use, and Costs Associated with Antiemetics Among Cancer Patients on Cisplatin-based Chemotherapy", evaluates the effect of AKYNZEO® on rates of chemotherapy-induced nausea and vomiting (CINV) events, inpatient and outpatient visits, as well as treatment costs. AKYNZEO® was compared to fosaprepitant/palonosetron (APPA) combination among patients who received cisplatin-based chemotherapy in the US. The study analyzed a medical and pharmacy claims data source which was created using the all-payer claims databases (APCD) compiled and maintained by the Agency for Healthcare Research and Quality. The dataset provides insight to nearly 80% of the US healthcare system, with patient-level data from all provider types.

Referring to the details of the publication below, these real-world data showed that healthcare resource utilization, such as CINV-related visits were significantly lower after AKYNZEO® compared to fosaprepitant/palonosetron (APPA). CINV-related healthcare costs were also statistically and/or numerically lower for patients receiving AKYNZEO® compared to APPA.

The study findings suggest that the downstream resource use and cost impact of AKYNZEO® and APPA is not equivalent. As clinicians are making therapeutic decisions on CINV prevention, the use of real-world data can contribute to thoughtful selection of therapy to result in better resource use and cost outcomes.

Dr. Rudolph Navari, MD, PhD, FACP, Hematologist Oncologist and Lead Author commented: "Despite many available antiemetic options, CINV control remains suboptimal, which carries a substantial economic and quality of care burden. There remains a gap between expected and actual patient outcomes as clinicians translate trial data and clinical guidelines into practice. Real-world studies like ours generate evidence based on day-to-day clinical experiences and can enable practical improvements in oncology practices."

Details of the publication:

- Title: Real-world Treatment Outcomes, Healthcare Resource Use, and Costs Associated with Antiemetics Among Cancer Patients on Cisplatin-based Chemotherapy
- Authors: Rudolph M. Navari, Winnie W. Nelson, Sofia Shoaib, Risho Singh, Weiping Zhang, William L. Bailey
- Link: https://link.springer.com/article/10.1007/s12325-023-02537-7

The study retrospectively analyzed claims data from 15,696 patients (421 AKYNZEO® and 15,275 APPA) who received cisplatin-based chemotherapy and the study antiemetic regimens between 1 January 2016 and 31 October 2020. Nausea and vomiting visit data were collected within 1 to 14 days after chemotherapy. A CINV-specific claim was defined as any post-chemotherapy claim during the 14-day follow-up period with nausea or vomiting in any position of the claim. In addition, all-cause and CINV-related HCRU for inpatient and outpatient settings were assessed, and costs were adjusted to 2021 US dollars. Logistic regression was used to evaluate the treatment outcomes in the follow-up period. Generalized linear models (GLM) were used to examine all-cause and CINV-related healthcare resource utilization and costs.

Results from the study reported all-cause and CINV-related resource use and costs of AKYNZEO® and APPA:

- The mean number of all-cause inpatient visits per patient was lower among AKYNZEO® patients (4.83 vs. 5.41, $p = 0.0195$).
- The mean number of all-cause outpatient visits per patient was not statistically different between study groups (39.23 vs. 42.90; $p = 0.0835$).
- The mean number of CINV-related inpatient visits per patient was lower among AKYNZEO® patients (0.20 vs. 0.32, $p<0.0001$).
- The mean number of CINV-related outpatient visits per patient was lower among AKYNZEO® patients (1.32 vs. 2.49, $p<0.0001$).
- Mean all-cause inpatient costs per patient were not significantly different between study groups ($32,457 vs. $30,735; $p = 0.0665$).
- Mean all-cause outpatient costs per patient were significantly lower for AKYNZEO® ($83,070 vs. $126,263, $p<0.0001$).
- Mean CINV-related inpatient costs per patient were significantly lower for AKYNZEO® ($33 vs. $163, $p<0.0001$).
- Mean CINV-related outpatient costs per patient were not significantly different between study groups ($7,848 vs. $8,690, $p = 0.4339$).

Limitations of this study include the potential errors in medical diagnostic coding in the insurance claims, the absence of clinical risk factors for nausea and vomiting in claims data, and the inability to track the use of low-cost medications such as olanzapine and dexamethasone. Lastly, statistical analyses for variables with a sample size less than 10 were not reported in accordance with the Agency for Healthcare Research and Quality's (AHRQ) data use agreement.

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.

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 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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