

Helsinn Group to Present a Poster at Academy of Managed Care Pharmacy (AMCP) Annual Meeting 2018

- *Poster: Budget Impact of Fixed Combination NEPA for the Prevention of Chemotherapy Induced Nausea and Vomiting*

Lugano, Switzerland, April 24, 2018 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, today announced it will be presenting a poster on the budget impact for payers of fixed combination netupitant/palonosetron (NEPA) for the prevention of chemotherapy-induced nausea and vomiting (CINV), at the AMCP Managed Care & Specialty Pharmacy Annual Meeting 2018 in Boston, MA, 23 – 26 April 2018.

The poster presentation, entitled “*Budget impact of fixed combination netupitant/palonosetron for the prevention of chemotherapy-induced nausea and vomiting*”, will take place on Wednesday 25 April, from 12:30pm – 2:30pm.

Payers determining the coverage of agents for CINV prophylaxis often lack information on total cost and rates of CINV. The objective of this study was to estimate the budgetary impact of adding NEPA to a US payer formulary for CINV prophylaxis. The findings demonstrated that adding NEPA to a payer formulary results in a net decrease in the total budget due to a significant (> 10:1) reduction in CINV event-related medical costs, relative to virtually no change in pharmacy costs.

Details of the abstract are as follows:

Abstract ID: 430851

Abstract Title: Budget impact of fixed combination netupitant/palonosetron for the prevention of chemotherapy-induced nausea and vomiting

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About NEPA (netupitant/palonosetron)

About Akynzeo[®]

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 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 highly emetogenic cancer chemotherapy.

Limitations of Use

AKYNZEO for injection has 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 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 capsules and injection: headache, asthenia, dyspepsia, fatigue, constipation and erythema

Drug Interactions

- Use with caution in patients receiving concomitant medications primarily metabolized by CYP3A4. 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 [Prescribing Information](#)

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

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