HELSINN
Building quality cancer care together

Helsinn to present a scientific poster on acute care use following CINV prophylaxis with agents in breast cancer patients at the San Antonio Breast Cancer Symposium (SABCS) 2019

Lugano, Switzerland, December 13, 2019 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, is presenting a scientific poster assessing acute care involving chemotherapy-induced nausea and vomiting (CINV) amongst breast cancer patients receiving various treatments for CINV prophylaxis including NEPA, at the San Antonio Breast Cancer Symposium (SABCS). The congress is taking place from 10-14 December 2019 and the presentation details are below.

This study evaluated rates of CINV-related acute care (emergency visits or inpatient admissions) from a prospective study of 400 patients receiving NEPA (AKYNZEO®) and patients receiving other antiemetics (n = 1,200) from a large electronic health record database of patients treated with anthracycline plus cyclophosphamide (AC), following the US Food and Drug Administration's framework on use of Real World Data (RWD) to support single-arm trials.

Lee Schwartzberg, MD, Executive Director of the West Cancer Center in Germantown, TN, Professor of Medicine at the University of Tennessee Health Science Center, Memphis, was lead investigator of the study. According to Dr. Schwartzberg: "The acute care associated with CINV among patients receiving AC in the standard delivery of care represents a shortcoming both in clinical and economic outcomes. We are encouraged by the results of this study to help address the unmet needs of CINV in patients taking AC chemotherapy."

Presentation Details

Abstract Title: Avoidable acute care involving chemotherapy-induced nausea and vomiting (CINV) among patients with breast cancer receiving anthracycline + cyclophosphamide (AC) with NEPA prophylaxis relative to other antiemetics: An external control arm analysis

Date: Friday 13th December 2019

Session Name: PS5. Poster Session 5

Time, Location: 5:00pm – 7:00pm

The full abstract can be viewed on the SABCS website:
https://www.abstractsonline.com/pp8/#!/7946

About AKYNZEO® (NEPA)

AKYNZEO® is the first and only 5-HT_3 and NK_1 receptor 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 days.

INDICATION

AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsules was approved 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 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-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: 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 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 or visit www.AKYNZEO.com

ENDS

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.

To learn more about Helsinn Group please visit www.helsinn.com

For more information:

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