Helsinn Group announces AKYNZEO® injection – a new liquid IV solution -- now available in the US

Lugano, Switzerland, August 20, 2020 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare disease products, is pleased to announce that the ready-to-dilute liquid formulation of AKYNZEO® (fosnetupitant/palonosetron) injection is now available in the US.

This new liquid solution AKYNZEO® injection provides several improvements to storage and handling:

- No refrigeration required at any stage of distribution, preparation, or storage
- Ready-to-dilute solution; no reconstitution required prior to dilution, reducing the preparation process for intravenous administration of AKYNZEO® to one step before use
- May be stored for up to 24 hours at room temperature after dilution, allowing more flexibility in preparation for busy clinicians
- Compatible with intravenous dexamethasone sodium phosphate which can be added to the AKYNZEO® solution or infused simultaneously

AKYNZEO® injection is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy in adults, when given with dexamethasone. It has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy. AKYNZEO® injection does not contain polysorbate 80 or allergenic excipients such as soy or egg lecithin.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: "At Helsinn, we are unwavering in our pursuit to help patients and clinicians in cancer care. These innovations to AKYNZEO® demonstrate our ongoing commitment to the many cancer patients who are at risk of CINV."

Paul Rittman, CEO, Helsinn Therapeutics (U.S.), Inc, said: "We are very pleased to launch the new IV solution of AKYNZEO, which provides customers with operational advantages for storage, handling, preparation, and administration. We hope that these features will be of assistance to

those administering the treatment, allowing for greater efficiency as they help prevent CINV in patients undergoing chemotherapy."

Clinicians wishing to order the new formulation should contact their GPO or distributor. The National Drug Code (NDC) number for AKYNZEO® injection is 69639-105-01 and the permanent J Code is J1454 (Injection, fosnetupitant 235 mg and palonosetron 0.25 mg; billing unit (single dose vial [SDV]).

About AKYNZEO®

AKYNZEO® is the first and only 5-HT_3 and NK_1 receptor antagonists 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 up to 5 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-HT_3) 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-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® capsules and injection: 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 acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with over 80 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

For more information:

Helsinn Group Media Contact:

Paola Bonvicini
Group Head of Communication
Lugano, Switzerland
Tel: +41 (0) 91 985 21 21
Email: Info-hhc@helsinn.com

For more information, please visit www.helsinn.com and follow us on Twitter, LinkedIn and Vimeo

V-AKIV-US-0010