



FDA Approves Akynzeo for Injection

FDA Approves Intravenous Formulation of Akynzeo (fosnetupitant/palonosetron) for Chemotherapy-Induced Nausea and Vomiting

Lugano, Switzerland April 20, 2018 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, today announces that the U.S. Food and Drug Administration (FDA) has approved the intravenous formulation of Akynzeo (NEPA, a fixed antiemetic combination of fosnetupitant, 235mg, and palonosetron, 0.25mg) as an alternative treatment option for patients experiencing CINV.

The FDA has approved Akynzeo IV 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. Akynzeo for injection has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.

Oral Akynzeo was previously approved by the FDA as a fixed combination oral agent in 2014 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 is an oral fixed combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

The bioequivalence of the IV with the oral formulation of netupitant was demonstrated and the safety of IV NEPA was established through a repeated dose safety study in cancer patients to potentially uncover adverse drug reactions that may appear during subsequent clinical practice. No anaphylactic and injection site reactions related to IV NEPA were reported in this study.

Currently a repeated dose safety study is ongoing in patients receiving anthracycline plus cyclophosphamide to further establish the safety profile in this setting.

The prevention of CINV has been refined in treatment guidelines over the past several decades. Currently the combination treatment of antiemetic medicines with different mechanisms of actions are recommended for the prevention of CINV.

The approval of Akynzeo in IV formulation will offer to US patients and healthcare providers an alternative route of administration of the only fixed antiemetic combination targeting two distinct CINV pathways in a single dose.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: "The approval of the intravenous formulation of Akynzeo paves the way to bring this important therapeutic option to more patients in a new formulation, and we are delighted that we are now able to push ahead with launching this product in the United States in May 2018"

Helsinn plans to launch Akynzeo in IV formulation in the US in May 2018.

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.

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.

Source: Helsinn

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