HELSINN
Building quality cancer care together

Helsinn announces European approval of the IV formulation of AKYNZEO® (fosnetupitant / palonosetron)

Lugano, Switzerland, March 23, 2020 – Helsinn, the Swiss pharmaceutical group focused on building quality cancer care products, today announces that the European Commission (EC) 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 preventing CINV.

The European approval follows a positive opinion by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP), in December 2019. Helsinn submitted its MAA to the EMA for AKYNZEO® IV in November 2018, as a line extension of oral AKYNZEO®.

AKYNZEO® hard capsules was previously approved by the European Commission as a fixed dose combination in 2015 for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

The approval of AKYNZEO® in IV formulation offers patients in Europe 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: "This approval is an important step in enabling Helsinn to offer this treatment option to a greater number of European patients suffering from CINV. We anticipate launching AKYNZEO® IV in Europe starting from the second quarter this year and remain committed to expanding the reach of this treatment across the globe."

About Akynzeo®

AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsules for oral use was approved in May 2015 in the EU. A line extension to introduce the IV formulation AKYNZEO® (fosnetupitant 235mg/palonosetron 0.25mg) powder for concentrate for solution for infusion was approved in

March 2020 in the EU. Fosnetupitant is a netupitant prodrug, which converts into netupitant once administered intravenously. Akynzeo® (oral and IV) is indicated in the EU for adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

For additional information please see the EU Summary of Product Characteristics.

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

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