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

Lugano, Switzerland, December 2, 2021 – Helsinn Group, a fully integrated, global biopharma company with a diversified pipeline of innovative oncology assets and strong track-record of commercial execution, is pleased to announce that the European Commission (EC) has approved the liquid formulation of AKYNZEO® (fosnetupitant/palonosetron).

AKYNZEO® 235 mg/0.25 mg concentrate for solution for infusion is indicated for the prevention of acute and delayed nausea and vomiting associated with both highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

The ready-to-dilute formulation provides several improvements to storage and handling in comparison to previously approved formulations:

- AKYNZEO®235 mg/0.25 mg concentrate for solution for infusion does not require refrigeration at any stage of distribution, preparation or storage.
- AKYNZEO® 235 mg/0.25 mg concentrate for solution for infusion eliminates the need for reconstitution prior to dilution, reducing the preparation process for intravenous administration of AKYNZEO® to one step before use.
- AKYNZEO® 235 mg/0.25 mg concentrate for solution for infusion may now be stored for up to 24 hours at room temperature after dilution, allowing more flexibility in preparation for busy clinicians.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: “The EU approval is an important milestone for this improved formulation of AKYNZEO®. The ready-to-dilute formulation allows easier preparation and administration of the drug, providing caregivers with an additional tool that we believe is important as they seek to reduce the debilitating side effect of chemotherapy-induced nausea and vomiting (CINV) in chemotherapy patients.”

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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. A line extension to introduce the IV formulation AKYNZEO® (fosnetupitant 235mg/palonosetron 0.25mg) concentrate for solution for infusion has being approved in EU on the 12th November 2021. 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 fully integrated, global biopharma company headquartered in Lugano, Switzerland. It is focused on improving the lives of cancer patients all over the world with a leading position in cancer supportive care and innovative pipeline of cancer therapeutics.

Helsinn is a third-generation family-owned company, that since 1976 has been focused on improving the lives of patients, guided by core values of respect, integrity and quality. It operates a unique licensing business model with integrated drug development and manufacturing capabilities. Helsinn has a commercial presence in over 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-standing trusted partners.

Helsinn 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

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