

Helsinn Group submits a new formulation of AKYNZEO[®] to the European Medicines Agency (EMA)

Lugano, Switzerland – April 2, 2025 – Helsinn Group ("Helsinn"), a global pharmaceutical company with a track record of nearly fifty years of commercial execution and a strong focus in supportive care, oncology and dermato-oncology, today announced the submission of a new formulation for AKYNZEO® to the European Medicines Agency (EMA).

AKYNZEO® 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.

Once approved, this new innovative formulation may offer benefits to cancer patients in addition to the already approved formulations.

The new AKYNZEO® formulation is expected to be launched in H1 2026.

Roberta Cannella, Chief Technical Officer, commented: "This submission brings us closer to offering patients a new option for AKYNZEO[®]. It not only demonstrates our commitment to enhancing patients' quality of life but also our dedication to innovation in supportive care."

About AKYNZEO®

AKYNZEO® is the first and only 5-HT₃ and NK₁ receptor antagonist fixed dose combination approved in adults for the prevention of acute and delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy.

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

About Helsinn

Helsinn is a global pharmaceutical company that builds, manufactures, launches, and commercializes products to improve the quality of life for patients with cancer and chronic disease, with a focus on supportive care, oncology and dermato-oncology. Helsinn, headquartered in Lugano, Switzerland, has direct commercial operations in the U.S. and a consolidated network of partners to reach out to patients in more than 190 countries worldwide.



Established in 1976, Helsinn is a fourth-generation family-owned company with broad pharmaceutical and technical expertise. Helsinn is proud of its history of operating with great integrity, passion and quality. The company is committed to continuously striving for innovation for its patients and embracing sustainable growth as a core element of its strategic vision.

To learn more about Helsinn, please visit <u>www.helsinn.com</u> or follow us on <u>LinkedIn</u> and <u>X</u>.

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