

AKYNZEO® demonstrates superior prevention of chemotherapy-induced nausea and vomiting compared to the standard of care in patients receiving Moderately Emetogenic Chemotherapy with additional predictive factors

Results from the MyRisk clinical trial, accepted for publication in the Annals of Oncology, will be presented today at ESMO 2025 as an oral presentation

Lugano, Switzerland, October 17, 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 announces that results from the MyRisk Trial with AKYNZEO®, a fixed antiemetic combination of netupitant and palonosetron, will be featured as an oral presentation at the European Society for Medical Oncology (ESMO) Congress today, on October 17, 2025.

The complete trial results have also been accepted for publication in the *Annals of Oncology*, underscoring their significance in advancing supportive care for patients receiving moderately emetogenic chemotherapy (MEC).

Patients receiving MEC are typically prescribed a 5-HT₃ receptor antagonist (RA) and dexamethasone (DEX) as standard antiemetic prophylaxis. However, some patients with additional risk factors for chemotherapy-induced nausea and vomiting (CINV) may benefit from enhanced antiemetic prophylaxis with an NK₁ RA–containing regimen.

The MyRisk trial was a Phase IV, interventional, open-label, randomized, multicenter, multinational trial conducted in seven countries. It is the first trial to prospectively incorporate a predictive risk factor algorithm to select patients at increased risk of CINV receiving MEC. The primary objective was to evaluate whether the use of AKYNZEO® + DEX was more effective than guideline-recommended standard of care (SOC; 5-HT3 RA + DEX) across three consecutive cycles.

A total of 388 patients were included in the analysis. The primary endpoint was met; patients receiving AKYNZEO® were significantly more likely to achieve a complete response (CR: no emesis and no use of rescue medication) than those in the SOC arm in the overall phase (0-120 h after chemotherapy), with 67% greater odds (OR = 1.67, 95% CI: 1.12, 2.49). The statistical model



estimated the probability of CR in the AKYNZEO[®] arm was 81.0% versus 71.8% in the SOC arm. This superiority was consistently observed across several secondary efficacy endpoints including "no nausea", typically the most challenging symptom to control.

Prof. Alex Molasiotis, University of Derby, Derby, United Kingdom, the lead author of the study, commented: "These results reinforce that standard doublet therapy may be insufficient for many patients, with the MyRisk trial highlighting the benefit of AKYNZEO®-based prophylaxis in individuals receiving moderately emetogenic chemotherapies. Importantly, initiating optimal prophylaxis from the first chemotherapy cycle is crucial, as CINV becomes significantly more difficult to control once experienced by patients, underscoring the need for proactive and tailored antiemetic strategies from the outset."

Silvia Olivari, Helsinn Group, Head of Medical Strategy & Excellence, added: "Patients receiving MEC represent a large part of the chemotherapy population and are often underserved by current standards. Tailoring antiemetic prophylaxis to individual patient characteristics can significantly enhance the prevention of CINV, with a particular benefit in controlling nausea, a persistent and often underestimated unmet need in supportive cancer care. We're also proud of the recognition by ESMO and Annals of Oncology."

The details of the ESMO presentation are as follows:

- **Title**: Personalizing Antiemetic Prophylaxis for Patients at High Emetic Risk: Results from the MyRisk Trial
- Authors: Alex Molasiotis (Derby, United Kingdom), Karin Jordan (Potsdam, Germany), Meinolf Karthaus (Munich, Germany), George Dranitsaris (Toronto, Canada), Eric J. Roeland (Portland, United States of America), Lee S. Schwartzberg (Reno, United States of America), Erminio Bonizzoni (Milan, Italy), Elena Brozos Vazquez (A Coruña, Spain), Tomas Buchler (Prague, Czech Republic), Yu Cheng (Shanghai, China), Daniel C. Christoph (Herne, Germany), Pilar García Alfonso (Madrid, Spain), Xin Lu (Shanghai, China), Margarita Majem (Barcelona, Spain), Dimitrios Mavroudis (Heraklion, Greece), Konstantinos Syrigos (Athens, Greece), Elaine Tomlins (London, United Kingdom), Zhen Zhou (Shanghai, China), Martina Zimovjanova (Prague, Czech Republic), Matti S. Aapro (Genolier, Switzerland)
- Presentation number: 28010
- Session title: Supportive and palliative care
- Date, time and location: Friday, October 17th, 16:00 17:30, Hanover Auditorium, Hall 7.2c

ESMO 2025 will be held from 17-21 October 2025 in Berlin, Germany. Further details can be found here: ESMO Congress 2025 | ESMO



About AKYNZEO® (NEPA: netupitant/palonosetron)

AKYNZEO® is the first and only 5-HT₃ and NK₁ receptor antagonist fixed antiemetic 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 the Helsinn Group

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 diseases, with a focus on supportive care, oncology, and dermato-oncology. Headquartered in Lugano, Switzerland, Helsinn has direct commercial operations in the U.S., manufacturing operations in Ireland, offices in China and a network of trusted partners enabling a commercial presence in 90 countries.

Established in 1976, Helsinn is a fourth-generation family-owned company with broad pharmaceutical and technical expertise. For nearly half a century, Helsinn has been operating with integrity, passion, and quality. The company continuously strives for innovation for its patients and embraces sustainable growth as a core element of its strategic vision.

To learn more about Helsinn, please visit www.helsinn.com or follow us on LinkedIn and x.