Helsinn announces presentation on CINV trial at European Society for Medical Oncology (ESMO) Asia

Lugano, Switzerland, November 29, 2022 - Helsinn Group ("Helsinn"), a fully integrated global biopharma company with a track record of over forty years of commercial execution and a strong focus in oncology and rare diseases announces, announces its poster presentation at the upcoming European Society for Medical Oncology (ESMO) Asia Congress, being held in Singapore from 2-4 December.

Helsinn will be presenting a poster on the ongoing *MyRisk* international trial, assessing whether the administration of a combined treatment of NEPA (Fixed Combination of Netupitant/Palonosetron) and dexamethasone is more effective than the current standard of care prophylaxis[1-2-3] (a combination of 5-HT_3 receptor antagonist and dexamethasone) in preventing Chemotherapy-induced Nausea and Vomiting (CINV) in patients at increased risk of emesis receiving moderately emetogenic chemotherapy.

Full details of the poster presentation are below:

- **Title**: Assessing the Benefit of NEPA (Fixed Combination of Netupitant/Palonosetron) for Preventing Chemotherapy-induced Nausea and Vomiting (CINV) in Patients at Increased Emetic Risk Receiving Moderately Emetogenic Chemotherapy
- **Author**: Alex Molassiotis, Matti Aapro, Alessandro Alonzi, Marika Chrápavá, Karin Jordan Eric J. Roeland, Lee Schwartzberg, Carole Terrasanta, Silvia Olivari Tilola, George Dranitsaris
- **Session**: Poster session, 03 December, 18:00 – 18:45
- **Abstract ID**: NCT04817189

Dr Silvia Sebastiani, Helsinn Group Head of Medical Affairs, commented: "We are pleased to present the design of this important ongoing study at the ESMO Asia congress. Despite the array of effective antiemetics, CINV still represents a huge unmet need in clinical practice. To further the goal of CINV prevention for all patients undergoing emetogenic chemotherapy, it is important to explore ways to optimize antiemetic selection, including exploring factors that may increase CINV risk for patients."

Prof. Alex Molassiotis, Pro Vice Chancellor and Dean, University of Derby, UK and Scientific Lead of the MyRisk study added: “In patients receiving moderately emetogenic chemotherapy (MEC), antiemetic guidelines generally recommend a setron + dexamethasone (DEX). However, one guideline committee (the National Comprehensive Cancer Network (“NCCN”)) recognized that this approach is inadequate prophylaxis for many patients and included an NK_1 RA-containing option selectively for those with individual emetic risk factors[2]. MyRisk is the first study prospectively exploring the role of NK_1 RA-containing regimen, Akynzeo in this case, in patients receiving MEC who have additional risk factors.”

About AKYNZEO®

AKYNZEO® is the first and only 5-HT_3 and NK_1 receptor antagonist fixed combination approved in adults for the prevention of acute and delayed nausea and vomiting associated with highly and moderately emetogenic chemotherapy. A single dose of AKYNZEO® given with dexamethasone has been shown to prevent chemotherapy-induced nausea and vomiting for up to 5 days.

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

About AKYNZEO® in the US

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 and AKYNZEO® injection was approved in May 2020 in the United States. Each 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 and AKYNZEO® injection have 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 ($5\text{-}HT_3$) 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.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron, one of the components of AKYNZEO®, with or without known hypersensitivity to other 5-HT3 receptor antagonists.

Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs. Serotonin syndrome can be life threatening. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes, autonomic instability, neuromuscular symptoms, seizures, and gastrointestinal symptoms. Patients should be monitored for the emergence of serotonin syndrome, and if symptoms occur, discontinue AKYNZEO® and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if AKYNZEO® is used concomitantly with other serotonergic drugs.

Adverse Reactions:

Most common adverse reactions for AKYNZEO®: headache, asthenia, dyspepsia, fatigue, constipation and erythema.

Drug-drug Interactions:

Use with caution in patients receiving concomitant medications primarily metabolized by CYP3A4 isoenzyme. The plasma concentrations of CYP3A4 substrates can increase when co-administered with AKYNZEO®. The inhibitory effect on CYP3A4 can last for multiple days.

Dexamethasone doses should be reduced when given with AKYNZEO®. A more than two-fold increase in the systemic exposure of dexamethasone was observed 4 days after a single dose of

netupitant or a single infusion of fosnetupitant.

Consider the potential effects of increased plasma concentrations of midazolam or other benzodiazepines metabolized via CYP3A4 (alprazolam, triazolam) when administering with AKYNZEO®. When administered with netupitant, the systemic exposure to midazolam was significantly increased.

Avoid concomitant use of AKYNZEO® in patients on chronic use of a strong CYP3A4 inducer such as rifampin as this may decrease the efficacy of AKYNZEO®.

Use in Specific Populations:

Avoid use of AKYNZEO® in patients with severe hepatic impairment, severe renal impairment, or end-stage renal disease.

Avoid use in pregnancy, limited data is available, may cause fetal harm.

For more information about AKYNZEO® please see the full US Prescribing Information

About Helsinn

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 a focus on cancer therapeutics and rare diseases.

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. Helsinn's unique business model enables it to in-license or acquire assets at a late stage of development. It has a commercial presence in 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-standing trusted partners. Helsinn also has a fully integrated supply chain and product development through its subsidiary in Ireland, Helsinn Birex Pharmaceuticals Ltd.

Helsinn plays an active and central role in promoting social transformation in favor of people and the environment. Sustainability 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 please visit www.helsinn.com

References:

[1] Roila F. et al. Ann Oncol. 2016 Sep;27(suppl 5):v119-v133. MASCC/ESMO Antiemetic Guideline 2016 V.1.4 last update July 2019. Available at: http://www.mascc.org/ /

[2] NCCN: National Comprehensive Cancer Network; NCCN Clinical Practice Guidelines in Oncology; Version 2.2022. Available at: www.nccn.org

[3] Hesketh J. et al. J Clin Oncol. 2020 Aug 20;38(24):2782-2797. doi: 10.1200/JCO.20.01296. Epub 2020 Jul 13

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