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Helsinn Group Announces Upcoming Presentation of Phase III data in NEPA (netupitant/palonestron) at MASCC/ISOO Congress in Washington DC

- ***Data demonstrates the non-inferiority of NEPA versus an aprepitant (APR)/granisetron (GRAN) regimen***

Lugano, Switzerland, June 20, 2017 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, today announces that data showing the non-inferiority of NEPA (netupitant/palonestron) versus a 3-day oral aprepitant (APR)/granisetron (GRAN) regimen, have been accepted for presentation at the upcoming Multinational Association of Supportive Care in Cancer (MASCC/ISOO) Congress, on June 22-24 2017.

NEPA is the first fixed combination of the selective NK_1RA, netupitant (300 mg), and the clinically and pharmacologically active $5\text{-}HT_3RA$, palonosetron (0.5mg) for the prevention of CINV, in a convenient single capsule.

This randomized, double-blind, Phase 3 study conducted in 828 chemotherapy-naïve Asian patients receiving cisplatin-based emetogenic chemotherapy (HEC) agents, is the first head to head study comparing NK_1RA regimens. Patients received a single oral dose of NEPA on day 1 or a 3-day oral APR/GRAN regimen (days 1-3). All patients received oral dexamethasone on days 1-4. The primary efficacy endpoint was complete response (CR: no emesis/rescue medication) during the overall (0-120h) phase. Non-inferiority was defined as a lower 95% CI greater than the non-inferiority margin set at -10%. Secondary endpoints included no emesis no rescue medication and no significant nausea (NSN: <25mm on 100mm VAS).

For the primary efficacy endpoint of overall CR, NEPA on day 1 was non-inferior to 3-day oral APR/GRAN regimen with a comparable safety profile. In addition the daily CINV events (emesis and/or rescue medication use) declined numerically over time with NEPA reaching the statistical significance at day 5 compared to APR/GRAN arm suggesting a benefit for delayed CINV.

Zhang Li, Sun Yat-sen University Cancer Center, Guangzhou, China, the author of the study, commented: "*The Phase 3 data suggest that NEPA, in a single dose, has equivalent efficacy to a 3-day oral aprepitant/granisetron regimen.*"

- **Title:** Phase 3 study of NEPA versus 3-day oral aprepitant regimen for prevention of chemotherapy-induced nausea and vomiting (CINV) in highly emetogenic chemotherapy (HEC) setting
- **Author:** Li Zhang, Shun Lu, Jifeng Feng, Arunee Dechaphunkul, Salvatore Chessari, Corinna Lanzarotti, Karin Jordan, Matti Aapro
- **Abstract Number:** PS049
- **Session Title:** Nutrition, Cachexia and Antiemetics
- **Date and Time:** Saturday June 24th, 11:30 - 12:30

The full Abstract is now available here (*pp. S55-S56*).

About NEPA

NEPA, Akynzeo® (netupitant 300mg/palonosetron 0.5mg) capsules for oral use was approved in April 2015 in the United States 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® is an oral fixed combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy. The fixed combination of NEPA IV is currently under FDA evaluation, this formulation is not approved for commercial use.

Akynzeo® has been recommended by various antiemetic guidelines: the National Comprehensive Cancer Network (NCCN) antiemetic guidelines, both in Highly Emetogenic Chemotherapy (HEC, AC and carboplatin AUC>4) and Moderately Emetogenic Chemotherapy (MEC); the American Society for Clinical Oncology (ASCO) in HEC and AC regimens and the MASCC/ESMO Guidelines in HEC, AC and carboplatin based chemotherapy. Helsinn currently has 20 licensing partners for Akynzeo® in 167 countries.

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Important Safety Information about Akynzeo®

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, have been reported 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: headache, asthenia, dyspepsia, fatigue, constipation and erythema

Drug Interactions

- Use with caution in patients receiving concomitant medications primarily metabolized by CYP3A4. 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 two-fold increase in the systemic exposure of dexamethasone was observed 4 days after single dose of netupitant.
- 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

For additional information about Akynzeo® please see the US full Prescribing Information at www.akynzeo.com

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 and the U.S., a representative office in China as well as a product presence in approximately 190 countries globally.

For more information:

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