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# Helsinn Group and Eisai Inc. Announce Top-Line Results for Pivotal Studies of the Investigational Fixed-Dose Combination of Netupitant and Palonosetron for Prevention of Chemotherapy-Induced Nausea and Vomiting

*Data to Be Presented at Annual Meeting of the American Society of Clinical Oncology (ASCO)*

**Lugano, Switzerland and Woodcliff Lake, NJ, USA, May 16, 2013** – Helsinn Group and Eisai Inc. announced today top-line results from Helsinn's pivotal clinical studies investigating the oral fixed-dose combination of netupitant and palonosetron (NEPA) being evaluated for the proposed indication of prevention of chemotherapy-induced nausea and vomiting (CINV). These data will be presented as poster discussions on June 1, 2013 at the annual meeting of the American Society of Clinical Oncology.

## About the Pivotal Phase III Study

The Phase III study of a single oral dose of NEPA (netupitant 300 mg + palonosetron 0.50 mg) versus a single oral 0.50 mg dose of palonosetron (PALO) being evaluated for the prevention of CINV following moderately emetogenic chemotherapy (MEC) showed that NEPA was superior to palonosetron in preventing CINV.

NEPA showed superior complete response rates (defined as no emesis and no use of rescue medication) compared with palonosetron during the delayed phase after chemotherapy administration (25 to 120 h), which was the primary endpoint of the study.

The most frequently reported study drug-related adverse events (AEs) for NEPA included headache (3.3 percent) and constipation (2.1 percent). The type and frequency of AEs were comparable between NEPA and PALO.

The global, randomized, double-blind, parallel group superiority study was designed to assess the efficacy and safety of a single oral dose of NEPA (netupitant 300 mg + palonosetron 0.50 mg) versus a single oral 0.50 mg dose of PALO in 1455 chemotherapy-naïve patients receiving anthracycline-based chemotherapy. All patients received oral dexamethasone on day 1. The primary efficacy endpoint was complete response during the delayed phase.

**About the Pivotal Phase II Study**
The Phase II study, which was designed to determine the proper dose of netupitant to combine with palonosetron, examined the efficacy of three different doses of NEPA for the prevention of chemotherapy-induced nausea and vomiting following highly emetogenic chemotherapy (HEC). The study showed that each NEPA dose resulted in a superior complete response rate compared with PALO during the overall phase (the primary endpoint of the study).

AEs were comparable across groups with no dose-response. The percentage of patients developing electrocardiogram changes was comparable across groups.

The Phase II trial was a 694-patient randomized, double-blind, parallel group study in chemotherapy-naïve patients undergoing cisplatin-based HEC. Four study arms compared three different oral doses of NEPA (netupitant 100, 200, 300mg + palonosetron 0.50 mg) with oral PALO 0.50 mg, all given on day 1. All patients received oral dexamethasone on days 1-4. The primary efficacy endpoint was complete response during the overall phase.

**About Netupitant-Palonosetron Fixed-Dose Combination (NEPA)**
NEPA is an investigational single-day, fixed-dose combination of a highly selective $NK_1$ receptor antagonist, netupitant, and a 5-$HT_3$ receptor antagonist, palonosetron, believed to target two critical pathways associated with chemotherapy induced nausea and vomiting (CINV).

The Phase III investigational program recently concluded and Helsinn plans to submit a New Drug Application for NEPA to the U.S. Food and Drug Administration (FDA) and a Marketing Authorisation Application to the European Medicines Agency (EMA) for the proposed indication of prevention of acute and delayed CINV following both highly and moderately emetogenic chemotherapy.

**About ALOXI® (palonosetron hydrochloride) Capsules for Oral Administration**
ALOXI® (palonosetron hydrochloride) Capsules 0.5 mg for oral administration is indicated for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy. One ALOXI® 0.5 mg capsule is administered approximately one hour prior to the start of chemotherapy.

**Important Safety Information**
ALOXI® is contraindicated in patients known to have hypersensitivity to the drug or any of its components. There were no adverse reactions that occurred greater than or equal to 5 percent for the 0.5 mg oral dose. The most commonly reported adverse reactions were headache (3.7 percent) and constipation (0.6 percent).

For more information about ALOXI® capsules see full prescribing information at http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022233LBL.pdf.

ALOXI® capsules are not currently marketed in the United States.

**About Helsinn and Eisai**
Helsinn signed a licensing agreement with Eisai Inc. granting Eisai commercial rights for the fixed-dose combination product in the United States (if approved). Under the terms of the agreement, Helsinn is responsible for conducting all development activities (Chemistry and Manufacturing Controls [CMC], preclinical and clinical), obtaining regulatory approvals and holding the New Drug Application (NDA). If approved by the FDA, the investigational fixed-dose combination product will be co-promoted in the United States by Eisai Inc. and Helsinn Therapeutics U.S. Inc., the U.S. company of the Swiss group.

**About the Helsinn Group**
Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland, the United States and China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in therapeutic niche areas. Helsinn is an important player in cancer supportive care. Helsinn Group in-licenses early-to-late stage new chemical entities, completes their development through the performance of pre-clinical /clinical studies and Chemistry, Manufacturing, and Control (CMC) development, and files and attains their market approvals worldwide. Helsinn's products are out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how whom Helsinn assists and supports by providing a full range of product and scientific management services, including commercial, regulatory, financial, legal, and medical marketing advice. The active pharmaceutical ingredients and the finished products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland and supplied worldwide to its customers.

Further information on Helsinn Group is available at www.helsinn.com.

**Eisai Inc.**
At Eisai Inc., *human health care* is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., our passionate commitment to patient care is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, manufacturing and marketing capabilities. Our key areas of commercial focus include oncology and specialty care (Alzheimer's disease, epilepsy and metabolic disorders). To learn more about Eisai Inc., please visit us at www.eisai.com/US.

Eisai Inc. has affiliates that are part of a global product creation organization that includes R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania, as well as a global demand chain organization that includes manufacturing facilities in Maryland and North Carolina. Eisai's global areas of R&D focus include neuroscience; oncology; metabolic disorders; vascular, inflammatory and immunological reaction; and antibody-based programs.

**Eisai Co., Ltd.**
Eisai Co., Ltd. is a research-based *human health care* (*hhc*) company that discovers, develops and markets products across the world through a global network of research facilities, manufacturing sites and marketing subsidiaries. For more information about Eisai's global operations, please visit www.eisai.com.

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