

## **HELINN GROUP AND EISAI INC. ANNOUNCE START OF PHASE III CLINICAL PROGRAM OF ORAL FIXED-DOSE COMBINATION OF NETUPITANT/PALONOSETRON (300 mg/0.50 mg) FOR PREVENTION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING (CINV)**

**Lugano, Switzerland and Woodcliff Lake, NJ, USA, September 23, 2011 -**

Helsinn Group and Eisai Inc. announced today that Helsinn has commenced a multi-centered Phase III clinical study program investigating the Netupitant/Palonosetron (300mg/0.50mg) oral fixed-dose combination for the prevention of chemotherapy-induced nausea and vomiting (CINV).

The Phase III program, reviewed by the FDA and EMA, consists of three studies which are expected to enroll 2,600 oncology patients receiving highly or moderately emetogenic chemotherapy in approximately 250 study sites in 18 countries.

“The commencement of this Phase III program is an important milestone in the development of this investigational compound, our commitment of giving cancer patients additional options for the prevention of CINV and for providing supportive care therapies for patients in their fight against cancer,” said Dr. Riccardo Braglia, Chief Executive Officer of Helsinn Group.

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 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.

Lyonel Coats, President and CEO of Eisai Inc., said: “We are pleased that the Phase III clinical program is underway and look forward to the possibility that, if approved, this investigational compound may one day bring benefit to patients who experience CINV.”

For more information regarding the ongoing clinical studies visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

### **About Netupitant**

Netupitant, an investigational compound, is a highly selective NK1 receptor antagonist that is thought to work by blocking the action of Substance P, an

endogenous neurotransmitter contained in high concentrations in the vomiting center of the brainstem that can stimulate the vomiting reflex.

### **About Palonosetron**

Palonosetron hydrochloride is a selective 5-HT<sub>3</sub> receptor antagonist, developed for the prevention of CINV.

Palonosetron has been developed by Helsinn Group of Switzerland and today it is marketed as Aloxi®, Onicit®, and Paloxi® in more than 50 countries worldwide. In the US, IV palonosetron injection 0.25mg is marketed as ALOXI®.

### **About ALOXI® (palonosetron hydrochloride) Injection 0.25 mg**

Palonosetron hydrochloride, marketed as ALOXI®, in the United States, is used in adults to help prevent nausea and vomiting on the day of chemotherapy that is highly likely to cause nausea and vomiting or up to five days following chemotherapy that is moderately likely to cause nausea and vomiting.

### **Important Safety Information**

- The most common side effects of ALOXI® for the prevention of CINV are headache and constipation.
- ALOXI® has not been studied in children under 18 years of age
- Tell your healthcare professional if you are taking other medications or if you are pregnant or breastfeeding.
- ALOXI® should not be taken if you have a hypersensitivity to the drug or any of its components.

For more information about ALOXI® see full prescribing information at [www.ALOXI.com](http://www.ALOXI.com).

ALOXI® is available by prescription only.

### **About the Helsinn Group**

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and the USA. Helsinn's business model is focused on the licensing of pharmaceuticals and medical devices in therapeutic niche areas. The Group in-licenses early to late stage new chemical

entities, completes their development from the performance of pre-clinical/clinical studies and Chemistry, Manufacturing and Control (CMC), development to the filing for and attainment of their market approval 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, and assisted and supported with 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 dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers. For more information about Helsinn Group, please visit the website: [www.helsinn.com](http://www.helsinn.com)

**About Eisai Inc.**

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit [www.eisai.com/US](http://www.eisai.com/US).

**About Eisai Co., Ltd.**

Eisai Co., Ltd. is a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Through a global network of research facilities, manufacturing sites and marketing subsidiaries, Eisai actively participates in all aspects of the worldwide healthcare system. Eisai employs approximately 11,000 employees worldwide.



Shaping alliances, building pharmaceuticals

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