



Helsinn Healthcare S.A. and Eisai Inc. Extend Relationship

Enter U.S. Licence and Co-promotion Agreement for Potential New Therapy in the Prevention of Chemotherapy-induced Nausea and Vomiting (CINV)

Lugano, Switzerland – Woodcliff Lake, NJ, USA, June 9, 2010 – Helsinn Healthcare S.A. and Eisai Inc. today announce the signing of a licensing agreement granting Eisai Inc. commercialization rights for a new product for potential use in the prevention of chemotherapy-induced nausea and vomiting (CINV) in the United States. The arrangement covers the development of a fixed-dose combination product (in both oral and IV forms) containing netupitant, a neurokinin-1 (NK₁) receptor antagonist, and palonosetron, a serotonin-3 (5-HT₃) receptor antagonist.

Under the terms of the agreement, Helsinn Healthcare S.A. will be responsible for conducting all development activities (CMC, preclinical and clinical), obtaining regulatory approvals, and holding the New Drug Application. If approved by the Food and Drug Administration, the fixed dose combination oral and IV products will be co-promoted in the United States by Eisai Inc. and Helsinn Therapeutics (U.S.) Inc. Helsinn's manufacturing affiliate in Ireland, Helsinn Birex Pharmaceuticals Ltd., will be responsible for the manufacture and supply of finished product for clinical and commercial use in the United States.

In addition, Helsinn Therapeutics (U.S.) Inc. has signed a Detail Service Agreement with Eisai Inc. to co-promote the existing brand Aloxi[®] (palonosetron hydrochloride) in the U.S. market. As a result, Helsinn Therapeutics (U.S.) Inc. will recruit and hire a dedicated sales force to visit primarily clinical oncologists in the United States.





Riccardo Braglia, CEO of Helsinn group, said: "We are very proud that the existing successful collaboration with Eisai Inc. in the U.S. for Aloxi[®] is now extending to a co-promotion of Aloxi[®] and, if approved, to Netupitant-Palonosetron FDC, and the strengths of our two companies will enable patients to have additional treatments for CINV now and in the future."

"Eisai is committed to satisfying unmet medical needs and contributing to the health and well-being of people worldwide," said Lonnel Coats, President and COO of Eisai Inc. "Our expanded relationship with Helsinn further demonstrates our focus on oncology and supportive care and will help to strengthen our presence in the area of anti-emesis therapy."

About Netupitant

Netupitant is a highly selective NK_1 receptor antagonist, an antiemetic that works 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. The fixed-dose combination of netupitant and palonosetron is entering Phase III for the prevention of acute and delayed nausea and vomiting following both highly and moderately emetogenic chemotherapy.

<u>About Aloxi[®]</u> About Palonosetron (Aloxi[®], Onicit[®], Paloxi[®])

Palonosetron hydrochloride is a selective $5-HT_3$ receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. Palonosetron demonstrates, in clinical trials and clinical practice, a unique long-lasting action in the prevention of CINV. The product has shown to be





effective in preventing both Day 1 and Days 2-5 CINV in patients receiving moderately emetogenic chemotherapies (MEC). A single intravenous dose of palonosetron (0.25 mg) provides better protection from CINV than first-generation 5-HT₃ receptor antagonists throughout a 5-day post-chemotherapy period in MEC setting. This means that a single administration of palonosetron also grants protection during the Days 2-5 phase of CINV. Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions (incidence \geq 2 percent) in CINV trials with palonosetron were headache (9 percent) and constipation (5 percent), and they were similar to the comparators.

For indications and dosages in your country, please refer to the Summary of Product Characteristics approved by your local authorities.

Palonosetron has been developed by Helsinn Group of Switzerland and today it is marketed as Aloxi[®], Onicit[®], and Paloxi[®] in more than 50 countries world-wide.

In the EU, palonosetron is marketed as Aloxi® through a distribution license granted by Helsinn to several pharmaceutical companies.

For more information about palonosetron please visit the website www.aloxi.com

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and 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 sold directly through the Group's subsidiaries or 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: <u>www.helsinn.com</u>

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 with fiscal year 2009 (year ended March 31, 2010) sales of approximately \$3.9 billion. 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.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, 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 <u>www.eisai.com</u>.





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