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Eisai Co., Ltd.

## **U.S. FDA APPROVES ANTIEMETIC AGENT AKYNZEO® FOR PREVENTION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING (CINV)**

*World's First Oral Fixed Combination Targeting Two Critical Pathways Involved in CINV*

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that Helsinn Healthcare S.A. (Headquarters: Lugano, Switzerland, CEO: Riccardo Braglia, "Helsinn") has received approval from the U.S. Food and Drug Administration (FDA) for AKYNZEO® (generic name: netupitant/palonosetron), indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including but not limited to highly emetogenic chemotherapy, in the U.S.

AKYNZEO is a new oral fixed combination that targets two critical signaling pathways associated with CINV, by combining netupitant, an NK<sub>1</sub> receptor antagonist, with palonosetron (brand name: ALOXI®), a 5-HT<sub>3</sub> receptor antagonist. This approval was based on the submission of data from Phase II and Phase III clinical trials of AKYNZEO in patients undergoing treatment with moderately and highly emetogenic chemotherapy regimens for a variety of tumor types. Based on a licensing agreement between Eisai and Helsinn signed in June 2010, AKYNZEO will be co-promoted in the U.S. by the two companies' respective U.S. subsidiaries: Eisai Inc. and Helsinn Therapeutics U.S. Inc. Eisai Inc. will book sales of the product in the U.S.

CINV is one of the most common side effects of chemotherapy. The management and prevention of CINV has been refined over the past several decades, however many patients still suffer from CINV, particularly during the delayed phase after chemotherapy. As the adjunctive use of antiemetics with multiple mechanisms is recommended in the prevention of CINV<sup>1</sup>, AKYNZEO has been designed to provide patients with two antiemetics in a single oral fixed combination.

Eisai defines oncology as a therapeutic area of focus and is committed to the development of new anticancer agents and treatments for supportive care. Through these efforts, Eisai will make further contributions to addressing the diversified needs of, and increasing the benefits to, patients and their families as well as healthcare professionals.

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## [Notes to editors]

### 1. About AKYNZEO®

AKYNZEO is a new oral fixed combination that targets two critical signaling pathways associated with CINV, by combining netupitant, an NK<sub>1</sub> receptor antagonist, with palonosetron, a 5-HT<sub>3</sub> receptor antagonist. Marketing authorization applications for AKYNZEO are currently being submitted in countries throughout the world. In January 2014, the European Medicines Agency began assessment of the marketing authorization application submitted by Helsinn Healthcare S.A. for a treatment combining netupitant and palonosetron for the prevention of acute and delayed nausea and vomiting associated with CINV. In addition, Eisai and Helsinn are currently developing an injectable formulation in order to further maximize the value of AKYNZEO to patients.

### 2. About the Helsinn Group

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the U.S. and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing preclinical and clinical studies and associated manufacturing activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge. Helsinn supports these partners by providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics U.S. Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn's products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers.

Further information on Helsinn Group is available at: [www.helsinn.com/](http://www.helsinn.com/)

### 3. About Eisai and the Helsinn Group

Helsinn Healthcare S.A. signed a licensing agreement with Eisai Inc. granting Eisai commercial rights for AKYNZEO in the U.S. Under the terms of the agreement, Helsinn Therapeutics S.A. 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). AKYNZEO will be co-promoted in the U.S. by Eisai Inc. and Helsinn Therapeutics U.S. Inc. Eisai Inc. will book sales of the product in the U.S.

<sup>1</sup> National Cancer Comprehensive Network (NCCN). Clinical Practice Guidelines in Oncology. Antiemesis. v 2.2014. [www.nccn.org](http://www.nccn.org). Accessed August, 2014.