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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

FDA Approves ALOXI® (Palonosetron HCl) Capsules for Prevention of Acute Chemotherapy-induced Nausea and Vomiting

Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman & CEO: Hajime Shimizu, "ECA"), a U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai"), and Helsinn Healthcare SA (Headquarters: Lugano, Switzerland, CEO: Riccardo Braglia), a partner of ECA, announced on August 23rd (EST) that the U.S. Food and Drug Administration (FDA) has approved a new oral formulation of ALOXI® (palonosetron hydrochloride), a 5-hydroxytryptamine-3 (5-HT_3) receptor antagonist, for the prevention of chemotherapy-induced nausea and vomiting (CINV).

ALOXI Capsules 0.5 mg for oral administration is indicated for the prevention of acute nausea and vomiting following initial and repeat courses of moderately emetogenic chemotherapy. A single 0.5 mg of ALOXI Capsule is administered approximately one hour prior to the start of chemotherapy.

ALOXI injection 0.25 mg has been available in the United States for intravenous administration since 2003 for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy, and for the prevention of acute nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy. A single 0.25 mg intravenous dose of ALOXI is administered approximately 30 minutes before the start of chemotherapy.

Eisai will continue to expedite the development of oncology and supportive care products to address unmet medical needs of patients with cancer.

[Please see the following notes for the product information and company profile]

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<Notes to Editors>

About Chemotherapy-Induced Nausea and Vomiting (CINV)

Research has shown that patients with cancer consider CINV among the most dreaded side effects following therapy. Despite prophylactic antiemetics, on the day of chemotherapy, about 30-45 percent of patients experience nausea or vomiting or require rescue therapy following administration of moderately emetogenic chemotherapy. Failure to control acute nausea and vomiting on the first day of chemotherapy will increase the risk of nausea and vomiting on subsequent days and in subsequent cycles of chemotherapy.

About ALOXI Capsules for Oral Administration

ALOXI (palonosetron HCl) Capsules 0.5mg 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 0.5mg capsule is administered approximately one hour prior to the start of chemotherapy.

About ALOXI Injection

ALOXI injection 0.25 mg is the first and only 5-hydroxytryptamine-3 ($5\text{-}HT_3$) receptor antagonist to be indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy, and for the prevention of acute nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy. ALOXI injection 0.075 mg is also approved as a single intravenous dose administered immediately before the induction of anesthesia for the prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery.

Eisai licensed the North American distribution and marketing rights for ALOXI from Helsinn Healthcare SA.

About HELSINN HEALTHCARE SA

HELSINN HEALTHCARE SA is a privately owned pharmaceutical group with headquarters in Switzerland and is the worldwide licensor of palonosetron. HELSINN's core business is the licensing of pharmaceuticals in therapeutic niche areas. The company's business strategy is to in-license early stage new chemical entities and complete their development from the performance of pre-clinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELSINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELSINN's cGMP facilities and supplied worldwide to its customers.
For more information about HELSINN, please visit the company's Web site at www.helsinn.com.

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