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**FDA APPROVES ALOXI<sup>®</sup> (PALONOSETRON HCL) INJECTION  
FOR PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING**

**Woodcliff Lake, NJ, March 2, 2008** – Eisai Corporation of North America, its U.S. subsidiary, MGI PHARMA, INC., and Helsinn Healthcare SA today announced that the U.S. Food and Drug Administration (FDA) has approved Aloxi<sup>®</sup> (palonosetron hydrochloride) injection for the prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

Aloxi, available in the United States since 2003, is the first and only 5-hydroxytryptamine-3 (5-HT<sub>3</sub>) receptor antagonist approved by the FDA 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.

The new indication is based on one double-blind Phase III study that evaluated the efficacy of three doses of Aloxi compared to placebo for the prevention of PONV. In the trial, 574 patients undergoing elective gynecologic or abdominal laparoscopic surgery (predominately in the out-patient setting) were randomized to receive one of three single intravenous doses of Aloxi (0.025 mg, 0.050 mg or 0.075 mg) or placebo prior to administration of anesthesia. The effectiveness of Aloxi in PONV was assessed on the day of surgery (0-24 hours) and for two subsequent days (24-72 hours).

The trial successfully met its co-primary endpoint of Complete Response (CR) – defined as no emesis (vomiting) or use of rescue medication – for the 0-24-hour time period (42.8% of patients treated with the approved dose of Aloxi 0.075 mg experienced a CR, compared to 25.9% of patients given placebo [p=0.0035]). For the co-primary endpoint of CR for the 24-72-hour postoperative period, 48.6% of patients treated with Aloxi 0.075 mg experienced a CR, compared to 40.7% of patients given placebo (p=0.1877, not significant).

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Further, Aloxi 0.075 mg reduced the severity of nausea compared to placebo, and this was supported by Phase II PONV trial results demonstrating that Aloxi significantly reduced the severity of nausea compared to placebo (p=0.009).

The incidence of adverse reactions was indistinguishable among all treatment groups, including placebo. The most frequently observed side effects with Aloxi equal to or greater than 2% were electrocardiogram (ECG) QT prolongation (5%), bradycardia (4%), headache (3%), and constipation (2%).

Included in the updated label with the PONV indication are the results of a study, in 221 healthy volunteers, on the effects of Aloxi at doses of 0.25 mg, 0.75 mg and 2.25 mg, compared to moxifloxacin, on several ECG intervals, a potential safety concern of drugs in the 5-HT<sub>3</sub> receptor antagonist class. The study demonstrated that Aloxi had no significant effect on any ECG interval including QTc duration (cardiac repolarization) at doses up to 2.25 mg.

“These results highlight the unique safety features of Aloxi and when combined with the clinical results, indicate a favorable risk/benefit ratio,” said Michael Cullen, M.D., Chief Medical Officer, MGI PHARMA, INC.

“This new indication is in keeping with our *human health care* mission to address the unmet medical needs of patients,” said Hajime Shimizu, Chairman and CEO, Eisai Corporation of North America. “A single intravenous dose of Aloxi can provide anesthesiologists with an effective option for the prevention of PONV for up to 24 hours.”

A recent study indicated that despite the use of multiple prophylactic agents, 33% of high-risk patients still require rescue therapy during the first six hours after surgery, and more than 40% suffer symptoms of PONV severe enough to warrant rescue therapy in the 24 hours after surgery.

An estimated 38 million general anesthesia procedures are performed each year in the United States (2006 figures), and 39% of these – 15 million procedures – utilize anti-emetic therapy for PONV. Of these 15 million procedures, 89%, or 13.4 million, use 5-HT<sub>3</sub> receptor antagonists, such as Aloxi.

“This is an important milestone for Aloxi, given the increasing use of antiemetic prophylaxis during surgical procedures,” said Riccardo Braglia, CEO, Helsinn Healthcare SA, a privately owned Swiss pharmaceutical group, holder of the Aloxi New Drug Application and partner of Eisai Corporation of North America. MGI PHARMA, INC. licensed the North American distribution and marketing rights for Aloxi from Helsinn.

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### **About Postoperative Nausea and Vomiting (PONV)**

Postoperative nausea and vomiting are common consequences of anesthetic and surgical procedures, and frequently occur following the procedures. Patients undergoing abdominal, gynecological, ear/nose/throat, or optical procedures are at highest risk for PONV. Additional factors that can increase the risk for PONV include female gender, non-smoking status, prior history of PONV or motion sickness, length of surgery, and the use of volatile anesthetics and opioids.

### **About Aloxi<sup>®</sup> Injection**

In addition to the new PONV indication, Aloxi (palonosetron HCl) injection 0.25 mg is the first and only 5-HT<sub>3</sub> 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 is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions in Aloxi chemotherapy-induced nausea and vomiting trials include headache (9%) and constipation (5%).

Please see the Aloxi package insert, available at [www.aloxi.com](http://www.aloxi.com), for important additional details.

### **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](http://www.helsinn.com).

### **About Eisai Corporation of North America**

Eisai Corporation of North America is a wholly-owned subsidiary of Eisai Co., Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: neurology, gastrointestinal disorders and oncology/critical care.

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Eisai Corporation of North America supports the activities of its operating companies in North America. These operating companies include: Eisai Research Institute of Boston, Inc., a discovery operation with strong organic chemistry capabilities; Morphotek, Inc., a biopharmaceutical company specializing in the development of therapeutic monoclonal antibodies; Eisai Medical Research Inc., a clinical development group; Eisai Inc., a commercial operation with manufacturing and marketing/sales functions; MGI PHARMA, INC.; and Eisai Machinery U.S.A., which markets and maintains pharmaceutical manufacturing machinery. For more information about Eisai, please visit [www.eisai.com](http://www.eisai.com).

**About MGI PHARMA, INC.**

MGI PHARMA, INC., a wholly-owned subsidiary of Eisai Corporation of North America, is a biopharmaceutical company focused in oncology and acute care that acquires, researches, develops, and commercializes proprietary products that address the unmet needs of patients. For more information about MGI PHARMA, INC., please visit [www.mgipharma.com](http://www.mgipharma.com).

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