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Eisai Co., Ltd.
Eisai Corporation of North America
Helsinn Healthcare SA

FOR IMMEDIATE RELEASE

FDA APPROVES ALOXI® (PALONOSETRON HCL) INJECTION FOR PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito), its U.S. subsidiary Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman and CEO: Hajime Shimizu), and Helsinn Healthcare SA (Headquarters: Switzerland, CEO: Riccardo Braglia) today announced that the U.S. Food and Drug Administration (FDA) has approved Aloxi

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_3 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.

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-hydroxytryptamine-3 (5-HT_3) receptor antagonists, such as Aloxi®.

In January, 2008, Eisai Co., Ltd. announced the completion of its acquisition of MGI PHARMA, INC. in order to create a base for growth with MGI PHARMA's marketed and pipeline products as well as its R&D and commercial capabilities. The new indication for Aloxi® will enable Eisai to make further contributions to increasing the benefits of patients and their families.

[Please see the following note for information regarding PONV and corporate profile