



**HELSINN AND MGI PHARMA ANNOUNCE ALOXI® sNDA APPROVAL
ALLOWING FOR REPEATED DOSING FOR CANCER PATIENTS RECEIVING
MULTIPLE DAY CHEMOTHERAPY REGIMENS**

*-Approximately Ten Percent of 5-HT₃ Receptor Antagonist Doses Administered for CINV are
Associated with Multi-Day Chemotherapy-*

Lugano, 4th September 2007 – Helsinn Healthcare SA, and its partner **MGI Pharma, INC.**, today announced approval of a supplemental New Drug Application (sNDA) for Aloxi® (palonosetron hydrochloride) Injection by the United States Food and Drug Administration (FDA). This sNDA includes the removal of a dosing recommendation, which limited Aloxi use to once per seven day interval, from the product's label. Data from several safety and efficacy trials that evaluated multiple day dosing of Aloxi were included in the sNDA. Aloxi is approved by the FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Multi-day chemotherapy regimens frequently used to treat certain lung, colon and testicular cancers, and leukemias, often present a significant challenge in preventing chemotherapy induced nausea and vomiting (CINV) due to the overlap of the acute and delayed phases of CINV. The elimination of this dosing restriction from the Aloxi label removes a barrier to health care providers administering Aloxi more than once per week, which may be necessary when treating cancer with multi-day chemotherapy regimens.

"We are glad to have achieved this label change and to be able to offer the medical community more flexible dosing for Aloxi. The data provided to the FDA underscore the safety and efficacy profile of this important cancer supportive care product," said Dr. Sergio Cantoreggi, Senior Director R&D, Helsinn Healthcare.

“Our objective is to continue to enhance the Aloxi label and we look forward to the submission of the sNDA for an oral Aloxi formulation later this year.”

“The approval of this sNDA further supports the safety profile of Aloxi and represents one of several efforts we have undertaken to expand the Aloxi franchise. At least ten percent of all 5-HT₃ receptor antagonist doses administered for the prevention of CINV are associated with multi-day chemotherapy regimens,” said Eric Loukas, Executive Vice President and Chief Operating Officer of MGI PHARMA. “The Aloxi post-operative nausea and vomiting sNDA is under review with a PDUFA date of March 4, 2008 and pre-launch activities are underway”.

About Aloxi® Injection

Aloxi is approved by the U.S. FDA for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Aloxi is the first and only 5-HT₃ receptor antagonist to be indicated for the prevention of delayed chemotherapy-induced nausea and

vomiting (CINV) caused by moderately emetogenic cancer chemotherapy. The most common adverse reactions related to Aloxi were headache (9%) and constipation (5%). Please see the Aloxi package insert, available www.mgipharma.com and www.aloxi.com, for important additional details.

About MGI PHARMA

MGI PHARMA, INC. 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. MGI PHARMA markets Aloxi® (palonosetron hydrochloride) Injection, Dacogen® (decitabine) for Injection, and Gliadel® Wafer (polifeprosan 20 with carmustine implant) in the United States. The Company directly markets its products in the U.S. and collaborates with partners to reach international markets. For more information about MGI PHARMA, please visit www.mgipharma.com.

About HELSINN HEALTHCARE

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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