



NEWS RELEASE

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MGI PHARMA AND HELSINN HEALTHCARE SA ANNOUNCE FDA APPROVAL OF ALOXI™

Aloxi™ is the first 5-HT₃ receptor antagonist to be indicated for the prevention of delayed CINV caused by moderately emetogenic cancer chemotherapy

MINNEAPOLIS, July 25, 2003 -- MGI PHARMA, INC., (Nasdaq: MOGN) an oncology-focused biopharmaceutical company, and HELSINN HEALTHCARE SA, a privately-owned Swiss pharmaceutical group, today announced that the U.S. Food and Drug Administration (FDA) has approved Aloxi™ (palonosetron hydrochloride) injection at a dose of 0.25 mg for:

- the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy, and
- the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

This approval comes approximately ten months after HELSINN's submission of the Aloxi™ New Drug Application (NDA) to the FDA. Aloxi™ is the first 5-HT₃ receptor antagonist to be indicated for the prevention of delayed chemotherapy-induced nausea and vomiting (CINV) caused by moderately emetogenic cancer chemotherapy.

Aloxi™ is a selective 5-HT₃ receptor antagonist with strong receptor binding affinity and an extended plasma half-life, approximately 40 hours, developed for the prevention of CINV. Results from Phase 3 clinical trials managed by HELSINN demonstrate that a single IV dose of Aloxi™ is effective in preventing both acute and delayed CINV in patients receiving moderately emetogenic chemotherapy, the most common chemotherapy regimens used in the treatment of cancer.

MGI PHARMA will host a conference call at 10:00 a.m. ET on Monday, July 28, 2003, to discuss the Aloxi™ approval. Lonnie Moulder, president and CEO, will host the call. The live webcast can be accessed by visiting the Investor Relations section of MGI PHARMA's website, www.mgipharma.com. An archived version of the call will be available via the MGI PHARMA website for seven days following the call.

“Despite standard treatment with currently available medications, our research shows that thirty percent of patients are not well controlled during the acute CINV phase and one-half of all chemotherapy patients still experience delayed nausea and vomiting,” stated Edward B. Rubenstein, M.D., Chief, Section of Medical Supportive Care at M.D. Anderson Cancer Center. “As the only approved agent for the prevention of delayed CINV associated with moderately emetogenic chemotherapy, Aloxi™ represents a meaningful advance in the field of oncology supportive care for both patients who are undergoing chemotherapy and their care providers.”

“We believe Aloxi™ is a differentiated supportive care product, with great potential to help cancer patients undergoing chemotherapy and MGI looks forward to making Aloxi™ available in September to clinicians and their patients,” said Lonnie Moulder, president and chief executive officer of MGI PHARMA. “As the U.S. licensee for Aloxi™, we are grateful to our partner HELSINN who led the successful pivotal trial program resulting in the achievement of this significant milestone.”

Aloxi™ Phase III Clinical Data

Three multicenter, double blind, phase 3 trials (99-03, 99-04 and 99-05) were conducted to compare the efficacy and safety of Aloxi™ with that of currently marketed 5-HT₃ receptor antagonists for prevention of CINV. Study endpoints in each trial included complete response, defined as the percentage of patients that did not experience vomiting or use rescue medication, during the 0-24 , 24-120, and 0-120 hour periods following chemotherapy. Approximately 1,800 patients were enrolled in the Phase 3 Aloxi™ clinical program.

Data from study 99-03 showed that the complete response rate for the 189 patients in the Aloxi™ 0.25 mg arm was significantly greater than the complete response rate among the 185 patients who received 32 mg ondansetron. During the acute phase (0 - 24 hours) following moderately emetogenic chemotherapy, 81% of the patients treated with a single intravenous dose of Aloxi™ achieved a complete response, compared to 69% of patients treated with ondansetron. During the delayed phase (24 -120 hours), 74% of patients treated with Aloxi™ had a complete response compared to 55% of patients in the ondansetron study arm. For the overall 0 – 120 hour period following chemotherapy, 69% of patients treated with Aloxi™ achieved a complete response, compared to 50% of patients treated with ondansetron. Results from the 99-03 trial were presented at the 2003 American Society of Clinical Oncology (ASCO) annual meeting.

Results of study 99-04 showed that 63% of the 189 patients treated with Aloxi™ 0.25 mg achieved a complete response during the acute phase following moderately emetogenic chemotherapy, compared to 53% of the 191 patients treated with 100 mg dolasetron. In the delayed phase, 54% of patients in the Aloxi™ arm had complete responses, compared to 39% of

patients in the dolasetron arm. For the overall 0 – 120 hour period following chemotherapy, 46% of patients treated with Aloxi™ achieved a complete response, compared to 34% of patients treated with dolasetron. Results from the 99-04 trial were first reported in June 2002 at the Multinational Association of Supportive Care in Cancer (MASCC) 14th International Symposium, and additional data from study 99-04 were presented at the 2003 ASCO annual meeting.

Patients receiving highly emetogenic chemotherapy were evaluated in study 99-05 which showed that 59% of the 223 patients treated with a single intravenous 0.25 mg dose of Aloxi™ achieved a complete response during the acute phase compared to 57% of 221 patients treated with 32 mg ondansetron. Consistent with medical practice, concomitant dexamethasone was allowed in this study involving highly emetogenic regimens and was received by 67% of the patients in each study arm. In those patients treated with a combination of Aloxi™ and dexamethasone, 65% of the patients achieved a complete response during the acute phase, compared to 56% of patients treated with the combination of ondansetron and dexamethasone. This data was presented in June 2003 at the MASCC 15th International Symposium.

Tolerability and Safety Profile

In clinical trials for the prevention of nausea and vomiting induced by moderately or highly emetogenic chemotherapy, 1,374 adult patients received palonosetron. Adverse reactions were similar in frequency and severity with Aloxi™ and the comparator agents. The most common adverse reactions related to the study drug at a dose of 0.25 mg were headache (9%) and constipation (5%). The effect of Aloxi™ on ECG parameters was comparable to ondansetron and dolasetron in clinical trials; it should be administered with caution in patients who have or may develop prolongation of cardiac conduction intervals. Please see the Aloxi™ package insert for important additional details, which will be available soon at www.mgipharma.com.

Chemotherapy-Induced Nausea and Vomiting (CINV)

If not prevented, CINV is estimated to afflict the majority of cancer patients undergoing chemotherapy and can result in a delay or even discontinuation of chemotherapy treatment. The advent of 5-HT₃ receptor antagonists has revolutionized the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy. The market in the United States for 5-HT₃ antagonists was approximately \$1.4 billion in 2002 and is growing, and includes the CINV prevention and treatment market, which is over \$800 million.

Updated Financial Guidance

MGI expects to achieve annual Aloxi™ sales of at least \$250 million approximately four years following launch, and we continue to expect sales of Aloxi™ in the first 12 months following launch to range from \$40 million to \$55 million. Within 2003, we expect Aloxi™ sales to range from \$5 million to \$10 million. Cost of sales as a percentage of sales revenue for Aloxi is expected to range from 35% to 37%. We expect to provide guidance for 2004 when we report our full-year results for 2003.

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of cancer patients. MGI has a balanced product portfolio of proprietary pharmaceuticals, and intends to become a leader in oncology. MGI markets Salagen® Tablets (pilocarpine hydrochloride) and Hexalen® (altretamine) capsules in the U.S. The Company directly markets its products in the United States and collaborates with various alliances in international markets. For more information about MGI, please visit the Company's Web site at 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.

This news release contains certain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements are not guarantees of MGI PHARMA's future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Factors that might cause the Company's results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, the ability of Aloxi™ to compete successfully with other CINV treatments; continued sales of MGI PHARMA's marketed products; development or acquisition of additional products; reliance on contract manufacturing and third party supply; changes in strategic alliances; continued access to capital; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission, including in Exhibit 99 to its most recently filed Form 10-Q or 10-K. MGI PHARMA undertakes no duty to update any of these forward-looking statements to conform them to actual results.

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