# Helsinn & MGI Pharma Announce Completion Of Pivotal Phase 3 Trials Of Palonosetron

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Lugano, Switzerland and Minneapolis, MN -- January 16, 2002 -- Helsinn Healthcare SA, a privately owned Swiss pharmaceutical group, and MGI Pharma, Inc., (Nasdaq: MOGN) an oncology-focused pharmaceutical company based in Minneapolis, today announced that patient treatment is completed and the data analysis is underway for the pivotal Phase 3 trials of their investigational agent, Palonosetron. Palonosetron is a potent, highly selective 5-HT3-receptor antagonist in development in North America and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). Submission of the New Drug Application (NDA) for Palonosetron is now planned to occur in the third quarter of 2002.

The Phase 3 clinical trial program was initiated in April 2000 and was designed to compare intravenous (IV) Palonosetron to currently marketed 5-HT3 antagonists. The trials were conducted at more than 130 medical centers across North America and Europe, with more than 1,800 cancer patients receiving either highly- or moderately-emetogenic chemotherapy. Based on the extended half-life of Palonosetron and the results of a Phase 2 trial, the efficacy of Palonosetron in the Phase 3 trial is being assessed over Day 2 through Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy.

"We are pleased to have completed all patient treatment and to have begun analysis of the data collected in the Palonosetron Phase 3 clinical program," said Luigi Baroni, senior director of Scientific Affairs Division at HELSINN. "The Phase 2 clinical trial results were promising, and we are hopeful that the Phase 3 Palonosetron data will demonstrate that it can make a difference for cancer patients suffering from CINV."

"The half-life of other available 5-HT3 receptor antagonists ranges from approximately five to nine hours, whereas Palonosetron has a plasma elimination half-life of nearly 40 hours," notes Dr. John MacDonald, senior vice president of Research and Development at MGI. "The activity seen with Palonosetron in the Phase 2 trial, coupled with its safety profile observed to date, led to the initiation of a Phase 3 program to assess the ability of the drug to provide prolonged protection against CINV with a single dose."

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