

PHASE 2 STUDY RESULTS POINT TO THE PROLONGED ACTIVITY OF PALONOSETRON

MGI Pharma, Inc. and Helsinn Healthcare SA announced Phase 2 results demonstrating the potential efficacy in the prevention of acute chemotherapy-induced nausea and vomiting

ORLANDO, Florida, May 20, 2002 – MGI PHARMA, Inc. and HELSINN HEALTHCARE SA announced Phase 2 results demonstrating the potential efficacy of their investigational agent palonosetron in the prevention of acute chemotherapy-induced nausea and vomiting (CINV) in patients who received highly-emetogenic chemotherapy. The study results, which were presented at the 2002 annual meeting of ASCO in Orlando, showed palonosetron was effective in the prevention of CINV during the initial 24-hour period and for several days beyond.

Palonosetron is a potent, highly selective 5-HT₃-receptor antagonist with an extended half-life (nearly 40 hours) and a strong receptor-binding affinity, in development for the prevention of chemotherapy-induced nausea and vomiting (CINV), which is estimated to occur in 85 percent of cancer patients undergoing chemotherapy. If untreated, CINV can result in a delay or even discontinuation of chemotherapy treatment. A New Drug Application submission for palonosetron is expected in the third quarter of 2002.

“These Phase 2 results with palonosetron are most encouraging,” commented Richard Gralla, MD, Associate

Director, Herbert Irving Comprehensive Cancer Center, Columbia University, New York City, New York. “Patients often receive chemotherapeutic agents that are associated with nausea and vomiting that can continue for several days after the administration of chemotherapy. While they can receive follow-on treatment for delayed nausea and vomiting, there is a need for agents that can provide



enhanced control and convenience over an extended period of time. We look forward to the results of the well-planned Phase 3 studies with palonosetron.”

PHASE 2 STUDY RESULTS

In this randomized, double-blinded, multicenter trial, dose ranging was performed to determine the clinical efficacy relationship among a range of different doses of palonosetron. Clinical efficacy in the 161 patients studied was assessed by a complete response rate, defined as the percentage of patients who did not experience vomiting or receive rescue medication. Patients received highly-emetogenic chemotherapy, primarily cisplatin.

During the first 24-hours following chemotherapy treatment (the acute nausea and vomiting period), across the dose ranges evaluated (0.3-1 mcg/kg through 90 mcg/kg), patients treated with a single IV dose of palonosetron achieved complete response rates up to 50 percent without concomitant corticosteroid administration. Encouraging complete response rates were also observed through the fifth day following the administration of a single intravenous dose of palonosetron. Adverse events associated with palonosetron, the most common being headache, were similar to those seen with other 5-HT₃-receptor antagonists.

“The complete responses observed across dose ranges and over several days in this patient population underscore the potential clinical benefit of the prolonged activity of palonosetron,” said John MacDonald, PhD, Senior Vice President, Research and Development at MGI PHARMA. “To further investigate the clinical potential of palonosetron, the design of the pivotal Phase 3 clinical trials program was based on this Phase 2 study.”

Please direct any further questions you may have to Maggie P. Knack, Director of Investor Relations at MGI – telephone 952-346-4771