

MGI Pharma Signs Exclusive License Agreement With Helsinn Healthcare SA, For Palonosetron, A Phase 3 Anti-Emetic | Evaluate

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Source Press Release

Company [Helsinn Group](#), [MGI Pharma](#)

Tags Licensing, Phase III, Gastro-Intestinal

Date April 10, 2001

Minneapolis, MN and Lugano, Switzerland -- April 10, 2001 -- [MGI Pharma](#), Inc., (Nasdaq: MOGN) and Helsinn Healthcare SA, a privately owned pharmaceutical group with headquarters in Switzerland, today announced that they have signed the definitive agreement granting [MGI Pharma](#) exclusive North American license and distribution rights to [palonosetron](#). The signing of the letter of intent for this agreement was previously announced in February. [Palonosetron](#) is a potent and selective [5-HT3](#) antagonist with an extended half-life, in Phase 3 development for the prevention of chemotherapy-induced nausea and vomiting (CINV). Completion of the Phase 3 trials could allow for NDA (New Drug Application) submission in the first half of 2002. When launched, [palonosetron](#) will compete in the \$1 billion North American CINV market.

"We are looking forward to entering the supportive care segment of oncology, the successful completion of the Phase 3 program and approval process for [palonosetron](#), and the opportunity to demonstrate the role that this novel agent can have in preventing chemotherapy-induced nausea and vomiting for cancer patients," commented Chuck Blitzer, president and CEO of [MGI Pharma](#). "[Palonosetron](#) is another exciting addition to our growing oncology product portfolio, representing another well-advanced product that can be commercialized in the near term."

"[Palonosetron](#) is our first product entry into the United States, and we are pleased to be working with [MGI Pharma](#) for the North American distribution of this innovative product in the supportive care segment of oncology," commented Riccardo Braglia, managing director of Helsinn. "We know that [MGI Pharma](#)'s proven commercial organization, its experienced oncology sales force, and its present and future commitment to [palonosetron](#)'s role within the [5-HT3](#) antagonist marketplace will ensure the success of our new partnership."

About [Palonosetron](#)

When launched as a marketed product, [palonosetron](#) will be one of four products competing in the \$1 billion North American market for [5-HT3](#) antagonists. The extended half-life of [palonosetron](#) as compared to the other agents and the results of Phase 2 trials assessing efficacy beyond 24 hours differentiates [palonosetron](#) from the three currently marketed [5-HT3](#) antagonists indicated for CINV.

CINV is estimated to occur in 85 percent of cancer patients undergoing chemotherapy and can result in delay or even discontinuation of treatment, and the advent of [5-HT3](#) antagonists has revolutionized the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy.

[Palonosetron](#) has been tested in a randomized, double-blind dose-ranging Phase 2 trial at multiple sites throughout the U.S. that evaluated its efficacy and safety when administered in a single intravenous dose for the prevention of nausea and vomiting in patients receiving highly emetogenic chemotherapy. Over 1,000 patients have participated in Phase 1 and Phase 2 trials of [palonosetron](#). Based on these results, Helsinn initiated a Phase 3 clinical trial program that is well-controlled, double-blind trials comparing [palonosetron](#) to currently available [Dr. Reddy's Laboratories, Ltd., et al.](#) [ral](#) in v.

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24-hour period after the start of chemotherapy. The most frequent adverse events associated with [palonosetron](#) are similar to those seen with other [5-HT3](#) antagonists and include headache and constipation.

Under the terms of the exclusive license agreement, [MGI Pharma](#) will make \$11 million in upfront payments, already including the initial \$5 million made upon signature of the letter of intent, and will make additional payments based on the achievement of certain milestones through the approval of [palonosetron](#) in the U.S. Helsinn will continue to fund and conduct all development of [palonosetron](#). [MGI Pharma](#) will also pay royalties and product supply fees based upon net sales. Helsinn will supply finished product ready for distribution, the active ingredient of which is manufactured at Helsinn's new state-of-the-art facility (Helsinn Advanced Synthesis SA) dedicated to the production of high-potency active ingredients.

About [MGI Pharma](#)

[MGI Pharma](#), Inc. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs and build shareholder value. MGI focuses its sales efforts solely in the United States and collaborates with other pharmaceutical or biotechnology companies for its products in international markets. For more information about MGI, please visit the Company's web site at [mgipharma.com](#).


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