Helsinn Healthcare Announce The Completion Of Patient Enrollment For First Palonosetron Phase 3 Pivotal Trial

Source	Press Release
Company	Helsinn Group, MGI Pharma
Tags	Phase III, Gastro-Intestinal
Date	October 03, 2001

Lugano, Switzerland -- October 3, 2001 -- Helsinn Healthcare SA announced the completion of patient enrollment for the first of the pivotal Phase 3 trials of palonosetron, a novel 5-HT3 antagonist. Palonosetron is a potent, highly selective 5-HT3 antagonist with an extended half-life, currently in Phase 3 development in the United States and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). HELSINN expects to complete patient enrollment for the remaining trials in the Phase 3 program near the end of 2001 and plans to submit a New Drug Application (NDA) in the U.S. and Europe in the first half of 2002.

The double-blinded, randomized Phase 3 clinical trial program aims to compare intravenous (IV) palonosetron to currently marketed 5-HT3 antagonists and is being conducted at medical centers across North America and Europe. It is expected that over 1,800 cancer patients receiving either highly- or moderately-emetogenic chemotherapy will be enrolled in the trials. Based on the extended half-life of palonosetron and the results of a Phase 2 trial, its efficacy 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.

Results of Phase 1 trials in healthy volunteers to assess the pharmacokinetic properties and safety of palonosetron were presented at this year's American Society of Clinical Oncologists (ASCO) meeting in May 2001. Palonosetron was found to have a plasma elimination half-life of 37 hours, which is at least three times longer than marketed agents in its class. This extended half-life of palonosetron and the results of Phase 2 trials assessing the efficacy beyond 24 hours differentiate palonosetron from the currently marketed 5-HT3 antagonists indicated for CINV.

Having been studied in more than 1,000 subjects in Phase 1 and Phase 2 trials, palonosetron was well tolerated and had no unexpected or serious adverse reactions. The most frequent adverse events associated with palonosetron are similar to those seen with other 5-HT3 antagonists and include headache and constipation, which are generally mild to moderate.

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

HELSINN is the worldwide licensor of palonosetron and is conducting the Phase 3 trials of palonosetron that will form the basis for its registration in the United States. In April of this year, MGI PHARMA, an oncology-focused pharmaceutical company based in Minneapolis, and HELSINN signed an agreement granting MGI the exclusive U.S. and Canadian licensing and distribution rights to palonosetron. Once approved, palonosetron will compete in the CINV treatment market, which is rapidly approaching $1 billion in North Ame

Helsinn Healthcare Announce The Completion Of Patient Enrollment For First Palonosetron Phase 3 Pivotal Trial

Source	Press Release
Company	Helsinn Group, MGI Pharma
Tags	Phase III, Gastro-Intestinal
Date	October 03, 2001

Lugano, Switzerland -- October 3, 2001 -- Helsinn Healthcare SA announced the completion of patient enrollment for the first of the pivotal Phase 3 trials of palonosetron, a novel 5-HT3 antagonist. Palonosetron is a potent, highly selective 5-HT3 antagonist with an extended half-life, currently in Phase 3 development in the United States and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). HELSINN expects to complete patient enrollment for the remaining trials in the Phase 3 program near the end of 2001 and plans to submit a New Drug Application (NDA) in the U.S. and Europe in the first half of 2002.

The double-blinded, randomized Phase 3 clinical trial program aims to compare intravenous (IV) palonosetron to currently marketed 5-HT3 antagonists and is being conducted at medical centers across North America and Europe. It is expected that over 1,800 cancer patients receiving either highly- or moderately-emetogenic chemotherapy will be enrolled in the trials. Based on the extended half-life of palonosetron and the results of a Phase 2 trial, its efficacy 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.

Results of Phase 1 trials in healthy volunteers to assess the pharmacokinetic properties and safety of palonosetron were presented at this year's American Society of Clinical Oncologists (ASCO) meeting in May 2001. Palonosetron was found to have a plasma elimination half-life of 37 hours, which is at least three times longer than marketed agents in its class. This extended half-life of palonosetron and the results of Phase 2 trials assessing the efficacy beyond 24 hours differentiate palonosetron from the currently marketed 5-HT3 antagonists indicated for CINV.

Having been studied in more than 1,000 subjects in Phase 1 and Phase 2 trials, palonosetron was well tolerated and had no unexpected or serious adverse reactions. The most frequent adverse events associated with palonosetron are similar to those seen with other 5-HT3 antagonists and include headache and constipation, which are generally mild to moderate.

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

HELSINN is the worldwide licensor of palonosetron and is conducting the Phase 3 trials of palonosetron that will form the basis for its registration in the United States. In April of this year, MGI PHARMA, an oncology-focused pharmaceutical company based in Minneapolis, and HELSINN signed an agreement granting MGI the exclusive U.S. and Canadian licensing and distribution rights to palonosetron. Once approved, palonosetron will compete in the CINV treatment market, which is rapidly approaching $1 billion in North America.

HELSINN's negotiations with potential European licensing partners are ongoing, and out-licensing activities for remaining markets will commence next year.

<img width="1" height="1" alt="" src="http://logw309.xiti.com/hit.xiti?s=558237&s2=&p=&an=&ac=" >