

The Latest From MGI PHARMA on Irofulven and Palonosetron



Irofulven

June 28, 2001 MGI PHARMA, INC., announced that the U.S. Food and Drug Administration (FDA)

has granted Fast Track designation for the use of irofulven (MGI 114; HMAF), the Company's novel anti-cancer compound, in patients with gemcitabine-refractory pancreatic cancer.

In February 2001, the company initiated a pivotal Phase 3 trial, designed as a randomized, 300-patient, multi-center, international trial, in which irofulven is tested in advanced-stage pancreatic patients who have failed gemcitabine, the current standard-of-care therapy. Irofulven (also known as MGI 114, hydroxymethylacylfulvene, or HMAF) is the first product candidate being developed by MGI PHARMA from its family of proprietary anti-cancer compounds called acylfulvenes. Irofulven has demonstrated promising anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers. Side effects from irofulven are comparable to those seen with marketed chemotherapies and include bone marrow suppression (decreases in platelets or white blood cell counts), nausea, vomiting and fatigue. Overall survival is the primary endpoint of this Phase 3 trial, which could serve as the basis for regulatory approval of irofulven in the United States and Europe. With full enrollment targeted to occur in the third quarter of 2002, MGI may complete its NDA filing in 2003, depending upon the period of time patients remain in the trial.

Pancreatic cancer is a deadly disease that has few effective treatment options. The American Cancer Society estimates that more than 29,000 new cases of pancreatic cancer will be diagnosed this year in the United States, out of an estimated 170,000

new cases worldwide. The death rates for pancreatic cancer are virtually equal to the incidence rates.

Palonosetron

In October, 2001 MGI PHARMA, Inc. and HELSINN HEALTHCARE SA announced the completion of a 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 of 37 hours, currently in Phase 3 development in the United States and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). Patient enrollment for the remaining trials in the Phase 3 program is expected to be completed near the end of 2001. Submission of the New Drug Application (NDA) in the U.S. and Europe is expected in the first half of 2002.

Results of the 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 the marketed agents in its class. This extended half-life of palonosetron and the results of Phase 2 trails 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 and moderate.

Clinical Trials Opportunity with MGI for Irofulven

Members of Oncology Associates seeking additional information on either palonosetron or irofulven and / or the opportunity to become involved in irofulven Phase 3 pancreatic clinical trials should direct their clinical trials coordinator to call MGI PHARMA's Medical Communications Help Line at 1-800-562-5580.

MGI Pharma

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that address unmet patient needs. 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 www.mgipharma.com.