



Horizon Therapeutics Announces Two Pivotal HZT-501 Phase 3 Trials Meet Primary Endpoints

Treatment demonstrates significant reduction in the incidence of NSAID-induced upper GI ulcers in patients with mild-to-moderate pain

SKOKIE, Ill., December 2, 2008 - Horizon Therapeutics, Inc., a privately held biopharmaceutical company, today announced that two pivotal Phase 3 trials evaluating its lead investigational product candidate, HZT 501, met all primary endpoints. HZT 501, a novel, proprietary fixed-dose combination product containing ibuprofen and famotidine, demonstrated a statistically significant reduction in the incidence of non-steroidal anti-inflammatory drug (NSAID)-induced upper gastrointestinal (gastric and/or duodenal) ulcers in patients with mild-to-moderate pain when compared to ibuprofen alone.

NSAIDs such as ibuprofen are among the most widely used drugs in the world. However, NSAIDs are associated with a range of adverse side effects, which primarily affect the gastrointestinal (GI) tract. Up to 30 percent of patients taking NSAIDs experience gastrointestinal ulcers and a greater percent suffer from upper GI symptoms (i.e., dyspepsia, heartburn).

"NSAIDs, while highly effective in treating pain and inflammation, often lead to serious safety concerns, including significant gastrointestinal damage," said Timothy P. Walbert, president and chief executive officer, Horizon Therapeutics. "We are committed to bringing this much needed treatment to physicians and patients as quickly as possible and plan on submitting these strong HZT 501 Phase 3 results to U.S. and European regulatory authorities in 2009."

REDUCE-1 and REDUCE-2 Trial Design and Results

The **R**egistration **E**ndoscopic Study to **D**etermine **U**lcer Formation of HZT 501 **C**ompared to Ibuprofen: **E**fficacy and Safety Study (REDUCE 1 and REDUCE 2) were two randomized, double-blind, controlled trials that enrolled more than 1,500 patients in the United States. The primary efficacy objective of REDUCE-1 was to evaluate HZT 501 in reducing the proportion of patients who develop endoscopically diagnosed gastric ulcers during the 24-week treatment period, as compared to ibuprofen, in patients at risk for NSAID-induced ulcers. The primary objective of REDUCE-2 was to evaluate HZT 501 in reducing the proportion of patients who develop endoscopically diagnosed gastric and/or duodenal ulcers during the 24-week treatment period, as compared to ibuprofen, in patients at risk for NSAID-induced ulcers. The trials were conducted via a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA).

Patients, who had mild-to-moderate pain, including those with osteoarthritis, were randomly assigned, in approximately a 2:1 ratio, to receive HZT 501 (800 mg ibuprofen and 26.6 mg famotidine) or ibuprofen (800 mg) alone orally three times daily for a 24-week treatment period or until patients developed either an endoscopically diagnosed upper gastrointestinal ulcer and/or prohibitive toxicity. Patients received endoscopies at baseline and weeks 8, 16 and 24.

In REDUCE-1, 24-week treatment with HZT 501 resulted in a statistically significant reduction in gastric ulcers versus treatment with ibuprofen alone. In REDUCE-2, 24-week treatment with HZT 501 resulted in a statistically significant reduction in gastric and/or duodenal ulcers versus treatment with ibuprofen alone.

Treatment with both HZT-501 and ibuprofen alone were well tolerated in the studies. The majority of adverse events were mild to moderate in severity. There were no significant differences between the two treatment groups' adverse event or serious adverse event profiles.

"NSAIDs can cause significant gastrointestinal damage, including ulcers of the stomach and duodenum" said Loren Laine, MD, professor of medicine, Division of Gastrointestinal and Liver Diseases, Keck School of Medicine, University of Southern California. "These results indicate that HZT-501 can reduce the risk of ulcers, potentially improving the GI safety for patients treated with NSAIDs."

About HZT 501

HZT 501 is a novel, proprietary fixed-dose combination formulation of the world's most prescribed NSAID, ibuprofen, with a high dose of the most potent H2 antagonist, famotidine (Pepcid®), in a single pill. It is anticipated that HZT 501 will provide effective pain relief and reduce stomach acidity during the peak time of ulceration risk, thus reducing the risk of NSAID-induced ulcers. HZT 501 has completed Phase 3 trials and the Company expects to submit a new drug application (NDA) to the U.S. federal drug administration (FDA) and a marketing authorization application (MAA) to the European Medicines Agency (EMA) in the second half of 2009.

About the Arthritis and Pain Market

According to the Arthritis Foundation, arthritis affects 46 million people in United States and costs the U.S. economy \$128 billion annually. According to a study by the Centers for Disease Control and Prevention (CDC) for the National Arthritis Data Workgroup, due to the increasing aging population, arthritis is projected to increase by 40 percent in the next two decades. The CDC estimates that 67 million people will be affected by arthritis by 2030. Additionally, chronic pain affects an estimated 86 million American adults. NSAIDs are among the most widely used drugs in the world for the treatment of arthritis and pain and are a major cause of gastrointestinal complications, including ulcers. NSAIDs block enzymes and reduce prostaglandins throughout the body and as a consequence, ongoing inflammation, pain, and fever are reduced. Since the prostaglandins that protect the stomach are reduced, NSAIDs often cause ulcers in the stomach. NSAID-induced GI toxicity causes an estimated 16,500 deaths and more than 107,000 hospitalizations annually in the United States alone.

If deaths from the gastrointestinal effects of NSAIDs were tabulated separately in the National Vital Statistics reports, these effects would equate to the 15th most common cause of death in the United States. Studies have shown that less than 30 percent of high-risk NSAID patients are co-prescribed a gastro-protective agent in combination with their NSAID. In addition, patient adherence to a regimen of separate pain and GI protective medications has also been shown to be poor.

About Horizon Therapeutics

Horizon Therapeutics, Inc. is a late-stage biopharmaceutical company focused on the development and commercialization of therapies for the treatment of mild-to-moderate pain and arthritis. Horizon's clinical portfolio includes innovative combination therapies in early- and late-stage development that are designed to improve safety, efficacy and patient compliance. For more information about the company and its products, please visit www.horizontherapeutics.com.

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