



## **Horizon Therapeutics Completes Enrollment in Phase 3 Trials for Lead Product Candidate HZT-501**

**Over 1,500 U.S. patients enrolled in studies examining potential new 'GI-friendly' treatment for mild to moderate pain. Clinical results expected in second half of 2008**

**PALO ALTO, Calif., February 11, 2008** – Horizon Therapeutics, Inc., a privately held biopharmaceutical company, today announced that it is closing enrollment in its two phase 3 trials HZ-CA-301 and HZ-CA-303 for its lead product candidate HZT-501, an investigational prescription NSAID (non-steroidal anti-inflammatory drug) designed to be “GI-friendly”.

“We enrolled over fifteen hundred patients in less than a year, which was well ahead of our projections,” said George F. Tidmarsh, M.D., Ph.D., co-founder and chief executive officer of Horizon Therapeutics. “We look forward to receiving the complete set of clinical results and safety data to review this Fall.”

The Phase 3 program is comprised of two trials involving a total of 1,500 patients with mild-to-moderate pain, including patients with osteoarthritis. Horizon Protocol HZ-CA-301 and HZ-CA-303 are evaluating the efficacy and safety of HZT-501 with a primary endpoint of reduction in the risk of development of ibuprofen-associated upper gastrointestinal (gastric and/or duodenal) ulcers in patients who require the use of ibuprofen.

The clinical trials are multi-center, randomized, controlled, and blinded for up to 24 weeks of treatment, followed by a 4 week safety evaluation period. The studies are being conducted in the United States.

“The Horizon studies are among the largest endoscopic trials ever conducted regarding NSAID-induced gastrointestinal ulcers” said Loren Laine M.D., professor of medicine in the Division of Gastrointestinal and Liver Diseases, University of Southern California. “The results should provide precise estimates of the potential benefit of HZT-501 in decreasing NSAID associated ulcers.”

In addition, a phase 3 follow-on safety study HZ-CA-304 is underway. The trial is a multi-center, double blind trial that will enroll approximately 200 patients who have participated in the 301 or 303 phase 3 trials. Study participants will continue to receive the same study medication they received in the other trials which was either HZT-501 (ibuprofen 800 mg/famotidine 26.6 mg) or ibuprofen 800 mg. Study participants will receive medication for up to 28 weeks.

### **About the Pain Market**

HZT-501 targets the widespread medication void in the mild-to-moderate pain market left by COX-2 inhibitors that have either been taken off the market or are being prescribed less frequently due to elevated cardiovascular risk. From 2004 to 2006, the U.S. NSAID market grew over 20 percent to 73 million prescriptions. Over 26 million ibuprofen prescriptions are now written annually in the United States alone.

However, while commonly prescribed to treat pain, NSAIDs have been linked to serious gastrointestinal (GI) side effects in up to 25 percent of all chronic arthritis patients. NSAID-induced GI toxicity causes an estimated 16,000 deaths and more than 100,000 hospitalizations annually in the United States. Despite this, studies have shown that as low as 30% of high-risk patients are commonly co-prescribed a gastro-protective agent in combination with their NSAID. In addition, patient adherence to a regimen of separate GI protective and pain medications has also been shown to be poor.

### **About Horizon Therapeutics**

Horizon Therapeutics, Inc. is a late stage biopharmaceutical company focused on therapeutic treatments for mild-to-moderate pain management. The Company is building a novel portfolio of therapies through innovative combinations of approved pharmaceutical products that seek to improve safety, efficacy, and patient compliance. Its lead product candidate, HZT-501, entered Phase 3 trials in 2007. In addition to HZT-501, Horizon has a pipeline of follow-on pain combination products in earlier stages of development. For more information visit [www.horizontherapeutics.com](http://www.horizontherapeutics.com).

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