



Horizon Pharma Presents HZT-501 Long-Term Safety Data and LODOTRA® Phase 3 Data at the American College of Rheumatology Annual Meeting

NORTHBROOK, III. – November 9, 2010 – Horizon Pharma, Inc., a biopharmaceutical company developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases, today announced results from a long-term safety study of HZT-501, a novel single-tablet formulation of ibuprofen (800 mg) and high-dose famotidine (26.6 mg). The results, which were presented at the American College of Rheumatology (ACR) Annual Scientific Meeting, showed that long-term safety of HZT-501 was comparable to ibuprofen alone. The results also showed that HZT-501 was associated with a two-fold reduction in the incidence of dyspepsia compared to ibuprofen alone, although not statistically significant due to small sample size. In addition, safety and efficacy data from two Phase 3 trials of LODOTRA®, a proprietary programmed-release formulation of low-dose prednisone, were also presented.

HZT-501 Data Presented

Patients with mild to moderate pain who completed one of two large 24-week double-blind prospective trials (REDUCE-1 or REDUCE-2), which assessed efficacy, as measured by endoscopically diagnosed gastrointestinal ulcers, and safety of HZT-501 compared to ibuprofen alone were eligible for an additional 28 weeks of treatment (for a total of 52 weeks). In REDUCE-1 and REDUCE-2, HZT-501 demonstrated a statistically significant decrease of approximately 50 percent in upper GI ulcers compared to ibuprofen (800 mg) alone over 24 weeks. During the follow-on study, safety data was reviewed, including serious adverse events (SAEs), treatment-emergent adverse events (TEAEs), clinical laboratory assessments and physical exams. A total of 179 patients entered the follow-on study from REDUCE-1 and REDUCE-2 and maintained their previous treatment of either HZT-501 (n=132) or ibuprofen tablets (n=47). A total of 150 patients completed the follow-on study.

“The results support the long-term safety and improved GI tolerability of HZT-501, as demonstrated by a two-fold difference in the incidence of dyspepsia compared to ibuprofen alone,” said Michael Schiff, MD, Clinical Professor of Medicine at the University of Colorado School of Medicine, Rheumatology Division. “Long-term safety associated with the use of HZT-501, together with the significant decrease in NSAID-induced upper GI ulcers demonstrated in the REDUCE trials, show that HZT-501 may offer a potential new option for osteoarthritis, rheumatoid arthritis and pain patients.”

LODOTRA® (modified-release prednisone) Data Presented

Horizon also presented data from its two pivotal Phase 3 trials, CAPRA-2 (Circadian Administration of Prednisone in Rheumatoid Arthritis-2) and CAPRA-1 (Circadian Administration of Prednisone in Rheumatoid Arthritis-1), evaluating LODOTRA®, a proprietary modified-release formulation of low-dose prednisone, in patients with rheumatoid arthritis (RA). Results from the U.S.-based CAPRA-2 trial showed a statistically significant and clinically relevant higher response rate evaluated by ACR response criteria in patients treated with 5 mg of LODOTRA® compared to placebo, in addition to standard RA therapy, after 12 weeks of treatment. The LODOTRA® patients also had a significant reduction in the duration of certain markers of disease activity, compared to placebo.

Twelve-month safety data from the open-label, double-blind, placebo-controlled European registrational trial, CAPRA-1, demonstrated that the incidence of serious adverse events (SAEs) and adverse events (AEs) in all treatments was low and comparable between LODOTRA® and immediate-release prednisone. Results were comparable to the placebo arm, with more AEs related to RA signs and symptoms (arthralgia and RA flare) in the placebo arm than in the LODOTRA® arm.

About HZT-501

HZT-501 is a novel single tablet formulation containing a fixed-dose combination of ibuprofen, one of the most widely prescribed NSAIDs, and high-dose famotidine, a well-established GI agent used to treat dyspepsia, gastroesophageal reflux disease (GERD) and active ulcers and to reduce the risk of NSAID-induced upper GI ulcers. Ibuprofen has proven anti-inflammatory and analgesic properties, and famotidine reduces the stomach acid secretion that can cause upper GI ulcers. Both ibuprofen and famotidine have well-documented and excellent long-term safety profiles, and both products have been used for many years by millions of patients worldwide.

HZT-501 is currently under review by the U.S. FDA with a PDUFA goal date of January 21, 2011. The Company also plans to submit a marketing authorization application (MAA) for HZT-501 in the European Union through the Decentralized Procedure in the fourth quarter of 2010.

About LODOTRA®

LODOTRA® is a proprietary programmed-release formulation of low-dose prednisone and has received regulatory approval in

Europe for reduction in morning stiffness associated with rheumatoid arthritis (RA). Merck KGaA holds marketing rights to LODOTRA[®] in Germany and Austria and Mundipharma holds marketing rights to LODOTRA[®] for the rest of Europe.

Horizon has completed a Phase 3 trial for LODOTRA[®] in the United States for the treatment of the signs and symptoms of RA. The company anticipates submitting a New Drug Application (NDA) for the treatment of the signs and symptoms of RA to the U.S. FDA in the fourth quarter of 2010.

About the Arthritis, Pain and Inflammation Market

Some of the most common and debilitating chronic inflammation and pain-related diseases are osteoarthritis, or OA, rheumatoid arthritis or RA, and acute and chronic pain.

Arthritis is a large and growing public health problem in the United States and continues to be the most common cause of disability. According to the CDC, arthritis costs the U.S. economy nearly \$128 billion annually in medical care and indirect expenses, including lost wages and productivity. From 2007-2009, approximately one in five (49.9 million) adults age 18 or older in the United States had self-reported doctor-diagnosed and 21.1 million adults (42.4% of those with arthritis) had self-reported arthritis-attributable activity limitation (AAAL). The CDC estimates that 67 million people in the U.S. will be affected by arthritis by 2030. Additionally, chronic pain affects an estimated 86 million American adults.

NSAIDs are very effective at providing pain relief, including pain associated with arthritis; however there are significant upper GI complications that can result from the use of NSAIDs, including ulcers. NSAID-induced GI toxicity causes an estimated 16,500 deaths and more than 107,000 hospitalizations annually in the U.S. alone. Recently published data also indicates that physicians only co-prescribe GI protective agents to NSAID users 24 percent of the time, and studies show sub-optimal patient compliance with the prescribed GI co-therapy.

About Horizon Pharma

Horizon Pharma, Inc. is a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. For more information, please visit www.horizonpharma.com.

Forward Looking Statements

This press release contains forward-looking statements regarding the regulatory review of HZT-501, the potential for HZT-501 as a treatment to reduce the risk of developing NSAID-induced upper gastrointestinal ulcers in patients with mild to moderate pain and arthritis, and the arthritis and pain markets, as well as the U.S. regulatory review of LODOTRA and the potential of LODOTRA for the treatment of the signs and symptoms of RA. Actual results may differ materially from those in these forward-looking statements as a result of various factors, including, but not limited to, risks regarding regulatory review and approval of its product candidates, the company's ability to commercialize products successfully, and competition in the markets for HZT-501 and LODOTRA. For a further description of these and other risks facing the company, please see the risk factors described in the company's Registration Statement on Form S-1 that was originally filed with the United States Securities and Exchange Commission on August 3, 2010, and the amendments thereto, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to update or revise these statements, except as may be required by law.

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