



## **Horizon Pharma, Inc Provides Update on November 4, 2010 FDA Gastrointestinal Drugs Advisory Committee Meeting**

**NORTHBROOK, III.** – November 5, 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 that on November 4, 2010, the FDA Gastrointestinal (GI) Drugs Advisory Committee voted in favor that endoscopically diagnosed upper GI ulcers are an adequate primary endpoint for evaluating products intended to reduce the risk of NSAID-induced upper GI toxicity.

The FDA held a meeting of its GI Drugs Advisory Committee yesterday to discuss the adequacy of endoscopically documented upper GI ulcers as an outcome measure to evaluate drugs intended to prevent complications of NSAIDs. The committee voted eight to four with one abstention that for GI protective agents such as misoprostol, histamine-2 receptor antagonists and proton pump inhibitors; endoscopically documented NSAID-induced upper GI ulcers are an adequate primary endpoint to reduce the risk of NSAID-induced GI ulcers. This endpoint was the primary endpoint as established in the Company's December 2006 special protocol assessment (SPA) for the two pivotal Phase 3 clinical trials, REDUCE-1 and REDUCE-2, for HZT-501. The FDA will take the Committee's recommendation into consideration and will make the final determination in this matter.

### **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 the Arthritis, Pain and Inflammation Market**

Some of the most common and debilitating chronic inflammation and pain-related diseases are osteoarthritis, or OA and 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](http://www.horizonpharma.com).

### **Forward Looking Statements**

This press release contains forward-looking statements regarding the company's plans to submit marketing applications for HZT-501, 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. 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 the company's ability to submit marketing applications for HZT-501 in the timeframe it expects, regulatory review and approval of its product candidates, the company's ability to commercialize products successfully, and competition in the markets for HZT-501. 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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