Horizon Pharma Announces FDA Approval of DUEXIS® (ibuprofen/famotidine) for the Relief of the Signs and Symptoms of Rheumatoid Arthritis and Osteoarthritis and to Decrease the Risk of Developing Upper Gastrointestinal Ulcers

NORTHBROOK, Ill. – April 25, 2011 **–** Horizon Pharma, Inc., a biopharmaceutical company developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases, announced today that the U.S. Food and Drug Administration (FDA) has approved **DUEXIS®**, (ibuprofen/famotidine) a novel tablet formulation containing a fixed-dose combination of ibuprofen (800 mg) and famotidine (26.6 mg). The FDA approval was supported by data from the pivotal REDUCE-1 and REDUCE-2 studies, which showed patients taking DUEXIS experienced significantly fewer upper gastrointestinal ulcers compared to patients receiving ibuprofen alone.

"We look forward to providing DUEXIS to the many patients suffering from osteoarthritis and rheumatoid arthritis, as it provides a new treatment option for those who may be at risk for upper gastrointestinal ulcers stemming from chronic NSAID use," said Timothy P. Walbert, chairman, president and chief executive officer of Horizon Pharma. "The approval of DUEXIS is a transformative event for Horizon Pharma, representing our first U.S. approval. We would like to thank the patients and clinical investigators who participated in the pivotal REDUCE-1 and REDUCE-2 trials."

DUEXIS was studied in more than 1,500 patients with mild-to-moderate pain or arthritis. The primary endpoint of the REDUCE-1 study was the reduction in incidence of gastric ulcers during the six month treatment period. The primary endpoint of the REDUCE-2 study was the reduction in incidence of upper gastrointestinal (defined as gastric and/or duodenal) ulcers during the six month treatment period. In REDUCE-1, DUEXIS demonstrated a statistically significant reduction in the incidence of gastric ulcers versus treatment with ibuprofen alone (8.7% versus 17.6%). In REDUCE-2, DUEXIS demonstrated a statistically significant reduction in the incidence of upper gastrointestinal ulcers versus treatment with ibuprofen alone (10.5% versus 20.0%).

The most common adverse reactions (≥1% and greater than ibuprofen alone) were nausea, diarrhea, constipation, upper abdominal pain and headache. Overall, the discontinuation rate in the REDUCE-1 and REDUCE-2 studies due to adverse events for patients receiving DUEXIS and ibuprofen alone were similar.

"The clinical data showed that DUEXIS helped reduce the incidence of upper gastrointestinal ulcers, which should be welcome news for physicians and patients concerned about the gastrointestinal impact of NSAID use," said Michael Schiff, M.D., Clinical Professor of Medicine at the University of Colorado School of Medicine, Rheumatology Division. "In my view, DUEXIS will allow more people access to the benefits of ibuprofen, while reducing the significant GI risk associated with its use."

Important Safety Information

Cardiovascular and Gastrointestinal Risks

- **Ibuprofen, a component of DUEXIS, may increase the risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. Risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.**
- **DUEXIS is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.**
- **NSAIDs, including ibuprofen, a component of DUEXIS, increase the risk of serious gastrointestinal (GI) adverse reactions including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Reactions can occur at any time without warning symptoms. Elderly patients are at greater risk.**

DUEXIS should not be given to patients who have experienced asthma, urticaria, or allergic reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylaxis with NSAIDs have been reported in such patients. DUEXIS is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. DUEXIS is contraindicated in patients in late stages of pregnancy. DUEXIS should not be administered to patients with a history of hypersensitivity to other H_2-receptor antagonists. Cross sensitivity with other H_2-receptor antagonists has been observed.

When active and clinically significant bleeding from any source occurs in patients receiving DUEXIS, the treatment should be withdrawn.

NSAIDs, including ibuprofen, which is a component of DUEXIS tablets, can lead to onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events.

Fluid retention and edema have been observed in some patients taking NSAIDs. DUEXIS should be used with caution in patients with fluid retention or heart failure.

Reports suggest that ibuprofen, a component of DUEXIS, may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking DUEXIS concomitantly with ACE-inhibitors.

As with other NSAIDs, the concurrent use of aspirin and DUEXIS may increase the risk of adverse events

Long-term administration of NSAIDs, including ibuprofen, which is a component of DUEXIS tablets, has resulted in renal papillary necrosis and other renal injury.

If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur, DUEXIS should be discontinued.

Bleeding has been reported when ibuprofen and other NSAIDs have been administered to patients on coumarin-type anticoagulants, prescribers should be cautious when administering ibuprofen to patients on anticoagulants.

Please see Full Prescribing Information for DUEXIS at www.DUEXIS.com**.**

About DUEXIS®

DUEXIS is a novel fixed-dose tablet combining the one of the world's most prescribed NSAIDs, ibuprofen, with the most potent H_2-antagonist, famotidine (800 mg/26.6 mg), in a single pill. Ibuprofen has proven anti-inflammatory and analgesic properties, whereas famotidine reduces the stomach acid secretion that can cause gastric and duodenal ulceration. By combining ibuprofen and famotidine into a single product, it is believed that ibuprofen's gastrointestinal safety profile will be improved without altering its ability to reduce pain and inflammation.

DUEXIS is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months.

DUEXIS will be available to U.S. physicians in the second half of this year. For more information, including full prescribing information, please visit www.DUEXIS.com.

Horizon submitted a Marketing Authorization Application (MAA) to the European Medicines Association (EMA) for DUEXIS in October 2010.

About the Arthritis Market
Osteoarthritis (OA) is a degenerative joint disease caused by the breakdown and eventual loss of the cartilage of one or more joints. It is the most common form of arthritis and the most common cause of chronic pain, affecting more than 150 million individuals worldwide and 27 million Americans. OA is caused by various factors, including older age, being overweight, joint injury or stress, heredity and muscle weakness. OA commonly affects the hands, spine or large weight-bearing joints, such as the hips and knees.

Rheumatoid arthritis (RA) is a chronic disease, mainly characterized by inflammation of the lining, or synovium, of the joints. It can lead to long-term joint damage, resulting in chronic pain, loss of function and disability.

According to the Arthritis Foundation, a leading non-profit arthritis research advocacy group, arthritis affects nearly 46 million people in the U.S. With the aging of the U.S. population, the prevalence of arthritis is expected to rise by approximately 40% by 2030, impacting 67 million people in the U.S.

NSAIDs are very effective at providing pain relief associated with OA and RA; however, there are significant upper GI-associated adverse events which can result from such treatments. Significant GI side effects, including serious ulcers, afflict up to approximately 25 percent of all chronic arthritis patients treated with NSAIDs for three months, and OA and RA patients are two to five times more likely than the general population to be hospitalized for NSAID-related GI complications. It is estimated that NSAID-induced GI toxicity causes over 16,500 related deaths in OA and RA patients alone and over 107,000 hospitalizations for serious GI complications each year in the U.S.

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 potential for DUEXIS to treat osteoarthritis and rheumatoid arthritis and to reduce the risk of developing ibuprofen-induced gastrointestinal ulcers, the ability of DUEXIS to allow greater patient access to ibuprofen, and the timing of DUEXIS's availability to physicians. 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 commercialize products successfully, whether physicians will prescribe and patients will use DUEXIS, once available, and competition in the market for DUEXIS. 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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