



Horizon Pharma Announces Launch of DUEXIS(R) (Ibuprofen/Famotidine) 800 mg/26.6 mg in the United States

DEERFIELD, IL -- (MARKET WIRE) -- 12/05/11 -- Horizon Pharma, Inc. (NASDAQ: HZNP) today announced that DUEXIS® (ibuprofen/famotidine), a proprietary single-tablet combination of ibuprofen (800 mg) and famotidine (26.6 mg), is now available to U.S. physicians for the relief of signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA) and to decrease the risk of developing upper gastrointestinal (GI) ulcers, which in Phase 3 clinical trials were 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 ulcers. Controlled trials do not extend beyond six months.

"With the launch of DUEXIS, patients who suffer from the pain and inflammation of rheumatoid arthritis and osteoarthritis, and who also may be at risk for developing upper gastrointestinal ulcers from NSAID use, have a new and potentially important treatment option," said Timothy P. Walbert, chairman, president and chief executive officer of Horizon Pharma. "Beginning today, our sales representatives are introducing DUEXIS to physicians across the United States. We expect broad managed care access to DUEXIS and plan to ensure it is available to patients at a reasonable out of pocket cost."

In April, the U.S. Food and Drug Administration (FDA) approved Horizon's new drug application (NDA) for DUEXIS. The NDA was supported by data from the pivotal REDUCE-1 and REDUCE-2 clinical studies that enrolled more than 1,500 patients. In REDUCE-1, DUEXIS demonstrated a statistically significant reduction in the incidence of non-steroidal anti-inflammatory drug (NSAID)-induced 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 ($\geq 1\%$ 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.

According to the Arthritis Foundation, arthritis affects nearly 46 million people in the United States. 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 United States.

NSAIDs are 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. DUEXIS reduced the risk of ibuprofen-induced upper GI ulcers by approximately 50% in REDUCE-1 and REDUCE-2. Patients with OA and RA on NSAIDs are at increased risk for upper GI ulcers.

About DUEXIS

DUEXIS, a proprietary single-tablet combination of the NSAID ibuprofen and the histamine H₂-receptor antagonist famotidine, 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.

Important safety information

Risk of Serious Cardiovascular and Gastrointestinal Events

See full Prescribing Information for complete boxed warning

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 has been reported in such patients. DUEXIS is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft surgery. DUEXIS is contraindicated in patients in late stages of pregnancy as premature closure of the ductus arteriosus in the fetus may occur. DUEXIS should not be administered to patients with a history of hypersensitivity to other H2-receptor antagonists. Cross sensitivity with other H2-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 preexisting hypertension, either of which may contribute to the increased incidence of cardiovascular events. Monitor blood pressure closely during treatment with DUEXIS.

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.

Long-term administration of NSAIDs, including ibuprofen, which is a component of DUEXIS tablets, has resulted in renal papillary necrosis and other renal injury. Use DUEXIS with caution in patients at risk (e.g., the elderly; those with renal impairment, heart failure or liver impairment and those taking diuretics or ACE inhibitors).

Hepatic injury ranging from transaminase elevations to liver failure can occur. If clinical signs and symptoms consistent with liver disease develop, if abnormal liver tests persist or worsen or if systemic manifestations occur, DUEXIS should be discontinued immediately.

Anaphylaxis may occur in patients with the aspirin triad or in patients without prior exposure to DUEXIS. If an anaphylactoid reaction occurs, DUEXIS should be discontinued immediately.

Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, which can be fatal, can occur. Discontinue DUEXIS if rash or other signs of local skin reaction occur.

Nursing mothers should use DUEXIS with caution, as it is not known if ibuprofen is excreted in human milk and famotidine is excreted in human milk.

The most common adverse reactions ($\geq 1\%$ and greater than ibuprofen alone) were nausea, diarrhea, constipation, upper abdominal pain and headache.

For further information on DUEXIS, please see full Prescribing Information at www.DUEXIS.com.

About Osteoarthritis

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.

About Rheumatoid Arthritis

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.

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, including statements regarding the potential for DUEXIS to treat osteoarthritis and rheumatoid arthritis and to reduce the risk of developing ibuprofen-induced gastrointestinal ulcers and the launch of DUEXIS, the anticipated level of managed care access to DUEXIS, and the future prevalence of arthritis in the United States. These forward-looking statements are based on management's expectations and assumptions as of the date of this

press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, risks regarding the company's ability to commercialize DUEXIS successfully, whether physicians will prescribe and patients will use DUEXIS, whether reimbursement will be available for DUEXIS, competition in the market for DUEXIS, future means of preventing and treating arthritis and Horizon's ability to successfully execute its sales and marketing plans. For a further description of these and other risks facing Horizon, please see the risk factors described in Horizon's filings with the United States Securities and Exchange Commission, 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 Horizon undertakes no obligation to update or revise these statements, except as may be required by law.

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