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Horizon Pharma to Receive Approval of DUEXIS(R) From the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)

DEERFIELD, IL -- (Marketwire) -- 12/21/12 -- Horizon Pharma, Inc. (NASDAQ: HZNP) today announced that the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA), based on the favorable recommendation of their Commission on Human Medicines (CHM), will grant a Marketing Authorization (MA) for DUEXIS® (ibuprofen/famotidine), pending review of updated licensing documents which the Company has provided to the MHRA. The MA of DUEXIS is for the treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS) and to decrease the risk of developing upper gastrointestinal ulcers. DUEXIS is approved and available in the United States.

The positive decision from the MHRA is the final regulatory step for DUEXIS to be marketed in the UK. The Company anticipates that granting of the UK Marketing Authorization for DUEXIS will facilitate progressive approval of the product in additional EU Member States through the Mutual Recognition Procedure under EU pharmaceutical law. Under this procedure, the UK will act as the Reference Member State.

"The approval of DUEXIS in the UK is the first step in gaining broad approval across Europe," said Timothy P. Walbert, chairman, president and chief executive officer, Horizon Pharma. "We will be seeking a potential commercial partner in the UK and other EU Member States where DUEXIS may be approved. Our primary focus remains in the U.S. where we believe the vast majority of the global NSAID market opportunity exists."

Horizon originally submitted its Marketing Authorization Application (MAA) in October 2010 to the MHRA through the Decentralized Procedure, with the UK as the Reference Member State. The Company subsequently modified the MAA submission in February 2012 to include the facility that serves as the primary manufacturing site for DUEXIS.

About DUEXIS
DUEXIS, a proprietary single-tablet fixed dose combination of the NSAID ibuprofen and the histamine H2-receptor antagonist famotidine, is indicated in the U.S. 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. For more information, please visit www.DUEXIS.com.

Important safety information

Risk of Serious Cardiovascular and Gastrointestinal Events

See full Prescribing Information for complete boxed warning (according to the U.S. FDA approval)

Ibuprofen, a component of DUEXIS, may increase the risk of serious cardiovascular 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 surgery.

Nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen, a component of DUEXIS, increase the risk of serious gastrointestinal 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 (≥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 an estimated 27 million individuals in the U.S. Worldwide, an estimated 9.6% of men and 18% of women 60 years of age and older have symptomatic OA.

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 that causes pain, stiffness and swelling, primarily in the joints. RA affects approximately 1.8 million people in the U.S. and is not associated with factors such as aging. Worldwide, RA has an estimated prevalence of 0.3 to 1% of the total adult population.

RA occurs when the body's immune system malfunctions, attacking healthy tissue and causing inflammation, which leads to pain and swelling in the joints and may eventually cause permanent joint damage and painful disability. The primary symptoms of RA include progressive immobility and pain, especially in the morning, with long-term sufferers experiencing continual joint destruction for the remainder of their lives.

About Ankylosing Spondylitis
Ankylosing spondylitis (AS) is a chronic, progressive, connective tissue disorder that is characterized by inflammation of the joints of the spine (vertebral joints), hipbones, and sacrum (sacroiliac joints). Symptoms of AS are similar to those of RA, including pain, swelling and stiffness in the affected joints. The disorder differs from RA in that spondylitis primarily affects the spine, forming bony outgrowths (syndesmophytes) between the vertebrae, which may fuse vertebrae and lead to total spinal immobility (ankylosis). The worldwide annual incidence of AS is estimated to be up to 7.3 per 100,000 individuals.

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 expected grant of a Marketing Authorization for DUEXIS, potential approval of DUEXIS in additional EU Member States and the Company's plans to find commercial partners for DUEXIS in the UK or other EU Member States where DUEXIS may be approved. 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, including, but not limited to, risks regarding the Company's ability to gain final marketing approval for DUEXIS in the UK or other EU Member States and the Company's ability to commercialize products successfully or to find partners to help it commercialize its products in the EU. 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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