



## Horizon Pharma Receives U.S. Patent Allowance for DUEXIS(R) in the United States

NORTHBROOK, IL -- (MARKET WIRE) -- 10/13/11 -- Horizon Pharma, Inc. (NASDAQ: HZNP) announced that it has received a Notice of Allowance from the United States Patent and Trademark Office for Application Serial No. 12/324808 entitled "Stable Compositions of Famotidine and Ibuprofen" with claims that cover DUEXIS®.

The Notice of Allowance concludes the substantive examination of this patent application and will result in the issuance of a U.S. patent after administrative processes are completed. The patent scheduled to issue from this application will expire in 2028.

"This recent notice of allowance, along with our previously announced 'method of use' patent allowance, represents an important expansion of the patent estate for DUEXIS," said Timothy P. Walbert, chairman, president and chief executive officer, Horizon Pharma.

On April 23, 2011, the U.S. Food and Drug Administration approved DUEXIS (ibuprofen/famotidine) for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers from ibuprofen. Studies with DUEXIS enrolled more than 1,500 patients with mild-to-moderate pain or arthritis.

### *About DUEXIS*

DUEXIS, a 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 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 ( $\geq 1\%$  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](http://www.DUEXIS.com).

#### *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, including statements regarding the issuance of a patent based on the notice of allowance from the U.S. Patent and Trademark Office and the launch of DUEXIS. 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 whether the administrative processes required for the issuance of a patent as indicated in the notice of allowance will be completed in a timely matter or at all, whether the patent, if issued as indicated in the notice of allowance, will provide sufficient protection and market exclusivity for DUEXIS, whether any patent issued to Horizon may be challenged, invalidated, infringed or circumvented by third parties, Horizon's ability to successfully recruit and retain sales and marketing personnel, and potential delays in commercially launching DUEXIS in the U.S. due to regulatory, manufacturing or operational difficulties, or otherwise. 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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