



Horizon Pharma, Inc. Announces Phase 3 Study of LODOTRA[®] Demonstrates 12-Month Sustained Efficacy in Rheumatoid Arthritis

- Results published in July Issue of *Annals of Rheumatic Diseases* -

NORTHBROOK, Ill. – June 12, 2010 – Horizon Pharma, Inc., announced today that results from the extended open label portion of the CAPRA-1 Phase 3 European registration study of the company's most advanced product, LODOTRA[®], a programmed-release, low-dose prednisone tablet, showed sustained improvement in morning stiffness in patients with Rheumatoid Arthritis (RA) over a 12 month period. The results were published in the July issue of the *Annals of Rheumatic Diseases* and were also recently presented at the European League Against Rheumatism (EULAR) Annual Congress.

"Symptoms of RA in patients, such as morning stiffness show pronounced circadian rhythms with the highest severity in the early morning," said Frank Buttgereit, M.D., senior consultant and deputy head of the Department of Rheumatology and Clinical Immunology, Charité Hospital, Berlin and lead author of the study. "The results from the open label portion of the CAPRA-1 study showed that the efficacy of glucocorticoid therapy can be sustained by targeting the drug release to the circadian rhythm of the underlying inflammation and resulting symptoms."

The CAPRA-1 (**C**ircadian **A**dministration of **P**rednisone in **R**heumatoid **A**rthritis-1) Phase 3 study of LODOTRA evaluated 288 patients with active RA in a three-month, double-blind study. Patients received either immediate release (IR) prednisone in the morning or LODOTRA (modified-release prednisone) in the evening. Following the double-blind portion of the study, 249 patients continued on to an open label portion for up to nine additional months, when all patients received only an evening dose of LODOTRA. Variables assessed included: reduction in the duration of morning stiffness (MS) of the joints, disease activity scores (DAS 28), a measurement of pain and swelling in 28 joints typically impacted by RA; American College of Rheumatology (ACR) 20 response criteria, which measures the percentage of patients that show a 20 percent improvement in a composite assessment of tender and swollen joint counts along with other measures of RA; plasma levels of interleukin-6 (IL-6). Clinical safety was also assessed.

Following six months of treatment in the open label portion of the study, morning stiffness was reduced in those who were in the IR prednisone group during the double-blind portion, by 54 percent compared to 56 percent in those taking LODOTRA in both portions of the study. At the end of 12 month period, those originally taking IR prednisone demonstrated a 45 percent reduction in morning stiffness compared to 55 percent for those taking LODOTRA in both portions of the study. DAS28 score was reduced from 5.8 at baseline to 4.8 for those taking LODOTRA and to 4.9 for the former IR prednisone group.

Of patients who completed a total of 12 months in the study (n=219), 37 percent achieved improvement in the ACR20 criteria; an improvement considered encouraging to researchers due to many patients' long-term glucocorticoid use prior to treatment and longstanding disease, which may have caused irreversible damage of synovium, cartilage and bone. IL-6 plasma levels were almost 50 percent less in the LODOTRA-treated patients compared to the IR prednisone-treated patients after both three and 12 months of treatment.

Adverse events were observed in 51 percent of the patients in the study. The most frequent events were RA-related symptoms (14.5 percent), upper respiratory tract infections (2.8 percent), back pain (2.8 percent) and weight increase (2.8 percent). Adverse events indicative of aggravated hypothalamic-pituitary-adrenal axis suppression were not observed. Adverse events rated as being possibly related to study medication were upper abdominal pain (1.2 percent), gastritis (1.6 percent) and weight increase (2.4 percent). A total of 12 patients (4.8 percent) withdrew from the study due to an adverse event.

"The results of this study suggest that low-dose modified-release LODOTRA may offer significant benefits over IR prednisone for the treatment of RA, and those benefits are maintained up to 12 months," said Jeffrey W. Sherman, M.D., executive vice president, development, regulatory affairs and chief medical officer, Horizon Pharma. "For RA patients struggling with the debilitating impact of morning stiffness, this study provides continued evidence that a potential treatment option may be emerging."



About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, progressive and disabling autoimmune disorder in which the immune system attacks the joints and other tissues of the body, causing tissue damage including erosion and destruction of the joint surface, as well as inflammation and joint pain. Approximately 1.7 million patients are diagnosed and treated in the in the United States, with an equal number estimated in Europe.

The 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 life. Morning stiffness of the joints is a hallmark of RA. Morning stiffness, with duration of at least one hour, has been adopted as a diagnostic criterion for the definition of RA by the American College of Rheumatology (ACR). Inflammation, soft tissue swelling, and the involvement of multiple joints (in particular the small joints in the hands and feet) are also common signs and symptoms that distinguish rheumatoid and other inflammatory arthritis.

Recent research conducted by Ipsos MORI market research involving people with RA and physicians from 11 European countries found that nearly two thirds (60 percent) of people with RA say that pain and stiffness in the morning controls their lives. Additionally, nearly three quarters (74 percent) of people with pain and stiffness in the morning as a result of their RA say that they are either unemployed, retired early or are on sick leave as a result of RA and more than half (58 percent) say they are frustrated emotionally because they find it difficult to do everyday tasks.

About LODOTRA

LODOTRA, a programmed-release, low-dose prednisone tablet, first launched in Germany in April 2009 and currently marketed for the reduction in morning stiffness associated with RA. A European Phase 3 trial of LODOTRA RA was completed in 2006 and then the regulatory application was submitted to 15 Member States of the European Union using the Decentralized Procedure with Germany as Reference Member State. The procedure was completed in December 2008, resulting in the recommendation to grant an approval of LODOTRA for the treatment of RA and associated morning stiffness in the Reference Member State and the other 14 Concerned Member States, namely Austria, Belgium, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, and the United Kingdom.

Merck KGaA holds marketing rights to LODOTRA in Germany and Austria and Mundipharma holds marketing rights to LODOTRA for the rest of Europe.

The company has completed a Phase 3 trial for LODOTRA in the United States for the treatment of the signs and symptoms of RA. The company anticipates submitting a New Drug Application (NDA) for LODOTRA for the treatment of the signs and symptoms of RA to the U.S. Food and Drug Administration in the second half of 2010.

LODOTRA is also being investigated for the treatment of severe nocturnal asthma and polymyalgia rheumatica (PMR).

About Horizon Pharma

Horizon Pharma, Inc. is a late-stage biopharmaceutical company focused on the development and commercialization of innovative medicines for pain-related diseases and chronic inflammation. Horizon's product portfolio includes innovative therapies in early- and late-stage development that are designed to improve the efficacy, safety and quality of life for patients with chronic pain and inflammation. Horizon's most advanced product is LODOTRA, a programmed-release low-dose prednisone for the treatment of the signs and symptoms of rheumatoid arthritis (RA), which has received a recommendation for granting of a national marketing authorization in certain Member States of the European Union. LODOTRA is already launched in Germany. The company's lead development stage product is HZT-501, a novel, proprietary fixed-dose tablet combining one of the most prescribed NSAIDs in the world, ibuprofen, with a high dose of the most potent H₂ antagonist, famotidine, in a single pill. In two Phase 3 clinical studies (REDUCE-1 and REDUCE-2), HZT-501 was shown to significantly reduce the incidence of NSAID-induced upper gastrointestinal (GI) ulcers in patients with mild-to-moderate pain and arthritis.

For more information about the company and its products, please visit www.horizonpharma.com.



Forward Looking Statements

This press release includes forward-looking statements that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, but not limited to, any statements regarding the future of any product or product candidate, including the potential anti-inflammatory properties of LODOTRA, including the potential for LODOTRA for the treatment of severe nocturnal asthma and timing of the submission of regulatory filings for approval of such products or product candidates and the timing of any regulatory approval; and any statements of the plans, strategies and objectives of management for future operations of the company. Such statements are only predictions, and actual events or results may differ materially from those projected in such forward-looking statements. Factors that could cause or contribute to the differences include, but are not limited to, the inherent risks of product development and approval, clinical outcomes, including the possibility that results in early stage trials may not be replicated in later, larger clinical trials, regulatory risks, risks related to proprietary rights, market acceptance and competition and risks associated with the company's ability to obtain additional capital to support its planned operation.

Contacts

Robert J. De Vaere
Executive Vice President and Chief Financial Officer
760-436-4010
bdevaere@horizonpharma.com

Molly Rabinovitz
WCG
312-646-6294
mrabinovitz@wcgworld.com