



Horizon Pharma, Inc. Announces Results of Phase 3 Study of LODOTRA® Demonstrate 12-Month Sustained Efficacy and Safety in Rheumatoid Arthritis

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

NORTHBROOK, III. – July 23, 2010 – Horizon Pharma, Inc. announced today the results from the extended open label portion of The Circadian Administration of Prednisone in Rheumatoid Arthritis-1 (CAPRA-1) Phase 3 European registration study of LODOTRA®, a programmed release formulation of low-dose prednisone, which showed sustained improvement in reducing the duration of 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 Buttgerit, 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 synchronizing the drug release with the circadian rhythm of the underlying inflammation and resulting symptoms.”

The CAPRA-1 study of LODOTRA® evaluated 288 patients with active RA in a 12-week, randomized, double-blind, placebo-controlled trial comparing bedtime administration of LODOTRA® with morning administration of immediate release (IR) prednisone at the same individual dose (an average dose of 6.7 mg). Following the double-blind portion of the study, 249 patients continued on to an open label extension study for up to nine additional months, during which all patients received only an evening dose of LODOTRA®. Variables assessed included, among other things: (i) reduction in the duration of morning stiffness (MS) of the joints; (ii) disease activity scores (DAS 28), a measurement of pain and swelling in 28 joints typically impacted by RA; (iii) American College of Rheumatology (ACR) 20 response rate, which measures the percentage of patients who have achieved a 20 percent improvement in tender and swollen joint counts as well as a 20 percent improvement in three of five other criteria of disease activity; and (iv) plasma levels of interleukin-6 (IL-6), a pro-inflammatory cytokine.

Following six months of treatment in the open label portion of the study, morning stiffness was reduced in those patients who were in the IR prednisone group during the double-blind portion by 54 percent compared to 56 percent for patients taking LODOTRA® in both portions of the study. At 12 months, the mean relative reduction in morning stiffness reached 55 percent in patients treated with LODOTRA® who continued treatment from the double-blind phase compared to 45 percent in the patient group who had switched from IR prednisone to LODOTRA®.

Of patients who completed a total of 12 months in the study (n=219), 37 percent achieved improvement in the ACR20 criteria. DAS 28 score was reduced from the mean 5.8 at baseline to 4.8 for those taking LODOTRA® and to 4.9 for the former IR prednisone group. IL-6 plasma levels were approximately 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 enrolled in the open label portion of the study. The most commonly reported treatment-emergent adverse events were a flare in 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, typical of high dose prednisone administration, 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 programmed-release LODOTRA® may offer significant benefits over IR prednisone for the treatment of RA, and those benefits are maintained for up to 12 months,” said Jeffrey W. Sherman, M.D., executive vice president, development, regulatory affairs and chief medical officer of Horizon Pharma. “For RA patients struggling with the debilitating impact of morning stiffness, we believe this study provides continued evidence that a better treatment alternative is emerging.”

About Rheumatoid Arthritis

RA is a chronic disease that occurs when the body's 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. It is estimated that between 3-4 million individuals in the U.S. and Europe are affected by RA.

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. Morning stiffness of the joints is a hallmark of RA. Morning stiffness, with a duration of at least one hour, has been adopted as a diagnostic criterion for the definition of RA by the 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 formulation of low-dose prednisone, was approved in Europe in March 2009 and has been initially launched in several European countries. LODOTRA[®] is currently marketed in Germany, Belgium, Denmark, Norway, and Finland, and the company's partner Mundipharma International is currently in the process of obtaining pricing and reimbursement approval for LODOTRA[®] in Austria, France, Italy, Luxembourg, Portugal, Spain, Sweden, and the United Kingdom.

Merck Serono GmbH holds marketing rights to LODOTRA[®] in Germany and Austria and Mundipharma International holds marketing rights to LODOTRA[®] for the rest of Europe.

The company has completed a Phase 3 trial for LODOTRA[®] in the United States (U.S.) 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 (FDA) in the fourth quarter of 2010.

LODOTRA[®] is also being investigated for the treatment of severe nocturnal asthma and polymyalgia rheumatica.

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. Horizon has two lead product candidates, HZT-501 and LODOTRA[®], which have both successfully completed multiple Phase 3 clinical trials. Horizon submitted an NDA for HZT-501, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and high-dose famotidine in a single pill, to the U.S. FDA in March 2010. In two Phase 3 clinical studies (REDUCE-1 and REDUCE-2), HZT-501 demonstrated a significant reduction in the incidence of upper gastrointestinal ulcers in patients with chronic pain or arthritis when treated with HZT-501 versus ibuprofen alone. LODOTRA[®], a programmed release formulation of low-dose prednisone, received regulatory approval in Europe in March 2009 for the reduction of morning stiffness associated with RA.

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 potential development and commercialization of LODOTRA[®] and HZT-501 and the efficacy and commercial and therapeutic potential of these product candidates, including the potential for LODOTRA[®] for the treatment of signs and symptoms of RA and the anticipated timing of the submission of an NDA for LODOTRA[®] and the potential for HZT-501 to reduce the incidence of upper gastrointestinal ulcers and the timing of approval of its NDA; 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 FDA may not agree with the company's interpretation of efficacy and safety results; LODOTRA[®] and HZT-501 may not receive regulatory approval on a timely basis or at all; the overall inherent risks of product development and approval, clinical outcomes, regulatory risks, risks related to proprietary rights, risks relating to obtaining price and cost reimbursement for marketed drugs, market acceptance and competition and risks associated with the company's ability to obtain additional capital to support its planned operations.

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