



Horizon Pharma, Inc. Presents Results of Phase 3 Studies of LODOTRA® Demonstrating Statistically Significant Improvement in Response in Rheumatoid Arthritis Patients

- LODOTRA® Demonstrates Sustained Efficacy and Safety in Rheumatoid Arthritis Patients for up to 12-months-

NORTHBROOK, III. – June 16, 2010 – Horizon Pharma, Inc., announced today that data from the Phase 3 U.S. registration study of LODOTRA, a circadian cytokine modulator and novel modified-release, low-dose prednisone tablet, showed a statistically significant improvement in American College of Rheumatology (ACR) response criteria in patients with rheumatoid arthritis (RA). These data, along with 12-month efficacy data from the company's Phase 3 European registration study, were presented at the 11th Annual Congress of the European League Against Rheumatism (EULAR) in Rome, Italy.

“Conditions like rheumatoid arthritis follow a very distinct circadian rhythm, in which symptoms are more severe at a specific time of day. In the case of RA, many patients feel stiff when they wake up and it has the potential to negatively impact their quality of life,” said Frank Buttgereit, M.D., senior consultant and deputy head of the Department of Rheumatology and Clinical Immunology, Charité Hospital, Berlin. “The results from this second, Phase 3 study demonstrate that compared to placebo, LODOTRA shows clinically and statistically higher response in reducing symptoms, such as tender and swollen joint counts and morning stiffness associated with RA, which may provide some needed relief for these patients when their symptoms may be at their worst.”

CAPRA-2 Results Demonstrate Statistically Significant Efficacy Versus Placebo

The 350 patient CAPRA-2 (Circadian Administration of Prednisone in Rheumatoid Arthritis-2) U.S. registration study was a 12-week, double blind, placebo-controlled trial evaluating LODOTRA compared to placebo in patients with active RA who were receiving ongoing disease-modifying anti-rheumatic drug (DMARD) therapy. The primary endpoint of the study was ACR 20 response rate, which signifies a 20 percent improvement in tender and swollen joint counts, as well as other criteria, at week 12. The secondary endpoint was relative reduction of morning stiffness associated with RA at week 12.

ACR 20 responses were statistically significant for patients treated with LODOTRA (48.5 percent) compared to patients treated with placebo (28.6 percent, $p=0.0002$). In addition, ACR 50 response, which signifies a 50 percent improvement, was also statistically significant for patients treated with LODOTRA (22.7 percent) compared to patients treated with placebo (9.2 percent, $p=0.0027$). While not statistically significant, and the study was not sized for this assessment, an improvement in ACR 70 response, which signifies a 70 percent improvement, was also demonstrated in patients treated with LODOTRA (7.0 percent) compared to patients treated with placebo (2.5 percent, $p=0.0955$). The relative reduction in morning stiffness compared to baseline (134 minutes) was -56.5 percent for LODOTRA patients and -33.3 percent in placebo patients at week 12, which was also statistically significant ($p=0.0008$).

In this study, the most commonly reported treatment-emergent adverse events reported with LODOTRA were arthralgia or joint pain (10.4 percent for LODOTRA compared to 20.2 percent for placebo), RA flare (6.5 percent for LODOTRA compared to 9.2 for placebo), nasopharyngitis (4.8 percent for LODOTRA compared to 3.4 percent for placebo) and headache (3.9 percent for LODOTRA compared to 4.2 percent for placebo).

Sustained Efficacy Demonstrated in European CAPRA-1 Study

Twelve-month follow-up data from the open-label, double-blind, placebo-controlled, CAPRA-1 (Circadian Administration of Prednisone in Rheumatoid Arthritis-1) European registration study was also presented today during the EULAR Congress. The trial evaluated 288 patients with active RA randomized to receive an evening dose of approximately 6 mg of LODOTRA or a morning dose of approximately 6 mg of immediate-release (IR) prednisone. Of the 288 patients enrolled in the initial three-month CAPRA-1 trial, 249 continued on to an open label study for up to nine additional months, during which time all patients received an average evening dose of approximately 6.8 mg of LODOTRA.

At the conclusion of the three-month, double-blind phase, patients treated with LODOTRA showed a statistically significant reduction in morning stiffness duration compared to those in the IR prednisone treatment group (22.7 percent compared to 0.4 percent, respectively, mean relative change to baseline; $p=0.045$).

In the open-label phase, at 12 months, the mean relative reduction in morning stiffness reached 55 percent in LODOTRA patients who continued on the drug from the double-blind phase compared to 45 percent in the patient group who had switched from IR prednisone to LODOTRA. Both groups of patients achieved a clinically relevant reduction in the Disease Activity Score (DAS) 28 score, a measurement of pain and swelling in 28 joints typically impacted by RA. At 12 months, both the LODOTRA

group and the IR prednisone group who had subsequently received LODOTRA also showed a reduction in pain intensity by 11 and 13 mm, respectively on the 100mm-Visual Analog Scale (VAS), a tool used to measure the amount of pain a patient feels. In both groups, the median reduction in IL-6 levels was about 50 percent. ACR 20 response at the end of the 12 month study period was achieved by 37.5 percent and 37.4 percent of LODOTRA patients and IR prednisone patients who had switched to LODOTRA, respectively.

In the double-blind phase of the study, the most commonly reported treatment-emergent adverse events were: RA flare (7.6 percent for LODOTRA compared to 9.0 percent for IR prednisone), abdominal pain (3.5 percent for LODOTRA compared to 5.6 percent for IR prednisone), nasopharyngitis (2.8 percent for LODOTRA compared 5.6 percent for IR prednisone), headache (4.2 percent for LODOTRA, 2.8 percent for IR prednisone) and flushing (2.8 percent for LODOTRA compared to 4.2 percent for IR prednisone). In the open label phase, the most common adverse events reported were RA flare, flushing, upper respiratory tract infections, weight gain and back pain.

“The CAPRA-2 findings, along with the positive 12-month data from CAPRA-1, demonstrate that LODOTRA may be an important new option for patients who suffer from the symptoms related to RA,” said Timothy P. Walbert, chairman, president and chief executive officer, Horizon Pharma. “We anticipate submitting a New Drug Application for LODOTRA for the treatment of the signs and symptoms of RA to the U.S. FDA later this year.”

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 a duration of at least one hour, has been adopted as a diagnostic criterion for the definition of RA by the American College of Rheumatology. 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.

About LODOTRA

LODOTRA, a circadian cytokine modulator, is a novel modified 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 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 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 circadian cytokine modulator (CCM) 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. The Company is financed by leading life-science investors Atlas Venture, Deutsche Bank AG, London, Essex Woodlands Healthcare Ventures, FirstMark Capital, Global Life Science Ventures, NGN Capital, Scale Ventures, Sutter Hill Ventures and TVM Capital.

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 any product or product candidate, 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 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 operations.

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