



Horizon Pharma, Inc. Presents Interim Results from a Pilot Clinical Study Evaluating LODOTRA® in the Treatment of Severe Nocturnal Asthma

Data Presented During the American Thoracic Society 2010 International Conference

NORTHBROOK, Ill. – May 19, 2010 – Horizon Pharma, Inc., a late-stage biopharmaceutical company focused on the development and commercialization of innovative medicines for pain-related diseases and chronic inflammation, today announced interim results from a pilot clinical study showing that LODOTRA® (modified release prednisone tablet) chronotherapy may improve asthma control and asthma-related quality of life when added to standard asthma therapy in patients with severe nocturnal asthma. The data were presented today during a poster session at the American Thoracic Society (ATS) 2010 International Conference in New Orleans, LA.

“Often, patients with severe nocturnal asthma have trouble controlling symptoms with their standard asthma therapy, and these pilot data suggest LODOTRA may improve patients’ quality of life and the number of times they are awakened by asthma symptoms during the night,” said Timothy P. Walbert, chairman, president and chief executive officer, Horizon Pharma. “These results underscore the versatility of the potential anti-inflammatory properties of LODOTRA, as it has also been shown in clinical studies to significantly improve the signs and symptoms of rheumatoid arthritis in patients, an indication for which we anticipate submitting a New Drug Application to the U.S. Food and Drug Administration later this year.”

The MONA (modified release prednisone for the treatment of nocturnal asthma) study is a two-stage, open-label, pilot trial assessing LODOTRA’s treatment effect in patients with severe nocturnal asthma who require treatment with oral prednisone in addition to standard asthma therapy. After a two week screening period, patients were treated with immediate release prednisone at 8 a.m. for four weeks and then switched to four weeks of the same dose of LODOTRA in the evening prior to sleep. The primary endpoint of the study was the number of nocturnal awakenings due to asthma in treated patients. Secondary endpoints include asthma control questionnaire responses, asthma quality of life questionnaire responses and general safety.

Interim Results of MONA Study

Data from five patients treated with 5 to 45 mg of daily prednisone in accordance with the study protocol showed clinically relevant improvements in nocturnal symptoms, asthma control and asthma-related quality of life. The study showed that LODOTRA chronotherapy was associated with an improvement in the mean number of nocturnal awakenings due to asthma, the primary endpoint of the trial, after patients switched from immediate release prednisone. The number of nocturnal awakenings changed from 9.2 ± 6.3 (standard deviation) with immediate release prednisone to 2.6 ± 5.3 under treatment with LODOTRA chronotherapy, in the last two weeks of each respective treatment period. General asthma control improved from a mean of 3.2 in the last week of patients receiving immediate release prednisone, to a mean of 2.0 in the last week of LODOTRA therapy¹. Asthma-related quality of life improved from a mean of 3.9 in the last week of immediate release prednisone treatment to a mean of 4.9 in the last week of LODOTRA therapy². The median number of as-needed inhalations of salbutamol per day decreased from 2.1 during the immediate release prednisone treatment period, to 1 during the LODOTRA treatment period, in the last two weeks of each respective treatment period. The incidence of adverse events was low throughout the study and comparable between the two treatment periods.

The MONA study is expected to complete enrollment of patients in the third quarter of 2010.



About Severe Asthma

Severe asthma is life-threatening and commonly results in visits to the emergency room. Sufferers of severe asthma frequently experience nocturnal symptoms, such as cough and dyspnoea (shortness of breath) accompanied by a nocturnal drop in lung function. The nocturnal symptoms are caused by circadian variations in airway inflammation, specifically an increase in pro-inflammatory cytokines. In addition, nocturnal symptoms also appear to be associated with mortality from asthma, with the majority of respiratory arrests and sudden deaths in subjects with asthma occurring between midnight and 8 a.m.

As asthma symptoms are usually more severe during the night, the administration of standard prednisone in the morning appears to be suboptimal as inflammatory cytokine levels have already peaked and receded by the time of need. LODOTRA is currently being investigated to determine if it may offer advantages over standard therapy, including the possibility of efficacy at lower doses, which may reduce the severe side effects associated with current standard treatments that rely on high doses of prednisone.

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 rheumatoid arthritis (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 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 DUEXA[®], 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), DUEXA 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 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. 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 combined company's ability to obtain additional capital to support its planned operations.

1 Asthma Control Scale: International guidelines that measure both the adequacy of asthma control and change in asthma control, which occurs either spontaneously or as a result of treatment.

2 Asthma-Related Quality of Life Scale Overview: Developed to measure the functional problems (physical, emotional, social and occupational) that are most troublesome to adults (17-70 years) with asthma.

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