



## Horizon Pharma Announces LODOTRA<sup>®</sup> and DUEXA<sup>®</sup> Data to be Presented at the European League Against Rheumatism (EULAR) Annual Congress

**Northbrook, Ill. – June 9, 2010** – Horizon Pharma, Inc., today announced that data on its two lead product candidates, LODOTRA<sup>®</sup>, a circadian cytokine modulator and novel modified release, low-dose prednisone tablet, and DUEXA<sup>®</sup>, a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and high-dose famotidine, will be presented during the European League Against Rheumatism (EULAR) Annual Congress taking place in Rome, Italy, June 16-19. A total of five studies will be presented; four studies evaluating the use of LODOTRA as a treatment for the signs and symptoms of rheumatoid arthritis (RA) and one study highlighting data from the Phase 3 study of DUEXA for the treatment of ibuprofen-associated, upper gastrointestinal ulcers in patients who require use of ibuprofen.

### LODOTRA Studies to be Presented

- *Safety data for low-dose glucocorticoid chronotherapy of rheumatoid arthritis with 5 mg modified-release (MR) prednisone in a randomized, double-blind, placebo-controlled trial*
  - Author: Frank Buttgereit, M.D., senior consultant and deputy head of the Department of Rheumatology and Clinical Immunology, Charité Hospital, Berlin
  - Abstract number: SCIE-4797
  - Date/time of presentation: Thursday, June 17, 2010, 12:00 p.m. – 1:45 p.m. CET
  - Location: Fiera Roma – Poster Areas, Halls 5 & 6
- *Low-dose glucocorticoid chronotherapy of rheumatoid arthritis: 12 week efficacy data of 5 mg modified-release (MR) prednisone*
  - Author: Frank Buttgereit, M.D., senior consultant and deputy head of the Department of Rheumatology and Clinical Immunology, Charité Hospital, Berlin
  - Abstract number: SCIE-4498
  - Date/time of presentation: Thursday, June 17, 2010, 12:00 p.m. -1:45 p.m. CET
  - Location: Fiera Roma – Poster Areas, Halls 5 & 6
- *Hypothalamus-pituitary-adrenal axis function in patients with rheumatoid arthritis treated with modified-release (MR) prednisone for 12 months*
  - Author: Rieke Alten, M.D., Schlosspark-Klinik, Teaching Hospital, Charité University Medicine
  - Abstract number: SCIE-1860
  - Date/time of presentation: Thursday, June 17, 2010, 12:00 p.m. -1:45 p.m. CET
  - Location: Fiera Roma – Poster Areas, Halls 5 & 6
- *Chronotherapy of rheumatoid arthritis: CAPRA-1 demonstrated sustained efficacy of modified-release prednisone over 12 months*
  - Author: Frank Buttgereit, M.D., senior consultant and deputy head of the Department of Rheumatology and Clinical Immunology, Charité Hospital, Berlin
  - Abstract number: SCIE-1881
  - Date/time of presentation: Thursday, June 17, 2010, 12:00 p.m. -1:45 p.m. CET
  - Location: Fiera Roma – Poster Areas, Halls 5 & 6

### DUEXA Study to be Presented

- *Independent predictors for the development of upper gastrointestinal ulcers with a NSAID: Results from two large trials of single-tablet combination of ibuprofen-famotidine vs. ibuprofen alone*
  - Author: Michael Schiff, M.D., clinical professor of Medicine, Rheumatology Division, University of Colorado, Denver School of Medicine
  - Abstract number: SCIE-1702
  - Date/time of presentation: Thursday, June 17, 2010, 12:00 p.m. – 1:45 p.m. CET
  - Location: Fiera Roma – Poster Areas, Halls 5 & 6



### **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 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 DUEXA**

DUEXA is a novel, proprietary fixed-dose tablet combining the one of the world's most prescribed NSAIDs, ibuprofen, with a high dose of the most potent H<sub>2</sub> antagonist, famotidine, in a single pill. Ibuprofen has proven anti-inflammatory and analgesic properties, whereas famotidine reduces the stomach acid secretion that can cause gastric and duodenal ulceration. By combining ibuprofen and famotidine into a single product, it is believed that ibuprofen's gastrointestinal safety profile will be improved - without altering its ability to reduce pain and inflammation.

### **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 H<sub>2</sub> 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.

For more information about the company and its products, please visit [www.horizonpharma.com](http://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 operations.

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