



Neuromed Announces Exalgo™ (hydromorphone HCl) Extended-Release Tablets (CII) Meets Primary Efficacy Endpoint in Pivotal Phase 3 Trial

CONSHOHOCKEN, PA and VANCOUVER, BC – March 23, 2009 – Neuromed Pharmaceuticals, Inc. today announced positive results of a pivotal phase 3 clinical trial of its lead investigational drug, Exalgo (hydromorphone HCl) Extended-Release Tablets [CII] (previously NMED-1077 and OROS® Hydromorphone). The trial met its primary efficacy endpoint, the mean change from baseline to week 12 (or last visit) of average weekly pain intensity scores, and the results were statistically significant ($p < 0.0001$). The primary efficacy endpoint was agreed upon with the U.S. Food and Drug Administration (FDA) during the Special Protocol Assessment (SPA) process.¹

Neuromed is seeking approval of Exalgo in the U.S. for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. The FDA has stated in an Approvable Letter that one successful adequate and well-controlled clinical trial will be needed to support approval of Exalgo. “The successful completion of our pivotal phase 3 clinical trial brings us closer to reaching our goal of providing an effective once-daily pain medication for opioid tolerant patients with moderate to severe pain requiring around-the-clock opioid analgesia for an extended period of time,” said Dr. Christopher Gallen, President and Chief Executive Officer of Neuromed. “We have now successfully completed a major milestone of our development plan and are on schedule to submit our FDA application planned for the second quarter of 2009.”

Martin E. Hale, M.D., Principal Investigator of the pivotal phase 3 clinical trial stated, “Hydromorphone is a clinically proven analgesic that is not currently available in a long acting oral formulation. Exalgo, if approved, will provide an additional option in the treatment of chronic moderate to severe pain in opioid tolerant patients.”

Study Design and Results

The pivotal phase 3 clinical trial of Exalgo was a double-blind, placebo-controlled study employing a randomized withdrawal design, conducted at 65 centers in the U.S. The study randomized 268 opioid tolerant patients with chronic moderate to severe low back pain for treatment of up to twelve weeks. Patients were considered to be opioid tolerant if they were on chronic opioid therapy at a dose equivalent to ≥ 60 mg/day of oral morphine for a period of time.

The primary efficacy endpoint was the mean change from baseline to week 12 (or last visit) of average weekly pain intensity scores compared to the placebo group, measured using an 11-point Likert Numerical Rating Scale (NRS) obtained from patient diaries. The study showed statistically significant ($p < 0.0001$) results in the protocol specified primary efficacy endpoint. In addition, results from statistical analyses of multiple secondary efficacy endpoints were consistent with the primary efficacy endpoint.

The overall safety profile and reported adverse events in the study were consistent with that of other strong opioids. The most commonly reported adverse events in the study were nausea, constipation, vomiting, arthralgia, insomnia and headache.

¹ A SPA is a procedure by which sponsors and the FDA reach agreement on the protocol design, primary efficacy endpoints, and the data analysis of clinical trials needed to support approval of a New Drug Application (NDA).

About Exalgo

Neuromed acquired from ALZA Corporation the U.S. marketing rights to Exalgo, an extended release formulation of hydromorphone. Hydromorphone is a Schedule II opioid that has been used for many years. Oral hydromorphone products currently available in the U.S. are immediate release formulations, requiring dosing several times per day. Exalgo, if approved, will employ the OROS[®] PUSH-PULL[™] osmotic delivery system designed to release hydromorphone at a controlled rate over an extended period of time. An identical formulation, under the trade name JURNISTA[®], has been launched in several countries by Janssen-Cilag. JURNISTA[®] was first launched in Germany in August 2006.

Exalgo is an investigational drug and has not been approved by the FDA. To date, Exalgo has been studied in more than 2,000 patients in clinical trials. The most common adverse events seen in those clinical trials to date are opioid-related events such as constipation, nausea, somnolence, headache, vomiting and dizziness. Respiratory depression is the most important hazard of opioid preparations including Exalgo.

About Neuromed

Neuromed is a privately held biopharmaceutical company in business to develop new and improved pain medicines. Neuromed has three programs aimed at addressing this important unmet medical need. Its lead product, Exalgo is an extended release formulation of hydromorphone in phase 3 clinical development. In collaboration with Merck, Neuromed is also developing oral drug candidates to block N-type calcium channels, a new and important target directly involved in pain signaling. Its third program is focused on producing promising T-type calcium channel blockers aimed at treating pain, epilepsy and hypertension. For more information visit our website at www.neuromed.com.

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