



Neuromed Concludes a Special Protocol Assessment (SPA) with FDA for a Pivotal Phase 3 Study on NMED-1077

CONSHOHOCKEN, PA and VANCOUVER, BC – October 15, 2007 – Neuromed Pharmaceuticals, a biopharmaceutical company developing new and improved chronic pain drugs, announced today it has successfully reached an agreement with the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) process for the planned pivotal Phase 3 clinical trial of NMED-1077 (OROS[®] Hydromorphone) for the treatment of chronic pain. A SPA is a procedure by which sponsors and the FDA reach agreement on the design and size of clinical trials intended to form the primary basis to support approval of a New Drug Application.

“The Special Protocol Assessment provides Neuromed with a clearly defined pathway for our Phase 3 trial to support regulatory approval of NMED-1077,” said Dr. Christopher Gallen, Neuromed’s President & CEO. “We believe a once-daily version of hydromorphone can be a significant benefit for patients with moderate to severe pain who require pain relief with opioids around the clock.”

The Phase 3 trial of NMED-1077 is designed as a randomized withdrawal, placebo-controlled, double-blind trial which is being conducted at multiple centers in the U.S. The primary outcome measure is pain intensity at endpoint assessed by patients with an 11 point Likert Numerical Rating Scale (NRS). The study will target enrollment of 272 patients into the double-blind randomized withdrawal phase, and will evaluate the safety and efficacy of NMED-1077 in the treatment of chronic low back pain.

The FDA has completed its review of Neuromed’s Investigational New Drug (IND) application for NMED-1077 and the IND is now open. Neuromed plans to begin enrollment in its first Phase 3 clinical trial of NMED-1077 later this year.

Neuromed acquired, from ALZA Corporation, the U.S. marketing rights to NMED-1077, an extended release formulation of hydromorphone. Hydromorphone is a Schedule II opioid that has been widely used for many years under the brand name DILAUDID[®] and is also available from various generic manufacturers. Current formulations of hydromorphone marketed in the U.S. are immediate release, requiring dosing several times per day. NMED-1077 employs the OROS[®] PUSH-PULL[™] osmotic delivery system to release hydromorphone at a controlled rate over an extended period. OROS[®] Hydromorphone has been approved in Germany and other European countries and is marketed by Janssen-Cilag under the name JURNISTA[™].

NMED-1077 is an investigational product and is not approved by the FDA for use in the U.S. NMED-1077 has been studied in more than 1,000 patients in analgesic trials. The most common adverse events seen in 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 NMED-1077.

Neuromed is also evaluating two pathways for the development of new classes of oral pain drugs. In collaboration with Merck, Neuromed is researching compounds designed to block the N-type calcium channel, a target linked to pain signal transmission. Separately, Neuromed is also developing T-type calcium channel blockers for the treatment of acute and chronic pain as well as other potential disorders such as hypertension and epilepsy.

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About Neuromed

Neuromed is a privately held biopharmaceutical company in business to develop safer and more effective pain drugs. We are combining our pharmaceutical expertise in research, development and commercialization to improve existing pain treatments as well as develop new pain medicines. For more information visit www.neuromed.com.

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