



Newron to initiate Phase IIb/III study of Ralfinamide in patients with Neuropathic Low Back Pain (NLBP)

- **Trial will evaluate Efficacy and Safety of ralfinamide versus placebo in approximately 400 patients**
 - **12 weeks treatment with double blind 40 week extension**
 - **First of two potentially pivotal studies in NLBP**

Milan, Italy – December 22, 2008 - Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, today announced that it has received approval to initiate its first phase IIb/III study of ralfinamide in patients with moderate neuropathic low back pain. The study will evaluate the efficacy and safety of two dose regimens of ralfinamide, compared to placebo. This study is one of the two potentially pivotal studies required for an approval in neuropathic low back pain, an indication with a prevalence of about 8 % of the population with no approved treatments currently available.

The study is a 12-week, randomized, double-blind, international (Europe and Asia), phase IIb/III trial. It will randomize approximately 400 patients with chronic NLBP of at least moderate severity as judged by the patients. Patients will be diagnosed in accordance with the diagnostic criteria proposed by the International Association for the Study of Pain (IASP). Patients will be randomized to treatment with ralfinamide at a daily dose of 160 mg, 320 mg, or matched placebo.

The primary efficacy measure of the trial will be based on the 11-point Likert Pain Scale that measures the intensity of pain as judged by the patient. Secondary efficacy measures will include patients' self ratings of the Visual Analogue Scale (VAS) as well as responder rates.

Patients who complete the 12 weeks of treatment will be eligible to enter a double-blind 40 week extension. Those who continue the study will remain on the same dose of study medication that they were receiving at the end of the 12 week treatment period.

The NLBP indication, the study design diagnostic criteria, outcome measures and statistical analysis plan have been discussed with major health authorities and the protocol reflects the agreements reached. The registration dossier would require positive results from two pivotal studies, 1,500 unique human exposures and at least 100 patients treated for one year.



About Ralfinamide

Ralfinamide is a unique New Chemical Entity that is believed to mediate analgesic and anti-inflammatory effects through the modulation of ion channels implicated in pain and the inhibition of substance P.

About Neuropathic Low Back Pain (NLBP)

Neuropathic Low Back Pain is by far the most common clinical emergence of neuropathic pain (about 50 % of patient prevalence and about 60 % of diagnoses). About 55 million patients in the USA, Europe and Japan experience NLBP. So far, no drugs have been approved for the treatment of this indication.

About Newron Pharmaceuticals

Newron Pharmaceuticals S.p.A. (www.newron.com) is a biopharmaceutical company focused on novel therapies for diseases of the Central Nervous System and pain. Newron is undertaking phase III trials with safinamide for the treatment of Parkinson's disease (PD) in conjunction with its partner, Merck Serono, which has exclusive worldwide rights to develop, manufacture and commercialize the compound in PD, Alzheimer's disease, and other therapeutic applications. Newron recently reported excellent results for its compound ralfinamide in patients with Nerve Compression and Entrapment conditions, of which neuropathic low back pain (NLBP) represents the most common indication.

In May 2008, Newron acquired Hunter-Fleming, a private UK bio-pharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.

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Newron does not undertake any obligation to publicly up-date or revise forward looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed.

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