



Newron randomizes first patients in Phase IIb/III study of ralfinamide in patients with Neuropathic Low Back Pain

- **EMA confirms**
 - **NLBP indication**
 - **Newron development program towards filing**
 - **Safety and Efficacy Measures**
 - **Diagnostic criteria**

Milan, Italy – March 31, 2009 - Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, today announced that it has randomized the first patients to treatment in its first phase IIb/III study of ralfinamide in patients with moderate Neuropathic Low Back Pain (NLBP). The SERENA study (**S**afety and **E**fficacy of **R**alfinamide in **n**europathic low back pain **p**atients) will evaluate the safety and efficacy of two dose regimens of ralfinamide compared to placebo. It could be one of the two pivotal studies required for an approval in NLBP, 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, to treatment with ralfinamide at a daily oral dose of 160 mg, 320 mg, or matched placebo. Patients will be diagnosed in accordance with the diagnostic criteria proposed by the International Association for the Study of Pain (IASP).

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 study has been approved by the national health authorities in Austria, Germany, India, Italy, Romania and the UK. The program was discussed with the EMA, who approved the plans for the NLBP indication, the study design, diagnostic criteria, outcome measures and statistical analysis plan.

Ravi Anand, Newron's Chief Medical Officer, commented: "The agreement by the EMA confirms the earlier consensus by a number of health authorities in North America and Europe, that successful development of ralfinamide in two pivotal trials and exposure of 1,500 patients would allow Newron or a potential partner to file for the NLBP indication. This would mean that

ralfinamide has the potential to be the first drug approved for this indication, in a very large market.”

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. In 2008 Newron 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. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.

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