



Newron reports SERENA trial top-line results for ralfinamide

Milan, Italy – May 6, 2010 – Newron Pharmaceuticals S.p.A. (“Newron” SIX: NWRN), a research and development company focused on novel CNS and pain therapies, today announced top-line results of its SERENA* study, a phase IIb/III study of ralfinamide in patients with at least moderate Neuropathic Low Back Pain (NLBP).

The 12-week SERENA study enrolled 411 patients with chronic NLBP of at least moderate severity and evaluated the safety and efficacy of two dose regimens of ralfinamide compared to placebo.

Available results on the primary endpoint of the study, the change from baseline for the 11-point Likert Scale, did not detect any significant difference between ralfinamide and placebo. Ralfinamide was well tolerated, with no clinically significant differences from placebo on safety measures.

Further analyses of the additional endpoints (VAS, PGI, CGI etc.)** are currently ongoing and will be reviewed with Newron’s external advisors. Based on the multiple CNS effects seen in animal pharmacology models, and the excellent human safety data, Newron will decide how to proceed further with the compound.

Luca Benatti, Newron’s Chief Executive Officer, commented: “We are extremely surprised and disappointed by the results, based on the statistically significant benefits shown in a phase II placebo-controlled trial, as well as the results from a large number of preclinical studies. We shall be working with our external advisors to make a complete assessment of the data prior to determining our next steps, including a review of our development resource needs going forward. We have a broad portfolio of products in various stages of development, addressing substantial market opportunities and this, combined with our existing cash resources and SEDA equity line, gives Newron continued potential for growth and value generation”.

In addition to ralfinamide, Newron has an advanced pipeline of innovative compounds, that include safinamide, currently in phase III development for the treatment of Parkinson’s disease (add-on treatment for all stages of PD) together with Merck Serono; NW-3509, an novel treatment for schizophrenia expected to enter human trials later this year, and HF0220, a potential disease-modifying therapy for neurodegenerative disorders, currently in phase II.



- * SERENA: **S**afety and **E**fficacy of **R**alfinamide in **n**europathic low back pain **p**Atients.
- ** VAS - Visual Analog Scale, PGI - Patient global impression of change, CGI - Clinical global impression of severity and change

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’s additional projects are in various stages of preclinical and clinical development, including NW-3509 for the treatment of schizophrenia and HF0220 for neuroprotection. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.

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