



Ralfinamide uniquely shows analgesic effects in a Central Pain model

- - Data presented at EFIC - -

Milan, Italy – September 11, 2009 – Newron Pharmaceuticals SpA, a research and development company focused on novel CNS and pain therapies, today announced positive results from a preclinical study showing that ralfinamide has statistically significant analgesic benefits against spontaneous chronic pain in an experimental model of central pain. The study was conducted by Professor Ze'ev Seltzer, Canada Senior Research Chair in Genetics of Pain, University of Toronto, Canada, and was presented yesterday (September 10, 2009) at the Sixth International Congress of the European Federation of IASP Chapters (EFIC), Lisbon, Portugal, September 9-12, 2009.

Highlights

- **The efficacy of ralfinamide in a preclinical model of central pain provides evidence that its analgesic effects in chronic pain operates on central nervous system targets, in addition to its known peripheral mechanisms**
- **Ralfinamide's unique ability to affect central targets widens its broad spectrum of analgesic mechanisms, supporting its therapeutic potential for alleviating Neuropathic Low Back Pain (NLBP) in the ongoing SERENA Phase IIb/III clinical trial**
- **The new data suggest that ralfinamide may be effective in central pain syndromes**

The study showed that ralfinamide significantly suppressed spontaneous pain behavior, expressed as self mutilation of the denervated hindpaw of a rodent, providing evidence that ralfinamide is a centrally acting analgesic. These effects were recorded both when ralfinamide was administered orally twice daily for one week before the surgery and stopped thereafter ('preemptive analgesia' regimen), as well as when it was administered only for 42 days postoperatively ('palliative analgesia' regimen). Analgesic effects were still noted 21 days after stopping drug administration on day 42. In this model of central pain, ralfinamide uniquely showed significant superiority compared to placebo, while pregabalin, used as an active control, failed to show significant benefits compared to placebo.

"Due to the CNS origin of pain in this rodent model, the analgesic effects of ralfinamide must have targeted mechanisms of neuropathic pain in the CNS", said professor Ze'ev Seltzer, the leading investigator of the study "The CNS target of this compound is yet to be discovered, but chronic alterations in the function of neurons and glial cells in the CNS are a seminal part of the development and maintenance of neuropathic pain in rodent models and in many pain syndromes in humans, including Neuropathic Low Back Pain, where ralfinamide is being evaluated in a Phase IIb/III clinical trial. Moreover, these new findings open the potential for new therapeutic perspectives for ralfinamide in central pain syndromes that are known to be refractory to current analgesics" he added.

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 Central Pain

Central pain syndrome is a neurological condition caused by damage to, or dysfunction of the central nervous system (CNS), which includes the brain, brainstem, and spinal cord. This condition can be produced by different causes such as stroke, brain or spinal cord trauma, avulsion injuries that tear nerve roots from the spinal cord, multiple sclerosis, tumours, epilepsy, congenital malformations, and more. A large number of patients worldwide are affected by central pain, with substantial impact on the quality of life, mood, sleep, cognition, social relations, work and domestic activities, etc. Central pain is usually treated with antidepressants, anticonvulsants, and opioids; treatments which provide partial pain relief at best, and which are often associated with major side-effects.

About Ralfinamide

Ralfinamide is a unique new chemical entity that is believed to mediate its potent analgesic effect through the inhibition of sodium channels, incl. Nav. 1.7, N-type Calcium channels and NMDA receptors. It is currently in Phase IIb/III development for Neuropathic Low Back Pain.

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 initiated SERENA, a potentially pivotal study with ralfinamide in patients with Neuropathic Low Back Pain (NLBP). There are no approved drugs for the treatment of NLBP, an indication experienced by about 55 million patients in the USA, Europe and Japan. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.

The poster presented at EFIC is downloadable at:

<http://www.newron.com/presentationandfactsheet.asp>

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