



NEWRON ANNOUNCES FDA APPROVAL OF US IND APPLICATION FOR RALFINAMIDE IN NEUROPATHIC PAIN

Milan, Italy – June 29, 2007 - Newron Pharmaceuticals S.p.A. (SWX: NWRN), a research and development company focused on novel CNS and pain therapies, today announced that it has received approval from the US Food and Drug Administration (FDA) for an Investigational New Drug (IND) application to conduct clinical trial(s) with ralfinamide for the treatment of neuropathic pain.

The IND was granted subsequent to the FDA's review of all preclinical and clinical data generated by Newron. All previous studies in human subjects have been performed in Europe and India. Newron and the FDA agreed on the procedures to be followed in future trials with ralfinamide in humans.

Newron anticipates initiating further trials by Q4 2007.

Ravi Anand, Newron's CMO, said: "The FDA feedback and concurrence with the plan for the further development of ralfinamide in neuropathic pain is very significant as it allows Newron to rapidly plan the US and global development of this exciting new chemical entity."

About ralfinamide

Ralfinamide is a potent voltage- and use-dependent ion channel blocker that showed good activity in several animal models of chronic pain. In addition, it has shown promising results in a pilot phase II clinical trial: Ralfinamide was well tolerated up to the maximal dose without the occurrence of any consistent pattern of clinically-relevant adverse change in vital signs, ECG and other laboratory values. It showed beneficial effects on symptoms and severity of pain. Ralfinamide is currently in a phase II MTD trial (maximum tolerated dose level), from which data are expected shortly.

About neuropathic pain

Neuropathic pain is a chronic, frequently progressive condition that seriously impacts the quality of life of patients who suffer from it. The disease is caused by damage to, or dysfunction of, the nervous system and typically results from damage to nerve cells. It encompasses a wide range of types of pain of diverse origins. The most commonly diagnosed types of neuropathic pain include diabetic neuropathy, cancer pain, HIV/AIDS-associated pain and post-herpetic neuralgia, a complication of "shingles", which is a

recurrence in adults of severe skin rashes caused by the herpes zoster virus. A large proportion of back pain is also categorised as neuropathic pain. Neuropathic pain typically has several distinct characteristics including shooting, lancinating or burning pain in the absence of any tissue damage, hypersensitivity of the skin or a sensation of pain from stimuli that would not be expected to cause 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, a unique molecule with multiple mechanisms of action, for the treatment of PD in conjunction with its partner, Merck Serono, which has the rights to develop the compound in PD, Alzheimer’s disease, other cognitive disorders and Restless Legs Syndrome. Recent results of a six-month phase III trial of safinamide in PD demonstrated its benefit in motor symptoms and activities of daily living, as well as its improvement in cognitive function and good tolerability. Newron and Merck Serono are planning to expand the development of safinamide to exploit its potential in Alzheimer’s disease. Phase II trials with safinamide in Restless Legs Syndrome have shown promising results. Newron is also conducting phase II trials with ralfinamide for the treatment of neuropathic pain. The drug has potential benefit in inflammatory pain, as well. Newron’s clinical pipeline is supported by a portfolio of early-stage proprietary compounds generated by its ion channel drug discovery platform. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SWX Swiss Exchange, trading symbol NWRN.

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