



**NEWRON PHARMACEUTICALS REPORTS THE START OF A PIVOTAL PHASE III STUDY  
WITH SAFINAMIDE IN MID –TO- LATE STAGE  
PARKINSON’S DISEASE PATIENTS**

Milan, Italy – November 27, 2006 – Newron Pharmaceuticals SpA, a research and development company focused on novel CNS therapies, announced today the initiation of its second phase III pivotal study of safinamide, in patients with mid-to-late stage Parkinson’s disease with motor fluctuations. The study is being conducted jointly with Serono SA who licensed safinamide from Newron as announced on October 16, 2006.

This international, six month, double-blind, randomized, placebo-controlled, parallel-group study, has been designed to demonstrate the efficacy and safety of safinamide in comparison to placebo in patients who were receiving stable doses of L-dopa with or without additional treatment with dopamine agonists and/or anticholinergic drugs. The study has been designed to demonstrate the efficacy of safinamide in increasing “on time” periods, i.e. periods of good functioning compared with placebo. Following completion of six months of dosing, patients will continue for an additional one year of treatment under blinded conditions designed to demonstrate a reduction in dyskinesias, i.e. involuntary, jerky movements that incapacitate Parkinson’s disease patients treated chronically with L-dopa.

The study will also evaluate changes in cognitive function that have been shown to be improved by safinamide in a previous phase III trial in early Parkinson’s disease patients treated with dopamine agonists.

This study follows the positive results of the first phase III study reported by Newron in June 2006. In October 2006, Newron and Serono signed a global development and commercialization agreement under which Newron has granted Serono exclusive worldwide rights to develop, manufacture and commercialise safinamide in Parkinson’s disease (PD), Alzheimer’s disease, other cognitive disorders and Restless Leg Syndrome.

Luca Benatti, CEO of Newron, said, “We are delighted to be starting a new pivotal phase III trial so soon after signing the deal with Serono. This demonstrates strong commitment from both parties to move expeditiously towards bringing safinamide to market.”

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**About safinamide**

Safinamide is an alpha-aminoamide derivative which is orally administered. Studies have shown that safinamide combines the inhibition of dopamine re-uptake and MAO-B, two key mechanisms involved in the control of dopamine concentration in the brain, and inhibition of glutamate release. Based on the results of prior clinical trials, Newron believes that safinamide, as an adjunctive treatment to dopamine agonists and levodopa, may have a competitive advantage over current therapies for Parkinson's disease.

**About Newron Pharmaceuticals**

Newron Pharmaceuticals S.p.A ([www.newron.com](http://www.newron.com)) is a biopharmaceutical company focused on novel therapies for diseases of the Central Nervous System, particularly Parkinson's disease (PD) 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, Serono S.A. which has the rights to develop the compound in PD, Alzheimer's disease, and other cognitive disorders. 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 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.

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