



PRESS RELEASE

Newron Pharmaceuticals Completes Enrollment in Safinamide Phase III Pivotal Clinical Trial for Parkinson's Disease

Milan, Italy – 21st July 2005 – Newron Pharmaceuticals SpA, a research and development company focused on novel CNS therapies, today announced the completion of patient enrollment in its phase III trial with Safinamide for the treatment of Parkinson's disease. Phase III testing is the final stage before submission to health regulatory authorities. A total of 260 patients in 26 centres worldwide have been randomised in the study, which aims to show efficacy and safety of safinamide used as adjunctive treatment to a dopamine agonist in patients with early-stage Parkinson's disease.

"Completing patient enrollment on schedule in our first phase III trial is a major achievement for Newron. We anticipate data from the study to be available in the first half 2006," commented Dr Luca Benatti, CEO of Newron Pharmaceuticals. "We will now accelerate the implementation of additional trials to allow regulatory filing of Safinamide worldwide".

Safinamide Phase III Study

The phase III trial has been designed as a double-blind, placebo-controlled, parallel-group, randomized, multi-national study during which patients will receive treatment for 18-months. Early-stage Parkinson's disease outpatients enrolled in the trial will receive a stable dose of a single dopamine agonist and, as an add-on therapy, one of two non-overlapping dose ranges of orally administered Safinamide (50-100, or 150-200 mg/day) or placebo. Patients enrolled and completing an initial 6-month of double-blind treatment will be eligible to enter a 12-month, double-blind continuation study. The primary efficacy measures will be the change from baseline to endpoint in mean value of UPDRS (Unified Parkinson's Disease Rating Scale) - Section III (motor score) and the CGI (Clinical Global Impression change from baseline to endpoint). The UPDRS and the CGI are specialised scoring systems used to rate the clinical severity and response to treatment in Parkinsonian patients, respectively.

The continuation study will measure the time for which the effect of Safinamide is maintained in these patients.

About Parkinson's Disease

Parkinson's disease is one of the major neurological disorders, affecting approximately 4 million people worldwide, according to the World Health Organisation. It is characterised as a chronic, progressive degeneration of nerve cells that use the neurotransmitter dopamine in a special area of the brain, called the Substantia Nigra (black substance) that controls muscle tone, initiation and smoothness of movements. Symptoms include limb tremors, muscle rigidity, slowness of motion and postural instability. Current treatments aim at replenishing the lost stores of dopamine or stimulating those dopamine receptors that carry forward dopamine motor messages.

About Safinamide

Safinamide is an investigational new drug currently in phase III clinical trials for the treatment of Parkinson's disease and in phase II for epilepsy and Restless Leg Syndrome (RLS). Safinamide is a unique molecule with multiple mechanisms of action, including potentiation of dopamine via inhibition of monoamine oxidase (MAO)-B and dopamine re-uptake and glutamate release inhibition. Safinamide has demonstrated robust efficacy in phase II clinical trials for Parkinson's disease. The development of Safinamide in Parkinson's disease is supported in part by a €2.7 million grant from the Italian Ministry of Productive Development's Innovation Technology Fund.

About Newron Pharmaceuticals S.p.A.

Newron Pharmaceuticals S.p.A (<http://www.newron.com>) is a research and development company focused on novel ion channel based therapies for diseases of the Central Nervous System (CNS), particularly Parkinson's disease, epilepsy and pain. Newron has initiated phase III trials with Safinamide, a unique molecule with multiple mechanisms of action, for the treatment of Parkinson's disease. Phase II trials with Safinamide in Epilepsy and Restless Leg Syndrome (RLS) are also ongoing. Newron is also conducting phase II trials with Ralfinamide, a potent sodium channel blocker, for the treatment of neuropathic pain. Newron's clinical pipeline is supported by a broad 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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