



Safinamide Significantly Improved Motor Function in Patients with Advanced Parkinson's Disease in a Phase III Pivotal Trial

- **The six-month primary efficacy endpoint of the study was met: both doses of investigational agent safinamide significantly increased "ON" time in levodopa-treated patients with mid- to late-stage Parkinson's disease**
- **Secondary efficacy endpoints of the study analyzed to date were met in both safinamide dose groups**

Milan, Italy – 3 February 2009 - Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, and its partner Merck Serono today announced that the first Phase III trial of investigational agent safinamide as adjunctive therapy to levodopa (study 016) met its primary endpoint by increasing daily "ON" time in mid- to late-stage Parkinson's disease patients with motor fluctuations by 1.3 hours. "ON" time represents periods when Parkinson's patients experience their best level of motor functioning.

The two safinamide treatment groups of the study (receiving either safinamide 50 mg orally once daily or safinamide 100 mg orally once daily as adjunctive therapy to levodopa) demonstrated a statistically significant increase of daily total "ON" time compared to placebo. Throughout the six months of the study, patients treated with both doses of safinamide experienced an average increase of "ON" time of 1.3 hours per day compared to baseline. Patients in the placebo group (receiving placebo in addition to levodopa and other anti-Parkinson therapies) reported an average increase of daily "ON" time of 0.7 hour compared to baseline. The differences between both safinamide dose groups and placebo were statistically significant with p-values of 0.008 (safinamide 50 mg daily) and 0.005 (safinamide 100 mg daily).

"The results indicate that safinamide, when used adjunctively to existing dopaminergic therapies for study patients in mid-to-late stages of Parkinson's disease, increases daily "ON" time of motor functioning," said Dr. Bernhard Kirschbaum, Merck Serono's Executive Vice President for Global Research and Development. "These results represent a further step toward our goal to provide patients and doctors with urgently needed new treatment possibilities in the Neurodegenerative Diseases therapeutic area."

Dr. Ravi Anand, Newron's Chief Medical Officer, said: "These results are extremely encouraging. In addition to increasing "ON" time and reducing total "OFF" time, as well as "OFF" time after morning dose in patients with mid- to late-stage Parkinson's disease receiving optimized treatment with drugs including levodopa, dopamine agonists, COMT inhibitors, anti-cholinergics and amantidine, the results indicate a statistically significant improvement of motor function. Previously reported results from Phase II and Phase III studies have shown improvement of motor symptoms in early Parkinson's disease patients on dopamine agonist monotherapy. These results from both early and advanced Parkinson's disease patients underline safinamide's potential to be used as adjunctive therapy along the continuum of Parkinson's disease."



This Phase III study was a six-month (24-week), randomized, double-blind, placebo-controlled international trial. It enrolled 669 patients with mid- to late-stage idiopathic Parkinson's disease (more than three years of disease duration) receiving stable doses of levodopa, who had motor fluctuations with >1.5 hours of "OFF" time¹ during the day. Additionally, patients may have received concomitant treatment with stable doses of a dopamine agonist and/or an anti-cholinergic drug. After a four-week levodopa dosage stabilization phase, study participants were randomized to one of the three arms of the trial (1:1:1) to receive either one of two different doses of safinamide (50 or 100 mg once daily: 223 and 224 patients, respectively) or matching placebo tablets (222 patients), as adjunctive treatment to their levodopa therapy. The primary efficacy endpoint of the study was the increase in mean daily "ON" time ("ON" time without dyskinesia plus "ON" time with minor dyskinesia) during an 18-hour period as assessed by patients' recordings on diary cards.

Out of the 669 randomized patients, 89% of patients treated with safinamide completed the study (91% in the 50 mg dose group and 87% in the 100 mg dose group) compared to 89% in the placebo group. Over 90% of patients who completed the initial 24 weeks of treatment elected to enter a 78-week, placebo-controlled double-blind extension study, which is ongoing, to specifically assess the effect on dyskinesias as primary endpoint.

Secondary efficacy endpoints of this study were also met, including decrease in daily "OFF" time, decrease in mean "OFF" time following first morning dose of levodopa, mean change from baseline in the Unified Parkinson's Disease Rating Scale (UPDRS)² Section III (motor) score during "ON" time and mean change in Clinical Global Impression of severity of disease and change from baseline (CGI)³. The incidence of dropouts, serious adverse events or clinically notable events among the three groups of the study were comparable.

Full study results after completion of ongoing analyses will be submitted for presentation at upcoming scientific meetings.

Merck Serono has exclusive worldwide rights to develop, manufacture and commercialize safinamide in Parkinson's disease, Alzheimer's disease and other therapeutic applications, as per the agreement signed with Newron in 2006.

Conference Call

Newron will hold a call to discuss today's news at 3.00pm CET. Dial-in numbers are as follows:

European dial-in: +41 (0)91 610 56 00
UK dial-in: +44 (0)207 107 06 11
USA toll free number: +1 866 291 41 66

Slides are available at www.newron.com in the Investors' section, under Reports, Presentations, Factsheet. An audio replay will be available upon completion of the call.

¹ "OFF" time refers to the times when people with Parkinson's disease have a decrease in the ability to move (hypomobility) and other symptoms that cause difficulty rising from a chair, speaking, walking or performing their usual activities. "OFF" episodes occur because the person's dose of levodopa has worn off or suddenly stopped providing benefit.



• The Unified Parkinson's Disease Rating Scale (UPDRS) is one of the most widely used rating scales used to follow the course of Parkinson's disease. It is made up of 44 items, scored from 0 to 4, to establish individual patients' mental status, activities of daily living, motor function and complications of therapy. These are evaluated by interview and clinical observation. Clinicians and researchers alike use the UPDRS and the motor section (Section III) in particular to follow progression.

• The Clinical Global Impression (CGI) is the general name for two rating scales that are commonly used in clinical trials. The CGI-C scale measures the change in the patient's clinical status from baseline. The CGI-S scale measures global severity of illness at a given point in time. Both CGI-C and CGI-S use a 7-point scale.

For more information, contact:

Media	Investors and analysts
<p>Italy Luca Benatti - CEO Phone: +39 02 6103 4 626 E-mail: pr@newron.com</p> <p>UK/Global media Julia Phillips Financial Dynamics Phone: +44 (0) 20 7269 7187</p> <p>Switzerland Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40</p>	<p>Stefan Weber - CFO Phone: +39 02 6103 46 30 E-mail: ir@newron.com</p>

About safinamide

Safinamide, an alpha-aminoamide derivative that is orally formulated, is currently being developed by Merck Serono and Newron as an add-on treatment for patients with Parkinson's disease. Safinamide is believed to have a novel dual mechanism of action based on the enhancement of the dopaminergic function (through reversible inhibition of monoamine oxidase-B [MAO-B] and dopamine uptake) and reduction of glutamatergic activity by inhibiting glutamate release.

About Parkinson's disease

Parkinson's disease is a degenerative disorder of the central nervous system that often impairs the patient's motor skills and speech. Parkinson's disease belongs to a group of conditions called movement disorders. It is characterized by muscle rigidity, tremor, a slowing of physical movement (bradykinesia) and, in extreme cases, a loss of physical movement (akinesia). The primary symptoms are the results of decreased stimulation of the motor cortex by the basal ganglia, normally caused by the insufficient formation and action of dopamine, which is produced in the dopaminergic neurons of the brain. Secondary symptoms may include high-level cognitive dysfunction and subtle language problems. Parkinson's disease is both chronic and progressive. It is estimated that more than 3 million people in the industrialized countries suffer from Parkinson's disease.

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 a Phase IIb/III 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 m patients in the USA, Europe and Japan.



In May 2008, Newron acquired Hunter-Fleming, a private UK bio-pharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.

Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's anticipated future revenues, capital expenditures and financial resources, and (4) assumptions underlying any such statements. In some cases these statements and assumptions can be identified by the fact that they use words such as "will", "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements.

By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions.

Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programmes, development activities, commercialisation plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions.

Newron does not undertake any obligation to publicly up-date or revise forward looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed.

This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.