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Merck Serono's 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**

Geneva, Switzerland, February 3, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, and its partner Newron Pharmaceuticals SpA (SWX: NWRN) announced today 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

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News Release

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” time[1] 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

News Release

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.

[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.

[2] 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.

News Release

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.

[3] 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.

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 Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. Its North American business operates in the United States and Canada as EMD Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alfa), endocrine and cardiometabolic disorders (Glucophage®, metformin); (Concor®, bisoprolol); (Euthyrox®, levothyroxine); (Saizen® and Serostim®, somatropin). Not all products are available in all markets.

With an annual R&D expenditure of around € 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

About Merck

Merck is a global pharmaceutical and chemical company with total revenues of € 7.1 billion in 2007, a history that began in 1668, and a future shaped by 32,458 employees in 59 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit www.merckserono.net or www.merck.de