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News Release

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Merck Serono Announces Top-Line Results of Long-Term Study of Safinamide as Add-on Treatment to Levodopa in Advanced Parkinson's Disease

Geneva, Switzerland, November 4, 2010 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, and its partner Newron Pharmaceuticals S.p.A. announced today the top-line results of an 18-month, double-blind, placebo-controlled extension study (study 018) of a previously completed and reported 6-month Phase III study (study 016) of safinamide. The objective of this extension study was to assess the long-term (24-month) efficacy and safety of two doses of safinamide (50 mg and 100 mg once daily tablets) as add-on therapy to levodopa in patients with advanced Parkinson's disease. While the primary efficacy endpoint of study 018 measuring dyskinesia after 24 months of treatment was not met, results of the exploratory analysis of the pre-specified main secondary endpoint were consistent with the effect on motor function observed in study 016. Results from the study also further support the safety profile of safinamide.

The primary efficacy endpoint of study 018 was the mean change in the ratings of the Dyskinesia Rating Scale[1] (DRS). After 24 months, non-statistically significant mean improvements of 0.19 and 0.28 in the DRS score were observed in patients who received safinamide 50 mg and 100 mg respectively, versus a worsening of 0.32 for the placebo group (respectively p=0.21 and p=0.15 versus placebo). Dyskinesia, which consists of involuntary and twisting movements of the face and body, is a major

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complication of levodopa therapy, resulting in a significant deterioration of patient quality of life. At baseline, 32% of patients showed troublesome dyskinesia.

Out of the 544 patients enrolled in the extension study, 81% of patients treated with safinamide completed the study (78% in the 50 mg dose group and 83% in the 100 mg dose group) compared to 81% in the placebo group. The incidences of dropouts, serious adverse events or clinically notable events among both groups treated with safinamide were comparable with those in the placebo group over 24 months and similar to the safety profile reported in study 016.

Pre-specified secondary endpoints were analyzed in an exploratory fashion. The significant effect on "ON" [2] time without troublesome or minor dyskinesia observed in study 016 (primary endpoint) was maintained at the end of the 24-month period for both safinamide doses (1.01 and 1.18 hours for the 50 mg and 100 mg dose groups respectively versus 0.34 hours for the placebo group; p=0.0031 and p=0.0002 for the 50 mg and 100 mg dose groups respectively versus placebo).

"These long-term treatment results are encouraging because they confirm the safety profile of safinamide and its effect on motor function observed in the six-month study in this advanced Parkinson's disease population," said Dr. Bernhard Kirschbaum, Merck Serono's Head of Global Research and Development. "The effect of safinamide on dyskinesia will be further explored in an ongoing dedicated pilot study."

"These results in such a rigorously controlled long-term double blind study are particularly relevant as they address key questions in terms of long-term safety and maintenance of the effect on motor function of safinamide over time," said Luca Benatti, Newron's CEO "These results may offer new hope to patients with Parkinson's disease as they need to take medications for long periods of time."

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

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The long-term safety data provided by the extension study 018 are part of the clinical development program of safinamide, together with completed studies 015, 016 and 017, as well as ongoing MOTION and SETTLE studies. This clinical program is designed to support an application for marketing authorization of safinamide as an add-on therapy of dopamine agonist therapy in patients with early Parkinson's disease and as an add-on of levodopa therapy in patients with advanced Parkinson's disease.

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.

Footnotes

[1] The Dyskinesia Rating Scale is designed: 1) to assess the severity of overall dyskinesia, based on interference with activities of daily living; 2) to distinguish chorea from dystonia, the two major types of dyskinesia in PD; and 3) to identify the single most disabling form of dyskinesia.
Dyskinesia is a major complication of levodopa therapy experienced by patients with Parkinson's disease and it consists of involuntary, unwanted and twisting movements of the face, body and limbs.

[2] The times in which the levodopa is effective and the person with Parkinson's disease is able to function normally is called "ON" time.

Study 018 design

The objective of this extension study was to evaluate the long-term efficacy and safety of a 50 mg and 100 mg/day dose of safinamide, compared with placebo, as add-on treatment to levodopa therapy in patients with mid- to late-stage Parkinson's disease experiencing motor fluctuations.

This Phase III study was a double-blind, randomized, placebo-controlled, 18-month extension study. Patients who completed the double-blind treatment period in Study 016 were eligible to enter the extension study and continued to take the same treatment originally administered in Study 016 (50 mg/day, 100 mg/day or placebo), along with the same dose of levodopa. It enrolled 544 patients from study 016 with mid- to late-stage idiopathic Parkinson's disease (more than 3 years of disease duration) receiving stable doses of levodopa, who had motor fluctuations with >1.5 hours of "OFF" time during the day.

Patients who entered the initial 6-month Phase III trial (study 016) were given the opportunity to continue the study for an additional 18 months, receive other treatments for Parkinson's disease, or to discontinue therapy. Of the 669 patients originally enrolled in Study 016, 544 entered the 18-month extension; 440 completed the 18-month extension period.

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About safinamide

Safinamide is an alpha-aminoamide that is currently being developed by Merck Serono and Newron as an add-on therapy to dopamine agonists or levodopa in patients with early or late-stage Parkinson's disease. It is believed to have both dopaminergic and non-dopaminergic activities, including selective and reversible inhibition of monoamine oxidase B (MAO-B), activity-dependent sodium channel antagonism and inhibition of glutamate release in vitro. Studies are ongoing to better understand safinamide's actions in patients with Parkinson's disease.

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 KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates.

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

With an annual R&D expenditure of more than € 1 billion, 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 € 7.7 billion in 2009, a history that began in 1668, and a future shaped by approximately 40,000 (including Merck Millipore) employees in 64 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.com or www.merck.de