

## News Release

October 21, 2011

### Merck Serono Returns Rights for Safinamide to Newron

Geneva, Switzerland, October 21, 2011 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today that it has decided to return all rights for safinamide to Newron Pharmaceuticals S.p.A. Merck Serono had acquired exclusive worldwide rights to develop, manufacture and commercialize safinamide in Parkinson's disease and other therapeutic applications, pursuant to its agreement with Newron signed in 2006.

The termination of this agreement will become effective in April 2012 and will result in approximately €40 million of additional costs for Merck Serono in the fourth quarter of 2011. These costs will be excluded from both the division's and the Merck Group's fourth quarter underlying core operating result.

Merck Serono's decision was made as part of the ongoing review and re-prioritization of its R&D pipeline. In Merck Serono's view, safinamide has a more limited market potential than originally anticipated by the Company. The book value of safinamide was initially written-down in Merck's Q4 2010 financial statements and its remaining book value was fully written-off during the second quarter of 2011.

Merck Serono will meet its contractual and ethical commitments regarding the ongoing clinical development program for safinamide. Merck Serono will work with Newron to execute an appropriate transfer of the program to Newron. The collaboration of Merck Serono and Newron on pruvanserin and sarizotan continues.

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### About safinamide

Safinamide is an alpha-aminoamide that is currently being developed as an add-on therapy to dopamine agonists or to levodopa in patients with early or mid- to late-stage Parkinson's disease (PD). 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 PD.

Safinamide is currently in Phase III for PD and its clinical program includes:

- The ongoing MOTION (safinaMide add-On To dopamine agonists for early Idiopathic ParkinsON's) study: a phase III, double-blind, placebo-controlled randomized six-month trial to evaluate efficacy and safety of two doses of safinamide (50mg/day or 100 mg/day), as add-on to dopamine agonist therapy versus dopamine agonist therapy alone, in early stage PD patients and the MOTION extension 18-month phase III, double-blind, placebo-controlled extension study designed to provide data on the long-term safety and efficacy.
- The ongoing SETTLE (SafinamidE Treatment as add-on To LEvodopa) study: a Phase III, double-blind, placebo-controlled six-month trial to evaluate efficacy and safety of a dose range of safinamide (50-100 mg/day) as add-on to levodopa therapy versus levodopa therapy alone, in mid- to late-stage PD patients.
- The completed 015 study: a phase III, double-blind, placebo-controlled six-month study to evaluate efficacy and safety of a low (50-100mg/day) and high (150-200mg/day) dose range of safinamide as add-on to dopamine agonist therapy versus dopamine agonist therapy alone in early stage PD patients.
- The completed 017 study (the 015 extension study): a phase III, double blind, placebo-controlled, 12-month extension study to evaluate the long-term efficacy and safety of a dose range of safinamide of 50-200mg/day, as add-on to dopamine agonist therapy versus dopamine agonist therapy alone in early stage PD patients
- The completed 016 study: a phase III, double-blind, placebo-controlled randomized six-month trial to evaluate efficacy and safety of two doses safinamide (50mg/day or 100mg/day) as add-on to levodopa therapy versus levodopa therapy alone, in patients with mid- to late-stage PD experiencing motor fluctuations.
- The completed 018 study (the 016 extension study): a phase III, double-blind, randomized, placebo-controlled, 18-month extension to Study 016, to evaluate the long-term efficacy and safety of a low (50 mg/day) and high (100 mg/day) dose of safinamide, compared with placebo, as add-on treatment to levodopa therapy in patients with mid- to late-stage PD experiencing motor fluctuations.

### 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.

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### About Merck Serono

Merck Serono is the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. In the United States and Canada, EMD Serono operates as a separately incorporated affiliate of Merck 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 metabolic disorders (Saizen® and Serostim®, somatropin), (Kuvan®, sapropterin dihydrochloride), (Egrifta®, tesamorelin), 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 over € 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 rheumatology.

### About Merck

Merck is a global pharmaceutical and chemical company with total revenues of € 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 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 shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

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