MERCK SERONO S.A.
Form 6-K
May 02, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2007

Commission File Number 1-15096

Merck Serono S.A.

(Translation of registrant s name into English)

15 bis, Chemin des Mines
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Switzerland

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F x Form 40-F o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): o

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Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes o No x

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- .

News Release

May 2, 2007

Phase III Data on Safinamide in Parkinson s Disease
Presented at American Academy of Neurology 59th Annual Meeting

Geneva, Switzerland, May 2, 2007 Merck Serono S.A. (virt-x: SEO) announced today that Phase III data on safinamide, a new agent in Phase III development for the treatment of Parkinson s disease symptoms, were presented by Professor Fabrizio Stocchi at the American Academy of Neurology 59th Annual Meeting in Boston, Massachusetts, USA. These data are from a 6-month (24 weeks), randomized, double blind, placebo-controlled, international trial.

These data are promising for patients with Parkinson s disease, said Fabrizio Stocchi, Professor of Neurology and Honorary Consultant at the IRCCS San Raffaele Rome, University La Sapienza, and principal investigator of the study. The data not only show the benefit of safinamide on motor symptoms and activities of daily living, but also indicate an effect on cognitive performance, which may represent a major advantage for the patient.

The data demonstrated that the addition of safinamide to a stable dose of a single dopamine agonist in patients with early stage Parkinson s disease resulted in a statistically significant improvement in motor symptoms, as measured by the Unified Parkinson s Disease Rating Scale(1) (UPDRS) Part III Motor Score (primary endpoint). After 24 weeks of treatment with safinamide at the dose of 50 to 100 mg once daily, the UPDRS Part III Motor Score was significantly improved over the effect of dopamine agonist monotherapy (difference between end of study and baseline of minus 6.0 ± 7.2 in the safinamide-treated group versus minus 3.6 ± 7.1 in the placebo group; p=0.0419; 95% CI=[-3.7;-0.1]).

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In addition, treatment with safinamide at the dose of 50 to 100 mg once daily over a 24-week period resulted in a significant improvement of UPDRS Part II Activities of Daily Living Score, compared with dopamine agonist monotherapy (difference between end of study and baseline of minus 2.2 ± 3.8 in the safinamide-treated group versus minus 1.2 ± 3.5 in the placebo group; p=0.0248; 95% CI=[-1.8;-0.1]).

Safinamide was also studied for effects on cognition. Compared with patients on dopamine agonist monotherapy, the addition of safinamide was associated with an improvement in cognitive function as shown by an improvement in tests assessing spatial working memory, strategic target detection and auditory number sequencing.

The side effects observed in the safinamide group were similar to those observed in the placebo group.

The trial was conducted in Europe, South America and Asia. A total of 270 early stage Parkinson s disease patients (less than 5 years of disease) treated with a stable dose of a single dopamine agonist for at least 4 weeks were randomized to one of the three arms of the study to receive either safinamide at a dose of 50 to 100 mg once daily (90 patients), or safinamide at a dose of 150 to 200 mg once daily (90 patients) or matching placebo tablets (90 patients), as an add-on treatment to dopamine agonist therapy.

The higher safinamide dose-range of 150 to 200 mg per day did not offer any incremental advantage over safinamide 50 to 100 mg per day dose-range based on UPDRS scoring.

A one-year (52-week) extension phase of this study is ongoing. A second Phase III pivotal study of safinamide, in patients with mid-to-late stage Parkinson s disease with motor fluctuations treated with a stable dose of levodopa, was initiated in November 2006.

Merck Serono has exclusive worldwide rights to develop, manufacture and commercialize safinamide in Parkinson s disease, Alzheimer s disease, other cognitive disorders and restless leg syndrome, as per the agreement signed with Newron in October 2006.

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(1) The UPDRS is one of the most widely used rating scales used to follow the course of Parkinson s disease.

It is made up of 42 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 in particular to follow the progression of a person s Parkinson s disease.

About safinamide

Safinamide is an alpha-aminoamide derivative which is orally administered. Studies suggest that safinamide may combine the inhibition of dopamine re-uptake and MAO-B, two key mechanisms involved in the control of dopamine concentration in the brain, and inhibition of glutamate release. If regulatory approvals are obtained, Merck Serono and Newron believe that safinamide, as an adjunctive treatment to dopamine agonists and levodopa, may have a competitive advantage over current therapies for Parkinson s disease.

About Parkinson s disease

Parkinson s disease is a degenerative disorder of the central nervous system that often impairs the sufferer 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.

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Forward-looking statements

Some of the statements in this press release are forward looking. Such statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Merck Serono S.A. and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Merck Serono s current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono s Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on February 28, 2006. These factors include any failure or delay in Merck Serono s ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, the outcome of any government investigations and litigation. Merck Serono is providing this information as of the date of this press release, and has no responsibility to update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

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About Merck Serono S.A.

Merck Serono S.A. is a global biotechnology leader, with sales in over 90 countries. The Company is the world leader in reproductive health, with Gonal-f®, Luveris® and Ovidrel®/Ovitrelle®. It has strong market positions in neurology, with Rebif®, as well as in metabolism and growth, with Saizen®, Serostim® and Zorbtive . The Company has recently entered the psoriasis area with Raptiva®. Merck Serono s research programs are focused on growing these businesses and on establishing new therapeutic areas, including oncology and autoimmune diseases.

Bearer shares of Merck Serono S.A., the holding company, are traded on the virt-x (SEO).

About Merck

Merck is a global pharmaceutical and chemical company with sales of EUR 6.3 billion in 2006, a history that began in 1668, and a future shaped by 35,091 employees in 62 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.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MERCK SERONO S.A.,
a Swiss corporation
(Registrant)

Date May 2, 2007

By: /s/ Francois Naef
Name: Francois Naef
Title: Chief Administrative Officer