MERCK SERONO S.A.
Form 6-K
January 24, 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 January 2007

Commission File Number 1-15096

Merck Serono S.A.

(Translation of registrant s name into English)

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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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): o

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 o.

News Release

January 24, 2007

Merck Serono Has Initiated the ONWARD Study to Evaluate Oral Cladribine as Add-on Treatment for Multiple Sclerosis

- ONWARD Phase II Trial Will Assess Therapeutic Benefit of Oral Cladribine Added-on to New Formulation of Rebif® in Multiple Sclerosis Patients

Geneva, Switzerland, January 24, 2007 Merck Serono (virt-x: SERO and NYSE: SRA) announced today that it has begun the ONWARD (**O**ral Cladribine Added O**N** To Rebif New Formulation in Patients **W**ith **A**ctive **R**elapsing **D**isease) Phase II study. The ONWARD study will evaluate the safety, tolerability and efficacy of two dose regimens of Merck Serono s proprietary oral formulation of cladribine when added to the new formulation of Rebif® (interferon beta-1a) in multiple sclerosis (MS) patients with active disease despite treatment with Rebif®. Oral cladribine is currently also evaluated as a monotherapy in a fully enrolled Phase III pivotal trial (the CLARITY study) for first-line treatment of relapsing forms of MS. The new formulation of Rebif® is under regulatory review by the European Medicines Agency, the US Food and Drug Administration and other healthcare authorities.

Multiple sclerosis patients with signs of active disease while on treatment with a disease modifying drug may benefit from adding another agent with a different mechanism of action, to complement and increase the overall efficacy while maintaining an acceptable safety and tolerability profile, said Bruno Musch, Merck Serono s Head of Neurology Clinical Development. The different mechanism of action and the oral intermittent administration of oral cladribine make it a potentially useful add-on therapy to Rebif® at a critical time of disease progression.

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Oral cladribine is currently being evaluated as a monotherapy in the CLARITY Phase III pivotal study and is on track to become the first oral therapy for first-line treatment of multiple sclerosis , said Franck Latrille, Merck Serono s Head of Product Development. We are now initiating the ONWARD study as we believe that oral cladribine also has a great potential as an add-on therapy, for patients who have signs of active relapsing disease while on a treatment.

The ONWARD study is a two-year (96 weeks), randomized, double-blind, placebo-controlled, international trial. The trial will be conducted in 40 sites located in the United States and in Europe. It will involve 260 MS patients who have experienced at least one relapse while taking Rebif® during the year prior to study enrollment. Study participants will be randomized in one of the three arms of the study to receive one of two different dose regimens of oral cladribine or matching placebo tablets, in addition to the new formulation of Rebif® 44 micrograms subcutaneous three times a week. In the study, oral cladribine is given in two or four treatment cycles in the first year, with each cycle consisting of daily administration for four or five consecutive days, which means study patients take oral cladribine therapy for only 8 to 20 days during that year. In the second year, two treatment cycles are administered in all dose regimens.

The primary safety endpoints of the ONWARD study consist of a wide range of safety and tolerability parameters measured during 96 weeks of treatment. The primary efficacy endpoint is the mean change in the number of new T1 gadolinium-enhanced lesions per subject per magnetic resonance imaging (MRI) scan from baseline to 96 weeks.

About oral cladribine

Merck Serono s proprietary oral formulation of cladribine is currently being evaluated in Phase III as a treatment for patients with relapsing forms of multiple sclerosis (MS). Cladribine is a small molecule that interferes with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are involved in the pathological process of MS. Through its differentiated mechanism of action, oral cladribine may offer a safe and effective new option to patients with MS.

About Rebif®

Rebif® (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS) and is similar to the interferon beta protein produced by the human body. Interferon helps modulate the body s immune system, fight disease and reduce inflammation.

Rebif®, which was approved in Europe in 1998 and in the US in 2002, is registered in more than 80 countries worldwide. In the United States, Rebif® is co-marketed by EMD Serono, Inc. (the US affiliate of Merck Serono) and Pfizer Inc. Rebif® has been proven to delay the progression of disability, reduce the frequency of relapses and reduce MRI lesion activity and area(1). Rebif® is not approved for treatment of chronic progressive MS. Rebif® is available in a 22 mcg and 44 mcg ready-to-use pre-filled syringe and a titration pack, and can be stored at room temperature for up to 30 days if a refrigerator is not available.

Most commonly reported side effects are injection site disorders, flu-like symptoms, elevation of liver enzymes and blood cell abnormalities. Patients, especially those with depression, seizure disorders, or liver problems, should discuss treatment with Rebif® with their doctors.

About Merck Serono and multiple sclerosis

Merck Serono is a leader in multiple sclerosis (MS) with Rebif® (interferon beta-1a), a disease-modifying drug used to treat relapsing forms of MS, which is registered in more than 80 countries worldwide. In addition to Rebif®, the Company also offers a second therapy within its US portfolio of MS therapies: Novantrone® (mitoxantrone for injection concentrate) for worsening forms of MS. Full prescribing information for these products can be obtained by contacting the Company or visiting its website. Additional therapeutic options are currently under development at Merck Serono, including oral cladribine, currently in Phase III and potentially the first oral therapy for MS, as well as several products in early stage development including: osteopontin, an MMP-12 inhibitor, a JNK inhibitor and interferon beta:Fc. Merck Serono also is taking a leading role in developing an understanding of the role of genetics in MS, with a whole genome scan currently

About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. The World Health Organization estimates that up to 2.5 million people suffer from MS worldwide. While symptoms can vary, the most common

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(1) The exact correlation between MRI findings and the current or future clinical status of patients, including disability progression, is unknown.

symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

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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

Merck Serono 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 (SERO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

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 about 35,000 employees (including Merck Serono) in 56 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 a 73% interest and free shareholders own the remaining 27%. 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: January 24, 2007

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