

MERCK SERONO S.A.  
Form 6-K  
January 18, 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)

15 bis, Chemin des Mines  
Case Postale 54  
CH-1211 Geneva 20  
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 ☒ Form 40-F ☐

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): ☐

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): ☐

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 ☐ No ☒

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

**News Release**

**January 16, 2007**

**Merck Serono Completes Patient Enrollment in CLARITY Phase III  
Pivotal Clinical Trial of Oral Cladribine**

- **Oral Cladribine on Track to Become First Oral Disease Modifying  
Treatment for Multiple Sclerosis**

Geneva, Switzerland, January 16, 2007 Merck Serono (virt-x: SEO and NYSE: SRA) announced today that patient enrollment has been completed in the CLARITY (CLAdRIbine Tablets Treating MS Orally) study, a Phase III pivotal clinical trial evaluating the efficacy and safety of Merck Serono's proprietary oral formulation of cladribine for the treatment of relapsing forms of multiple sclerosis (MS).

The completion of patient enrollment into the CLARITY pivotal trial is a major milestone in the development program of oral cladribine, said Franck Latrille, Merck Serono's Head of Product Development. It brings us one step closer to our objective of offering patients the first oral therapy for first line treatment of multiple sclerosis, with the convenience of short courses of therapy given intermittently.

The CLARITY study is a two-year (96 weeks), randomized, double-blind, placebo-controlled, international trial. It enrolled more than 1,300 patients and will provide data on key endpoints including clinical relapses, disability progression and magnetic resonance imaging (MRI). Study participants have been enrolled 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 the study, oral cladribine is given in two or four treatment cycles in the first year, with each cycle consisting of daily administration for five consecutive days, which means study patients take oral cladribine therapy for only 10 or 20 days during the year. In the second year, two treatment cycles are administered.

**Merck Serono**

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The increased convenience resulting from the oral intermittent administration of oral cladribine has the potential to address an important unmet medical need in patients with MS.

Oral cladribine was designated a Fast Track product by the US Food and Drug Administration (FDA) in September 2006. Under Fast Track designation, oral cladribine is eligible for Priority Review and the FDA may consider portions of the marketing application for review before the New Drug Application (NDA) is completed.

#### **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 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 underway.

#### **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

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 (SEO) 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 5.9 billion in 2005, 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.

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## 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 18, 2007

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

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