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 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- .

News Release

January 16, 2007

Merck Serono Announces Positive Results from Phase III Diet Study of Phenoptin for phenylketonuria

- Phenoptin Significantly Increases Phenylalanine Tolerance in BH4-Responsive Patients; All Pre-Specified Endpoints Met

Geneva, Switzerland, January 16, 2007 Merck Serono (virt-x: SEO and NYSE: SRA) today announced positive results from the Phase III diet study of Phenoptin (sapropterin dihydrochloride), in combination with diet, in 4-12 year old patients. Phenoptin is an investigational oral small molecule, being developed in partnership with BioMarin, for the treatment of patients with phenylketonuria (PKU), who have elevated phenylalanine (Phe) levels. The results show that all pre-specified efficacy and safety endpoints of the double-blind, placebo-controlled study were met. Phenoptin treatment caused a significant increase in phenylalanine tolerance as well as a reduction in blood phenylalanine levels. In addition, the data showed that Phenoptin was well tolerated in younger PKU patients who were under dietary control.

Dr. Harvey Levy, Professor of Pediatrics at Harvard Medical School and Senior Associate in Medicine and Genetics atChildren s Hospital Boston, stated, This is the first time a controlled study has demonstrated the potential of tetrahydrobiopterin, or 6R-BH4, to liberalize diet in PKU patients. If approved, Phenoptin offers patients who respond to BH4 a real opportunity to relax their diets and the possibility to perhaps reduce or even eliminate the need for nutritional supplementation from medical food.

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Key findings from the study:

- In the primary endpoint, Phenoptin enabled a mean increase of 20.9 mg/kg/day in Phe supplementation for those patients on Phenoptin ($p<0.001$). Patients treated with Phenoptin were able to, on average, double their baseline intake. At week 10, they were able to take a mean total Phe intake of approximately 43.8 mg/kg/day, while maintaining controlled blood Phe levels. The mean Phe tolerance represents approximately half the amount of Phe in a normal diet.

- The two secondary endpoints were also met:

- Phenoptin provided a mean reduction of 148.5 µmol/L (from a starting mean of 275.7 µmol/L) in blood Phe level from baseline to week 3 (prior to Phe supplementation) ($p<0.001$).

- At the end of the study, patients on Phenoptin were able to increase their daily Phe supplement by a mean of 20.9 mg/kg versus a mean of 2.9 mg/kg for placebo patients ($p<0.001$).

- The incidence and types of adverse events were similar in both the placebo and Phenoptin groups and all reported events were mild or moderate in severity. There were two serious adverse events (one in the Phenoptin group and one in the placebo group), neither of which were considered drug-related. The most frequently reported adverse events were headache, abdominal pain, fatigue, and diarrhea.

The 11-week multi-center double-blind, placebo controlled Phase 3 study enrolled 90 patients between the ages of 4 and 12 years, with blood Phe levels below 480 µmol/L. Patients were screened for responsiveness to Phenoptin with an open-label one-week treatment at a dose of 20 mg/kg/day (Part 1). Of the 89 patients who completed Part 1, 50 subjects demonstrated a blood Phe reduction of at least 30%, and 45 were randomized to Phenoptin (20 mg/kg/day) or placebo in a 3:1 ratio, and enrolled in the 10-week double-blind, placebo-controlled portion of the study (Part 2). For the first three weeks, patients maintained their pre-existing restricted diet with no supplementation of phenylalanine. Thereafter, every other week, specific amounts of phenylalanine were added (or removed) to the restricted diet of each patient according to pre-defined blood phenylalanine levels. The maximum amount of Phe that could be added to a patient diet during the study was 50 mg/kg/day.

BioMarin and Merck Serono remain on track to file the New Drug Application in the US and Marketing Authorization Application in Europe for Phenoptin in PKU in the second and third quarters of 2007, respectively.

About Phenoptin

Phenoptin is an investigational oral small molecule therapeutic for the treatment of PKU. The active ingredient in Phenoptin, sapropterin dihydrochloride, is the synthetic form of 6R-BH4 (tetrahydrobiopterin), a naturally occurring enzyme cofactor that works in conjunction with phenylalanine hydroxylase (PAH) to metabolize Phe. Preliminary clinical data have suggested that Phenoptin has a potential to produce significant reductions in blood Phe levels in the subset of patients who are BH4-responsive. BioMarin and Merck Serono estimate that Phenoptin could be a potential treatment option for approximately 30 percent to 50 percent of the estimated 50,000 individuals in the developed world who have been diagnosed with PKU.

Phenoptin received orphan drug designation to treat PKU from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMEA). If Phenoptin becomes the first drug therapy approved for the treatment of PKU, Phenoptin would receive seven years of market exclusivity in the United States and 10 years in the European Union for this indication. Additionally, the FDA has granted Phenoptin Fast Track designation, which is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

Under the terms of the agreement with BioMarin, Merck Serono has exclusive rights to market Phenoptin in all territories outside the United States and Japan. BioMarin has exclusive rights to market Phenoptin in the United States.

About PKU

PKU, a genetic disorder affecting approximately 50,000 diagnosed patients in the developed world, is caused by a deficiency of the enzyme phenylalanine hydroxylase (PAH). PAH is required for the metabolism of phenylalanine (Phe), an essential amino acid found in most protein-containing foods. If the active enzyme is not present in sufficient quantities, Phe accumulates to abnormally high levels in the blood and brain, resulting in a variety of complications including severe mental retardation and brain damage, mental illness, seizures and tremors, and cognitive problems. As a result of global newborn screening efforts implemented in the 1960s and early 1970s, virtually all PKU patients in developed countries have been diagnosed at birth. The only treatment currently available for PKU patients is a highly restrictive and expensive medical food diet that most patients fail to adhere to the extent needed for achieving adequate control of blood Phe levels. To learn more about PKU, please visit www.PKU.com. Information on this website is not incorporated by reference into this press release.

Positive Results from Phase III Clinical Study of Phenoptin for PKU

Positive results of a Phase III, double-blind, placebo-controlled clinical study of Phenoptin (sapropterin dihydrochloride), an investigational oral small molecule for the treatment of phenylketonuria (PKU) were reported on March 15, 2006. Results confirmed that all pre-specified primary and secondary endpoints were met and data demonstrated a statistically significant reduction at six weeks in blood phenylalanine (Phe) levels ($p<0.0001$) in patients receiving Phenoptin, compared with those receiving placebo.

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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.

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