SERONO S A
Form 6-K
January 05, 2005

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

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

For the month of January, 2005

Serono S.A.
(Registrant's Name)

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Case Postale 54
CH-1211 Geneva 20
Switzerland
(Address of Principal Executive Offices)

1-15096
(Commission File No.)

(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

(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 X

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

SERONO

Media Release

FOR IMMEDIATE RELEASE

SERONO COMPLETES PATIENT ENROLLMENT IN
REBIF(R) VERSUS COPAXONE(R) COMPARATIVE CLINICAL TRIAL

HEAD-TO-HEAD TRIAL WILL PROVIDE DATA ON THE COMPARATIVE EFFICACY AND SAFETY OF REBIF(R) AND COPAXONE(R) IN TREATMENT OF PATIENTS WITH MULTIPLE SCLEROSIS

GENEVA, SWITZERLAND, JANUARY 5, 2005 - Serono (virt-x: SEO and NYSE: SRA) announced today that patient enrollment has been completed in a multi-national Rebif(R) (interferon beta-1a) versus Copaxone(R) (glatiramer acetate) comparative clinical trial. This two-year trial is designed to compare the efficacy of the two therapies in patients with relapsing remitting multiple sclerosis (RRMS), who were previously untreated with disease modifying therapies.

Over 700 patients have been enrolled and are being treated either with Rebif(R) 44 mcg administered three times per week by subcutaneous injection or Copaxone(R) 20 mg administered daily by subcutaneous injection. The primary outcome of the trial is time to first relapse. Secondary outcomes include assessments of MRI (magnetic resonance imaging) brain scans and disability progression. Physicians performing the neurological examinations and radiologists assessing the MRI scans do not know what treatment each patient has been allocated to.

"We believe that a head-to-head trial is necessary to provide scientific data that can be used to compare different therapeutic options. In the past, we have provided such data, comparing Rebif(R) with Avonex(R) in the landmark EVIDENCE trial, which allowed Rebif(R) to gain market approval in the U.S. under the terms of the Orphan Drug Act," said Paul Lammers, Chief Medical Officer of Serono, Inc. "The ongoing Rebif(R) versus Copaxone(R) trial will provide comparative data that will support an evidence-based approach for rational treatment decisions in multiple sclerosis, and we expect the data to support Rebif(R) as the foundation therapy for treatment of multiple sclerosis."

Rebif(R) is the only approved MS therapy proven in a four-year clinical study in all three key measures of treatment effectiveness: reducing MRI lesion area and activity(1), reducing relapses and delaying the progression of disability. Rebif(R) is the most prescribed MS disease modifying drug outside the US and is the fastest growing one in the US.

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1 The exact relationship between MRI findings and the clinical status of patients is unknown.

ABOUT EVIDENCE

In the EVIDENCE study, Rebif(R) was shown to be superior over Avonex(R) in reducing relapses and MRI measures at 24, 48 weeks and at trial completion (average of 64 weeks)(1). The study involved 677 patients with relapsing remitting multiple sclerosis (RRMS), and was designed to compare the proportion of patients who were treated with either Rebif(R) (44 mcg three times weekly, subcutaneously) or Avonex(R) (30 mcg once weekly, intramuscularly) who remained relapse-free after 24 weeks (primary endpoint) and 48 weeks of therapy. The results showed that patients treated with Rebif(R) were significantly more likely to remain relapse free at 24 and 48 weeks than were patients treated with

Avonex(R). In addition, patients taking Rebif(R) had fewer active lesions per MRI scan for all studied activity measures and there was an approximate one-third relative difference in favor of Rebif(R) for measures of MRI lesion activity. A comparison of safety based on the EVIDENCE study 48-week results indicates that both Rebif(R) and Avonex(R) are associated with a similar overall side effect profile, including flu-like symptoms, headache, fatigue and muscle ache that occur in about half of the patients treated. Adverse events reported more frequently with Rebif(R) were injection site reactions, asymptomatic liver function test changes and white blood cell abnormalities. Flu-like symptoms were reported in significantly more patients treated with Avonex(R) than with Rebif(R).

ABOUT REBIF(R)

Rebif(R) (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis 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(R), 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(R) is co-marketed by Serono, Inc. and Pfizer Inc. Rebif(R) has been proven to reduce MRI lesion activity and area(1), reduce the frequency of relapses, and delay the progression of disability. Rebif(R) is available in a 22 mcg and 44 mcg ready-to-use pre-filled syringe 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(R) with their doctors.

ABOUT MULTIPLE SCLEROSIS

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. Multiple sclerosis may affect approximately two million people worldwide. While symptoms can vary, the most common symptoms of multiple sclerosis include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of multiple sclerosis are the most common.

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1 The exact relationship between MRI findings and the clinical status of patients is unknown.

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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 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 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 March 25, 2004. These factors include any failure or delay in 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, and government regulations limiting our ability to sell our products. Serono 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 SERONO

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R), Zorbtive(TM) and Raptiva(R). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth and has recently entered the psoriasis area. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US$2,018.6 million, and a net income of US$390.0 million, making it the third largest biotech company in the world. Its products are sold in over 90 countries. Bearer shares of 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).

FOR MORE INFORMATION, PLEASE CONTACT:

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SIGNATURES

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.

SERONO S.A.
a Swiss corporation
(Registrant)

January 5, 2005

By: /s/ Stuart Grant

Name: Stuart Grant
Title: Chief Financial Officer