SERONO S A
Form 6-K
November 20, 2003

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 November, 2003

Serono S.A.
(Registrant's Name)

15 bis, Chemin des Mines
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

STUDY IN NEW ENGLAND JOURNAL OF MEDICINE SHOWS EXTENDING RAPTIVA(TM) TREATMENT PROVIDES RAPID AND CONTINUOUS BENEFIT

GENEVA, SWITZERLAND - NOVEMBER 20, 2003 - Serono S.A. (virt-x: SEO and NYSE: SRA) announced today results of a study published in the New England Journal of Medicine in which patients with moderate-to-severe plaque psoriasis who extended treatment from 12 to 24 weeks both improved and maintained response with continuous Raptiva (efalizumab) therapy.

Raptiva is designed to provide continuous control of chronic moderate-to-severe plaque psoriasis and can be self-administered by patients as a single, once-weekly, subcutaneous injection. The results published today are from one of four randomized, placebo-controlled Phase III studies that were included in the Serono's application to market Raptiva in the EU and other countries.

"Psoriasis is a life-long, chronic disease that requires continuous control of symptoms," said Dr. Mark Lebwohl, chairman, Department of Dermatology, Mt. Sinai School of Medicine. "These data support Raptiva's effectiveness in treating psoriasis and its ability to deliver rapid and sustained improvement of symptoms in patients."

77 PERCENT OF PATIENTS SUSTAINED RESPONSE WITH CONTINUED TREATMENT
The study reported today is based on a Phase III randomized, double-blind, parallel-group, placebo-controlled, multi center study, involving 597 patients aged 18 to 75 with moderate-to-severe plaque psoriasis. Patients were randomized to receive subcutaneous Raptiva (1 or 2 mg/kg/wk) or placebo for 12 weeks. Based upon response after 12 weeks, patients either received an additional 12 weeks of Raptiva or placebo. Treatment was discontinued at 24 weeks and patients were followed for a further 12 weeks.

At week 12, more than half of Raptiva-treated patients experienced a clinically meaningful benefit, with some patients achieving clinical benefit as early as four weeks. After 12 weeks of Raptiva therapy, 22 percent of patients receiving 1 mg/kg of Raptiva and 28 percent of patients receiving 2 mg/kg of Raptiva reached the primary efficacy endpoint of 75 percent or greater improvement in Psoriasis Area and Severity Index (PASI) scores compared to five percent of placebo-treated patients. Over this same interval, 52 percent and 57 percent of patients receiving 1 or 2 mg/kg Raptiva, respectively, achieved 50 percent or greater improvement in PASI compared to 16 percent of placebo-treated patients. Of the Raptiva-treated patients with 75 percent or greater PASI scores at week 12, 77 percent who were continued on Raptiva

maintained improvement through week 24 compared with 20 percent of patients switched to placebo. Approximately 90 percent of these patients maintained a 50 percent PASI improvement score at Week 24.

"The strength of these results clearly illustrates the benefit of continuous therapy with Raptiva and supports the efficacy seen in over 3,000 patients treated with Raptiva," said Frank Latrille, Serono's Senior Executive Vice President Global Product Development.

ABOUT RAPTIVA(TM)

As a targeted T-cell modulator, Raptiva is designed to block the activation of T-cells that cause psoriasis without destroying them.

Raptiva has been studied as a once-weekly therapy for the continuous treatment of moderate-to-severe plaque psoriasis. In clinical trials, Raptiva was administered via subcutaneous injection and in several of the trials was self-administered by some patients in their homes.

Serono has the rights to develop and market Raptiva(TM) worldwide outside of the United States and Japan. Development and marketing rights in the United States remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA). On October 27, 2003, Raptiva was approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy. Raptiva is not yet approved outside of the US.

More than 3,000 patients have been treated with Raptiva to date, creating the largest existing database of patients treated with a biologic therapy for psoriasis.

ABOUT PSORIASIS

Psoriasis occurs when new skin cells grow abnormally, resulting in thick, red, scaly, inflamed patches. Plaque psoriasis, the most common form of the disease is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known cure.

ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa), Ovidrel(R)/Ovitrelle(R) (choriogonadotropin alfa for injection), Rebif(R) (interferon beta-1a), Serostim(R) [somatropin (rDNA origin) for injection] and Saizen(R) [somatropin (rDNA origin) for injection]. (Luveris(R) is not approved in the USA). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are over 30 projects in development.

Serono was awarded the International James D. Watson 2003 Helix Award from the Biotechnology Industry Organization (BIO) in recognition of the Company's outstanding leadership and highest standards of scientific and product achievement.

In 2002, Serono achieved worldwide revenues of US$1.538 billion, and a net income of US$321 million, making it the third largest biotech company in the world. The Company operates in 44 countries, and its products are sold in 94 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).

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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 April 17, 2003. 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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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)

November 20, 2003

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer