SERONO S A
Form 6-K
May 30, 2003

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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 May, 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 Ö 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-_____)

Media Release

FOR IMMEDIATE RELEASE

FINAL 63-WEEK EVIDENCE STUDY DATA CONTINUE TO SHOW
REBIF® SIGNIFICANTLY MORE EFFECTIVE THAN AVONEX® IN REDUCING
FREQUENCY OF RELAPSES AND MRI ACTIVITY
IN RELAPSING FORMS OF MS

Geneva, Switzerland, Rockland, MA, and New York, NY, May 30, 2003, Serono, S.A. (virt-x: SEO and NYSE: SRA) and Pfizer Inc (NYSE: PFE)

Serono, S.A. and Pfizer Inc today announced that the final 63-week findings from the Rebif® (interferon beta-1a) vs. Avonex® (interferon beta-1a) EVIDENCE head-to-head study continue to show that Rebif® is significantly more effective in reducing frequency of relapses and MRI activity as compared to Avonex®.[1] These newly released data further support the benefit of increased dose and frequency of interferon administration in the treatment of relapsing forms of multiple sclerosis (MS). The findings are consistent with data comparing Rebif® and Avonex® at 24 and 48 weeks.[2] The 63-week results will be presented by Hillel Panitch, M.D., a University of Vermont College of Medicine clinical researcher and member of the EVIDENCE Study Group, at the annual meeting of the Consortium of Multiple Sclerosis Centers held this week in San Diego, CA.

This additional data comparing Rebif® and Avonex® provides further information for physicians and people with relapsing forms of MS in choosing an interferon treatment, said Dr. Panitch. It adds to the weight of scientific data supporting the clinical superiority of Rebif® over Avonex® at reducing frequency of relapses as observed at 24 and 48 weeks, he added.

The EVIDENCE study, which involved 677 patients with relapsing remitting MS, was designed to compare the proportion of MS patients treated with either Rebif® (44 mcg three times weekly, subcutaneously) or Avonex® (30 mcg once weekly, intramuscularly) who were relapse-free after 24 weeks (primary endpoint) and 48 weeks. Approximately 90% of patients continued in the study for an average of 63 weeks.

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[1] The exact relationship between MRI findings and clinical outcomes for patients is unknown.

[2] Panitch H, Goodin DS, Francis G, et al. Randomized, comparative study of interferon beta-1a treatment regimens in MS: The EVIDENCE (Evidence for Interferon Dose-response European-North American Comparative Efficacy) Trial. Neurology 2002; 59: 1496-1506.

EVIDENCE Study data over 63 weeks consistent with previous findings

At 63 weeks, 56% of Rebif® patients versus 48% of Avonex® patients remained relapse free (p=0.023). Rebif® patients had a 17% relative increase in the risk to remain relapse free as compared to Avonex® patients, and is consistent with previously published EVIDENCE Study data. Other relapse measures such as overall relapse rate, time to first relapse, and steroid use for relapses were also significantly better in Rebif® than Avonex® patients.

Regarding MRI activity, mean T2 active lesion count was 0.9 for Rebif® treated patients and 1.4 for Avonex® treated patients (p<0.001); mean proportion of active scans per patient was 27% for Rebif® treated patients and 44% for Avonex® treated patients (p<0.001); and the proportion of patients with no active scans was 58% for Rebif® treated patients and 38% for Avonex® treated patients (p<0.001). The exact relationship between MRI findings and clinical outcomes for patients is unknown.

No new safety concerns were noted with comparable numbers of treatment discontinuations in both groups. Adverse events reported more frequently with Rebif® 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® than with Rebif® (p=0.031).

Additional Information

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. MS may affect approximately two million people 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.

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

Rebif® was approved in the US on March 7, 2002, for the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability. Rebif®, which is co-promoted in the United States by Serono and Pfizer Inc, is the only drug to gain exception to the marketing exclusivity provision of the Orphan Drug Act based on superior efficacy. The Orphan Drug Act, enacted in the US in 1983, provides drug makers with commercial incentives to encourage the development of treatments for patients with rare and debilitating diseases. Rebif® was approved in Europe in 1998 and is registered for use in more than 70 countries worldwide.

US residents can find more information about Rebif® in the full prescribing information, on line at www.mslifelines.com or by calling MS LifeLines at 1-877-44REBIF. Patients should be instructed to read the Medication Guide accompanying the product. 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 with their doctors whether Rebif® is right for them.

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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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About Serono

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F® (follitropin alfa for injection), Luveris® (lutropin alfa), Ovidrel®/Ovitrelle® (choriogonadotropin alfa for injection), Rebif® (interferon beta-1a), Serostim® [somatropin (rDNA origin) for injection] and Saizen® [somatropin (rDNA origin) for injection]. (Luveris® is not approved in the USA).[3] 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 Helix 2003 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$1.546 billion, and a net income of US$321 million, making it the third largest biotech company in the world. The Company operates in 45 countries, and its products are sold in over 100 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).

About Pfizer

Pfizer Inc discovers, develops, manufactures and markets leading prescription medicines for humans and animals and many of the world s best-known consumer brands.

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[3] Package inserts for Serono's US marketed products are available at www.seronousa.com or by calling 1-888-275-7376.

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)

May 30, 2003

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer