

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
April 28, 2004

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 April, 2004

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  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- )

-----

[GRAPHIC OMITED]

Edgar Filing: SERONO S A - Form 6-K

MEDIA RELEASE

FOR IMMEDIATE RELEASE

-----  
MS PATIENTS TAKING HIGH DOSE HIGH FREQUENCY REBIF(R) SUSTAINED REDUCTION IN  
ACCUMULATION OF MRI BRAIN LESIONS OVER LONG TERM

NEW DATA PRESENT COMPREHENSIVE LONG-TERM  
MRI EVALUATION OF TOTAL LESION AREA IN MS

SERONO (VIRT-X: SEO AND NYSE: SRA), PFIZER INC (NYSE: PFE)

SAN FRANCISCO, CA (APRIL 28, 2004) - New long-term data support the importance of early treatment with high dose, high frequency Rebif(R) (interferon beta-1a) 44 mcg in reducing the long-term accumulation of brain lesion volume in patients with relapsing remitting multiple sclerosis (MS). These findings, presented at the 56th Annual Meeting of the American Academy of Neurology, provide a comprehensive long-term evaluation of MS brain lesion volume as measured by magnetic resonance imaging (MRI) and show the sustained effects of Rebif 44 mcg (three times weekly, subcutaneously).

"This is good news for people with relapsing remitting multiple sclerosis as it shows that earlier initiation of high dose, high frequency interferon beta-1a therapy with Rebif(R), compared to a two-year delay, is associated with a greater likelihood of reduction in total lesion accumulation over time," said Dr. David Li of the University of British Columbia in Vancouver, British Columbia, Canada.

The findings show that Rebif(R) 44 mcg continued to have an impact in reducing the accumulation of MS lesion volume, as measured on MRI, in patients with relapsing remitting MS (RRMS) after 7-8 years of follow up. MRI lesions provide one of the most sensitive measures of MS disease activity for many patients. The poster reports the results of long-term changes in the accumulation of MRI T2 lesion volume among RRMS patients, who were initially randomized to receive Rebif(R) 44 mcg, Rebif(R) 22 mcg (three times weekly subcutaneously) or placebo, in the PRISMS(1) long term follow up (LTFU) study. After the initial two-year time frame, placebo patients commenced therapy with Rebif(R) for subsequent years.

-----  
1 PRISMS: Prevention of Relapses and disability by Interferon beta-1a Subcutaneously in Multiple Sclerosis.

1/3

The PRISMS LTFU MRI evaluation compared lesion volume change from baseline to the LTFU visit (an average of 7.4 years later). In the PRISMS LTFU study, patients initially randomized to Rebif(R) 44 mcg were less likely to have increased lesion area than those initially given Rebif(R) 22 mcg or placebo for two years followed by Rebif(R) for up to 5.5 years. The proportion of patients showing an increase in total lesion burden over an average of 7.4 years was lowest for Rebif(R) 44 mcg (54%), followed by Rebif(R) 22 mcg (66%) compared to the placebo/Rebif(R) patients (73%). This represents a 26% relative reduction

## Edgar Filing: SERONO S A - Form 6-K

in the risk of lesion accumulation for Rebif 44 mcg (three times weekly) initiated early compared to delayed initiation of treatment. The exact relationship between MRI findings and the clinical status of patients is unknown.

### ABOUT THE PRISMS AND THE PRISMS LONG-TERM FOLLOW UP (LTFU) STUDIES

The long-term MRI lesion area data come from an observational follow-up of the patients originally enrolled in the PRISMS study, a double blind, placebo-controlled study, which began in 1994, and involved 560 patients at 22 centers in 9 countries. Patients were originally randomized to receive Rebif(R) 44 mcg three times weekly (184 patients), Rebif(R) 22 mcg three times weekly (189 patients) or placebo (187 patients). After the first two years, placebo patients were re-randomized to receive one of the two active doses of Rebif(R), while patients already on active treatment continued with the same dose. Overall, 68% of the original randomized cohort returned for the Long Term Follow Up.

The two-year results from the PRISMS study showed that both doses of interferon beta-1a significantly reduced MRI activity and area, relapse rates, as well as reduced progression of Expanded Disability Status Scale (EDSS) scores. Dose-blinded extension data to four years demonstrated sustained treatment benefit over time, with increasing evidence of a dose-effect that favored Rebif(R) 44 mcg. The Long-Term Follow Up assessment was then performed on the seventh or eighth anniversary of patients' enrollment in the original PRISMS study, and these data provided a comprehensive long-term clinical and MRI assessment of cohort of MS patients on therapy with interferon. The LTFU results support the long-term effectiveness of Rebif(R) 44 mcg in the treatment of RRMS.

### ABOUT REBIF(R)

Rebif(R) (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of MS 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, 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.

People in the US with relapsing forms of MS can find more information about Rebif(R) in the full prescribing information, online at [www.Rebif.com](http://www.Rebif.com) or by

-----  
calling MS LifeLines(TM) toll-free at 1-877-44REBIF (1-877-447-3243). 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 treatment with Rebif(R) with their doctors.

MS 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.

###

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.

###

## ABOUT SERONO

Serono is a global biotechnology leader. The Company has seven recombinant products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R) and Zorbtive(TM) (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 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).

## 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.

FOR MORE INFORMATION, PLEASE CONTACT:

## SERONO IN GENEVA, SWITZERLAND:

## MEDIA RELATIONS:

Tel: +41-22-739 36 00

Fax: +41-22-739 30 85

<http://www.serono.com>

## INVESTOR RELATIONS:

Tel: +41-22-739 36 01

Fax: +41-22-739 30 22

Reuters: SEO.VX / SRA.N

Bloomberg: SEO VX / SRA US

## SERONO, INC., ROCKLAND, MA

## MEDIA RELATIONS:

Michele Rozen

Tel: +1 781 681 2481

Email: [michele.rozen@serono.com](mailto:michele.rozen@serono.com)<http://www.seronusa.com>

## INVESTOR RELATIONS:

Tel: +1 781 681 2552

Fax: +1 781 681 2912

Edgar Filing: SERONO S A - Form 6-K

PFIZER INC, NEW YORK, NY  
MEDIA RELATIONS:  
Alison Lehanski  
Tel: +1 212 733 8087  
Email: Alison.lehanski@pfizer.com

3/3

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)

April 28, 2004

By: /s/ Allan Shaw

-----  
Name: Allan Shaw  
Title: Chief Financial Officer