

Edgar Filing: SERONO S A - Form 6-K

SERONO S A
Form 6-K
February 26, 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 February, 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 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-_____)

SERONO

MEDIA RELEASE

FOR IMMEDIATE RELEASE

Edgar Filing: SERONO S A - Form 6-K

SERONO SUBMITS APPLICATION FOR EUROPEAN UNION APPROVAL OF RAPTIVA(TM) FOR PSORIASIS

GENEVA, SWITZERLAND - FEBRUARY 26, 2003 - SERONO S.A. (VIRT-X: SEO AND NYSE: SRA) Serono announced today that it has submitted a Marketing Authorization Application (MAA) to the European Agency for the Evaluation of Medicinal Products (EMA) for Raptiva(TM) (efalizumab) for the treatment of adults with moderate-to-severe psoriasis. The EMA has confirmed that the application is valid, and that the regulatory procedure has commenced.

"With the filing of Raptiva in Europe, Serono is one step nearer to entering a new therapeutic area, " said Ernesto Bertarelli, Serono's Chief Executive Officer. "The treatment advance represented by Raptiva will address many of the unmet needs of people with psoriasis."

This submission is based on efficacy and safety studies in more than 2,100 patients with psoriasis. In these clinical trials, Raptiva(TM) showed fast onset of clinical response - as early as two weeks - and control of plaque psoriasis over a one year period of treatment.

The company plans to submit the applications for the marketing authorization of Raptiva(TM) with Canadian, Australian and Swiss authorities by the end of this quarter.

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), who filed a Biologics License Application (BLA) with the FDA in December 2002.

ABOUT RAPTIVA(TM)

Raptiva(TM), a recombinant humanized monoclonal antibody, is designed to inhibit the adhesion of T-lymphocytes to other cell types by inhibiting the binding of LFA-1 to ICAM-1. This mechanism of action has a number of effects depending upon the cell type, which include: (1) inhibition of T-lymphocyte interactions with tissue-specific cells, (2) inhibition of T-lymphocyte migration, (3) inhibition of T-lymphocyte activation, proliferation and cytokine release. In the clinical Phase III studies, Raptiva(TM) was given as a once-a-week subcutaneous injection. Raptiva(TM) is currently in Phase II trials in Rheumatoid Arthritis and is being also evaluated for the treatment of Psoriatic Arthritis.

-more-

ABOUT SERONO

Serono is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Rebif(R), Serostim(R) and Saizen(R) (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.

In 2002, Serono achieved worldwide revenues of US\$1.546 billion, and a net

Edgar Filing: SERONO S A - Form 6-K

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).

###

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 May 21 2002. 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.

###

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: SEOZ.VX / SRA.N

Bloomberg: SEO VX / SRA US

SERONO, INC., ROCKLAND, MA

MEDIA RELATIONS:

Tel. +1 781 681 2340

Fax: +1 781 681 2935

<http://www.seronusa.com>

INVESTOR RELATIONS:

Tel. +1 781 681 2552

Fax: +1 781 681 2912

GENENTECH:

MEDIA CONTACT:

Tara Cooper: +1 (650) 225-5505

INVESTOR CONTACT:

Kathee Littrell: +1 (650) 225-1034

www.gene.com

-end-

Edgar Filing: SERONO S A - Form 6-K

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)

February 26, 2003

By: /s/ Allan Shaw

Name: Allan Shaw
Title: Chief Financial Officer