SERONO S A Form 6-K June 24, 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 June, 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 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

CHMP GIVES POSITIVE OPINION TO PSORIASIS PRODUCT RAPTIVA(R)

European Commission Marketing Authorisation expected during third quarter of 2004

GENEVA, SWITZERLAND - JUNE 24, 2004 - Serono (virt-x: SEO and NYSE: SRA) announced today that it has received a unanimous positive opinion from the Committee of Medicinal Products for Human Use (CHMP) recommending approval of its psoriasis product Raptiva(R) (efalizumab). The positive recommendation has been issued during this week's meeting of the CHMP, the scientific committee that evaluates medicinal products for human use within the EU since the accession of the 10 new member states on May 1, 2004.

Raptiva received the CHMP positive opinion for the 'Treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate and PUVA'. Serono expects the European Commission's Marketing Authorisation during the third quarter of this year and plans to initiate the launch of the product in EU countries shortly thereafter.

"The CHMP's positive opinion is very good news for people with psoriasis as Raptiva can offer an effective therapy to those whose needs are not met by current treatments," said Ernesto Bertarelli, Chief Executive Officer of Serono. "This indication is entirely consistent with the results of our CLEAR study, which showed that Raptiva is safe and efficacious in this significant group of high-needs patients."

Serono received authorisation for Raptiva in Switzerland in March and in Argentina last month and is awaiting the outcomes of marketing applications in a number of other territories for which it is responsible. Raptiva has also been available since November 2003 in the U.S., where it is marketed by Genentech for the treatment of moderate to severe chronic plaque psoriasis in adults aged 18 or older who are candidates for systemic therapy or phototherapy.

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Serono will hold a conference call for investors on June 25, 2004 starting at 3:00 pm CET during which its management will discuss the CHMP opinion on Raptiva. Details of the conference call are available at the end of this press release.

Additionally JPMorgan will host an Investor Day on July 7, 2004 in Geneva starting at 2:00 pm CET during which Serono management will provide an update for investors on Raptiva. This JPMorgan event will also be relayed by live audio webcast, which will be accessed through the following link: http://events.genesysrichmedia.com/JPMORGAN/2004/07/07/.

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## ABOUT RAPTIVA(R)

Raptiva(R) is a humanized therapeutic antibody designed to selectively and reversibly block the activation, reactivation and trafficking of T-cells that lead to the development of psoriasis symptoms. Raptiva is designed to be administered once weekly via subcutaneous injection and can be self-administered by patients at home.

Serono has the rights to develop and market Raptiva worldwide outside of the United States and Japan. On March 16, 2004, Serono announced approval for Raptiva in Switzerland for adult patients with moderate-to-severe plaque psoriasis. Serono announced in February 2003 that it had submitted a Marketing Authorization Application (MAA) to the European Agency for the Evaluation of Medicinal Products (EMEA) for European Union Approval of RAPTIVA in psoriasis. Development and marketing rights in the United States remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA).

More than 3,500 patients in the U.S. and Europe have been included in Raptiva trials to date, creating the largest existing database of patients taking part in studies with a biological therapy for psoriasis.

#### ABOUT PSORIASIS

Psoriasis is a T-cell mediated disease which occurs when 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.

## BACKGROUND MATERIAL

For free B-roll, video and other content about Raptiva, psoriasis and Serono, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can

download print-quality images and receive broadcast-standard video digitally or by tape from this site. Registration and video is free to the media.

### CONFERENCE CALL

Serono will hold a conference call for investors on June 25, 2004 starting at 3:00 pm CET during which its management will discuss the CHMP opinion on Raptiva. To join the telephone conference please dial 412 858 4600 (from the US), 091 610 5600 (from Switzerland), 0207 1070611 (from the UK) and +41 91 610 5600 (from elsewhere). Telephone playback will be available one hour after the conference call and until close of business 5.00 pm ET on July 2nd, 2004. To access this playback please dial the following numbers: 412 3170 088 (from the US), 091 612 4330 (from Switzerland), 0207 866 4300 (from the UK) and +41 91 612 4330 (from elsewhere) and enter the PIN code 149# from a touch tone telephone.

The conference call will also be relayed by live audio webcast, which interested parties may access via Serono's Corporate home page, www.serono.com. A link to the webcast will be provided immediately prior to the event and will be available for replay following the event.

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## 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).

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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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FOR MORE INFORMATION, PLEASE CONTACT:

CORPORATE MEDIA RELATIONS: CORPORATE INVESTOR RELATIONS:

Tel: +1 781 681 2552 Fax: +1 781 681 2912

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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)

June 24, 2004 By: /s/ Francois Naef

Name: Francois Naef Title: Secretary