

Edgar Filing: SERONO S A - Form 6-K

SERONO S A
Form 6-K
July 29, 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 July, 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-_____)

SERONO

Media Release

FOR IMMEDIATE RELEASE

Edgar Filing: SERONO S A - Form 6-K

PRELIMINARY DATA SHOWED SUSTAINED CLINICAL BENEFIT FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS PATIENTS TREATED WITH RAPTIVA FOR 30 MONTHS

GENEVA, Switzerland - July 29, 2004 - Serono (virt-x: SEO and NYSE: SRA) today announced preliminary 30-month (120 weeks) results from an open-label study evaluating the safety and efficacy of long-term continuous treatment with Raptiva(R) (efalizumab) in adults with moderate-to-severe chronic plaque psoriasis. The study results were presented as a poster at the American Academy of Dermatology ACADEMY 2004 meeting in New York. The results of this study suggest that continuous, weekly dosing of Raptiva provided sustained clinical benefit over two-and-a-half years.

Of the 159 subjects participating in the study who completed 30 months of treatment, a 75% or greater improvement on the Psoriasis Area Severity Index (PASI 75) was observed in 78% (124/159) of patients with weekly Raptiva therapy. Ninety-one percent (145/159) of patients achieved a PASI 50 response, and 45 % of patients (71/159) achieved a 90 % or greater PASI improvement (PASI 90).

"Given that psoriasis is a chronic condition, dermatologists are looking for treatment options that can provide these patients with continuous control of their disease over the long-term," said Dr. Craig Leonardi, MD Associate Clinical Professor of Dermatology, St Louis University Medical School, USA, and a study investigator. "These data represent the first 30-month data available for any advanced therapy for plaque psoriasis and support the continued use of Raptiva as an important treatment option for patients afflicted with this chronic disease."

STUDY DESIGN

In this study, 339 patients received Raptiva weekly for an initial 12 weeks and patients with a PASI 50 response or a static Physician's Global Assessment response of 'mild' or better after 12 weeks of treatment were eligible to continue on a once-weekly maintenance dose of 1mg/kg Raptiva for 12 week periods starting at week 13. Of the 339 subjects who started the study, 290 qualified for continued treatment beyond 12 weeks. For each successive three-month period of treatment, dropouts during that period were analyzed using their last available PASI assessment, but were excluded from the subsequent cohorts.

"These 30-month data give dermatologists additional insight into how Raptiva may be used to develop long-term treatment strategies for the psoriasis patients where we have approval in Switzerland and Argentina and positive opinion in Europe and Australia," said Dr. Franck Latrille, Senior Executive Vice President Global Product Development of Serono.

1/3

Adverse events in this study were similar to what has been observed in previous clinical trials of Raptiva, and include headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. Further, there was no evidence of accumulation or cumulative toxicity. At 30-months, the occurrence of serious adverse events was infrequent which is consistent with data from previous Raptiva Phase III studies.

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

Edgar Filing: SERONO S A - Form 6-K

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 and on June 24, 2004 that it had received a unanimous positive opinion from the Committee of Medicinal Products for Human Use (CHMP) recommending approval in the European Commission region. The company has also received a positive opinion for Raptiva in Australia and launched the product in Argentina following approval there.

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.

ABOUT SERONO

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R), Zorbtive(TM) and Raptiva(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 and has recently entered the psoriasis area. 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).

###

2/3

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

Edgar Filing: SERONO S A - Form 6-K

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.

###

FOR MORE INFORMATION, PLEASE CONTACT:

CORPORATE MEDIA RELATIONS:	CORPORATE INVESTOR RELATIONS:
Tel: +41 22 739 36 00	Tel: +41 22 739 36 01
Fax: +41 22 739 30 85	Fax: +41 22 739 30 22
www.serono.com	Reuters: SEO.VX / SRA.N
-----	Bloomberg: SEO VX / SRA US
	INVESTOR RELATIONS, USA
	Tel: +1 781 681 2552
	Fax: +1 781 681 2912

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)

July 29, 2004

By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary