SERONO S A
Form 6-K
June 22, 2006

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of June

**Commission File Number 1-15096**

# Serono S.A.

(Translation of registrant s name into English)

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**Case Postale 54**
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**Switzerland**

(Address of principal executive office)

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 o

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): o

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): o

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 o No x

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**

## COMPELLING EVIDENCE OF RAPTIVA® 12-WEEK CLEAR TRIAL DATA IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS PUBLISHED IN *BRITISH JOURNAL OF DERMATOLOGY*

### *The efficacy and safety of Raptiva® were comparable between refractory patients and the more general moderate-to-severe plaque psoriasis patients*

***Geneva, Switzerland June 22, 2006*** Serono (virt-x: SEO and NYSE: SRA) announced today that the 12-week data from the clinical study CLEAR (**CL**inical **E**xperience **A**cquired with **R**aptiva®), demonstrating that Raptiva® produced significant clinical improvements and was generally well tolerated among patients refractory, intolerant or contraindicated to systemic therapies as well as in the total population of patients with moderate-to-severe plaque psoriasis, was published in this month s edition of the British Journal of Dermatology.(1)

*Data from the CLEAR study show compelling evidence of the benefit of Raptiva®* not only in the general moderate-to-severe psoriasis patient population, but also in patients in which previous treatments have failed due to efficacy, or in whom existing therapies cannot be prescribed due to contraindications or safety concerns , said Franck Latrille, Senior Executive Vice President, Corporate Global Product Development of Serono. This creates a significant unmet medical need that Raptiva® is able to address.

*Following the 12-week treatment, Raptiva®* demonstrated a favorable safety profile and was clinically superior to placebo in showing a statistically significantly higher PASI(2) 75 rate, the primary efficacy endpoint of the study. 793 patients were enrolled in this clinical trial, of which 526 comprised the refractory group. In the overall patient population, 31.4% of those treated with Raptiva® reached a ≥ 75% PASI improvement, compared to 4.2% of patients treated with placebo ($P < 0.0001$); in the refractory patient population, 29.5% versus 2.7% reached a PASI 75 rate ($P < 0.0001$).

Biological therapies are a major progress in the treatment of psoriasis, a frequent and disabling skin disease. Raptiva® is the only EU approved biological molecule to specifically target T cells. The CLEAR study is of major importance as it prospectively demonstrates the efficacy and safety of Raptiva® in moderate-to-severe patients as well as in patients who have little or no treatment options left available to them. The CLEAR study confirms the hope offered to our patients by this original therapeutic approach , said Louis Dubertret, professor and chairman of one of the leading global centers for Dermatology at the Hospital Saint Louis, Paris, and first author of this publication.

*CLEAR is the first and currently only multinational, randomized, double-blind, placebo-controlled, parallel-group trial demonstrating the efficacy of a biological therapy in an international patient population, where patients have previously failed to respond to other systemic therapies, or where these were inappropriate due to contraindications or intolerance. CLEAR prospectively and uniquely demonstrates that Raptiva®* is an effective therapy in moderate-to-severe plaque psoriasis patients regardless of previous systemic treatments.

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(1) Dubertret L, Sterry W, Bos JD, Chimenti S, Shumack S, Larsen CG, Shear NH, Papp KA, CLEAR Multinational Study Group. Clinical experience acquired with the efalizumab (Raptiva®) (CLEAR) trial in patients with moderate-to-severe plaque psoriasis: results from a phase III international randomized, placebo-controlled trial. *Br J Dermatol* 155:170 181.

(2) Psoriasis Area and Severity Index; most commonly used clinical scoring system to assess disease severity in clinical trials

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Psoriasis is a debilitating chronic inflammatory skin disease for which there is currently no permanent cure, and patients require long-term treatment to control the disease. While various systemic therapies and phototherapies are available, treatment options are limited for many patients as these treatments potentially have serious side effects in the long-term management of the disease. In responding patients, the biological agent Raptiva® offers a new treatment paradigm for the continuous management of the disease, increasing their quality of life(3). Globally, more than 30,000 patients have received Raptiva®, both during clinical trials and post registration. This represents more than 17,500 patient years of exposure, creating one of the largest existing databases of patients taking a biological therapy for psoriasis.

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**About the CLEAR Study**

CLEAR (**CL**inical **E**xperience **A**cquired with **R**aptiva®) is the first multinational, randomized, double blind, placebo-controlled, parallel-group trial designed to evaluate the safety and efficacy of Raptiva® compared to placebo. Patients with moderate-to-severe plaque psoriasis, including refractory patients, defined as those for whom at least two systemic therapies were unsuitable because of lack of efficacy, intolerance or contraindication, were randomized in a 2:1 ratio to receive either once weekly for 12 weeks 1mg/kg Raptiva® or placebo.

This prospective trial consisted of three periods: an initial 12-week double-blind treatment period, an observation period of up to 24 weeks and a 12-week open-label re-treatment period. The primary efficacy endpoint was the proportion of patients achieving ≥ 75% PASI improvement at week 12. The secondary endpoints included changes in PASI, static Physician s Global Assessment, Physician s Global Assessment of change from baseline and percentage of body surface area affected.

793 patients were included in this prospective trial, thereof 529 were randomized to Raptiva® and 264 to placebo. Amongst the 793 patients, 526 were refractory patients (342 randomized to Raptiva® and 184 to placebo). At week 12, Raptiva® achieved significantly higher PASI-75 rates in both, the refractory patients 29.5% for Raptiva® compared to 2.7% for placebo; (P< 0.0001) and the overall study population 31.4% for Raptiva® versus 4.2% for placebo; (P < 0.0001). Superiority of Raptiva® to placebo was shown in both groups, the overall patient population and the refractory patients, for all secondary endpoints.

Overall, the safety profile of Raptiva® in the initial 12 weeks of the CLEAR study is consistent with that reported in previous US phase III clinical studies. The incidence of serious adverse events affecting the skin was 2.5% among efalizumab-treated patients and 2.3% among placebo-treated patients. The frequency of serious arthritis-related adverse events was 0.9% with efalizumab compared with 0.4% with placebo. In the first 12 weeks of this study, adverse events considered potentially infection-related were reported 28.4% of efalizumab-treated patients and 20.1% of placebo-treated patients. No malignancies were reported and there were no reports of thrombocytopenia. The most frequently reported events in the CLEAR study were headache, influenza-like illness, arthralgia, rigor, pyrexia, nasopharyngitis, myalgia, and pruritus.

Data on the 24-week observation and 12-week re-treatment period were presented at the European Academy of Dermatology and Venerology in London, UK, in October 2005.(4)

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(3) Impact of efalizumab on patient-reported outcomes in high-need psoriasis patients: results of the international, randomized, placebo-controlled Phase III Clinical Experience Acquired with Raptiva (CLEAR) trial, Ortonne J-P et al.; BMC Dermatology 2005, 5:13

(4) The safety of efalizumab in patients with moderate-to-severe plaque psoriasis: results from the CLEAR study beyond 12 weeks, J. Ring, L. Dubertret, T. May, S. Chimenti & W. Sterry, JEADV (2005) 19 (Suppl. 2), 1 412 poster P06.87

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**About Raptiva®**

Raptiva® (efalizumab) 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.

Raptiva® received EU approval 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* .

Adverse events observed with Raptiva® 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. There is no evidence of accumulation or cumulative toxicity to date.

Serono has the rights to develop and market Raptiva® worldwide outside of the United States and Japan. To date, Raptiva® is available in over 50 countries, amongst them many countries in Europe, Latin America, Asia as well as Australia. Development and marketing rights in the United States, where Raptiva® has been available since November 2003, remain with Genentech Inc. (NYSE:DNA) and its U.S. partner XOMA (Nasdaq: XOMA).

**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 knees, elbows, trunk, and scalp. 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 permanent cure.

**Background material**

For free B-roll, video and other content for Serono and its products, 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®, Gonal-f®, Luveris®, Ovidrel®/Ovitrelle®, Serostim®, Saizen®, Zorbtive and Raptiva®. 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, including oncology and autoimmune diseases. Currently, there are more than 25 on-going development projects.

In 2005, Serono, whose products are sold in over 90 countries, achieved worldwide revenues of US$2,586.4 million. Reported net loss in 2005 was US$106.1 million, reflecting a charge of US$725 million taken relating to the settlement of the US Attorney s Office investigation of Serostim. Excluding this charge as well as other non-recurring items, adjusted net income grew 28.4% to US$565.3 million in 2005. 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 February 28, 2006. 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, the outcome of government investigations and litigation 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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**SIGNATURE**

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.

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SERONO S.A.,
a Swiss corporation
(Registrant)

Date June 22, 2006

By: /s/ Stuart Grant
Name: Stuart Grant
Title: Chief Financial Officer

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