SERONO S A
Form 6-K
May 23, 2005

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 May, 2005

Serono S.A.

(Registrant's Name)

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Case Postale 54
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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
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73 PERCENT OF MODERATE-TO-SEVERE PSORIASIS PATIENTS WHO REMAINED ON CONTINUOUS RAPTIVA(R) THERAPY IN A 3-YEAR STUDY ACHIEVE PASI 75

HIGH-NEED PATIENTS OF THE CLEAR-STUDY BENEFIT EQUALLY WELL FROM TREATMENT WITH RAPTIVA(R) AS BROADER MODERATE-TO-SEVERE PATIENT POPULATION TO ACHIEVE EFFICACIOUS AND WELL-TOLERATED CONTINUOUS CONTROL OF THE DISEASE

GENEVA, SWITZERLAND - MAY 23, 2005 - Serono (virt-x: SEO and NYSE: SRA) announced today data from a clinical trial presented at the 3rd Spring Symposium of the European Academy of Dermatology and Venereology in Sofia, Bulgaria showing that in a 3-year continuous treatment with Raptiva(R), 73% of moderate-to-severe psoriasis patients who remained on therapy for 36 months achieved a 75% or greater improvement of their Psoriasis Area Severity Index (PASI 75). A second study, the CLEAR trial, demonstrated that high need patients benefit equally well from treatment with Raptiva(R) as the broader moderate-to-severe patient population.

"Dermatologists must weigh the efficacy and safety of different treatment options, in the long-term treatment of a chronic disease, such as psoriasis," said Nikolai Tsankov, Professor at the Department of Dermatology and Venereology of the Sofia School of Medicine, Bulgaria. "As Raptiva(R) has a favorable benefit-risk profile during continuous therapy for disease control, it should be considered as one of the best choice biological treatments for moderate-to-severe psoriasis, when a biological treatment is indicated."

A 3-year, phase IIIb open-label study performed in North America evaluated the long-term safety and efficacy of continuous treatment with Raptiva(R) in moderate-to-severe psoriasis patients. At the end of the final period of this trial, 73% of patients (82/113) who remained on therapy demonstrated a sustained clearing of psoriasis symptoms, showing a 75% or greater improvement in their Psoriasis Area Severity Index (PASI 75) and 40% of patients (45/113) who remained in the study showed a 90% or greater PASI improvement (PASI 90). Raptiva(R) showed a consistent safety profile during the 3-year continuous therapy with no cumulative end-organ toxicity or increased malignancy or infection.

A sustained benefit in continuous treatment with Raptiva(R) could also be confirmed in a second study. This multicenter, multi-national CLEAR trial evaluated the safety and efficacy of Raptiva(R) in patients with moderate-to-severe psoriasis. The response of patients with an extended treatment with Raptiva(R) over a 24-week period, who achieved a score between > PASI 50 and PASI <75 in the initial 12-week treatment, continued to improve
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over time and nearly 50% of them (56/118) achieved a PASI 75 score by week 24. High need patients that were not controlled by, intolerant to or contraindicated to at least two currently available systemic therapies responded with a similar efficacy and safety profile to the treatment with Raptiva(R) as the broader moderate-to-severe patient population.

As demonstrated in clinical trials, the long-term treatment with Raptiva(R) of responding patients with moderate-to-severe psoriasis results in an efficacious continuous control of the disease with a good safety profile.

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(R) is designed to be administered once weekly via subcutaneous injection and can be self-administered by patients at home.

Raptiva(R) 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'.

Serono has the rights to develop and market Raptiva(R) worldwide outside of the United States and Japan. To date, Raptiva(R) has been launched in 17 countries, amongst them many countries in Europe, Latin America, Asia as well as Australia. Development and marketing rights in the United States, where Raptiva(R) has been available since November 2003, 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(R) trials to date, creating the largest existing database of patients taking part in studies with a biological therapy for psoriasis.

ABOUT THE 36-MONTH PHASE IIIB OPEN-LABEL STUDY

This three-year study is the longest study of psoriasis patients receiving continuous treatment with a biologic treatment. In this study, 339 patients received Raptiva(R) 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 1 mg/kg Raptiva(R) for 12-week periods starting at week 13. A total of 290 subjects entered this second phase of the study. 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.

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

The full results of this study were presented at the American Association of Dermatology ACADEMY 2005 meeting in New Orleans.

ABOUT THE CLEAR STUDY

In this prospective, multicenter, multi-national study, a total of 793 patients were recruited and randomized in a 2:1 ratio to either Raptiva(R) treatment or placebo for 12 weeks (first treatment period). After 12 weeks, patients achieving > 75% improvement in the Psoriasis Area and Severity Index (PASI 75) were observed either until they relapsed or for a maximum of 24 weeks (observation period). Patients then started treatment with Raptiva(R) for 12 weeks (re-treatment period) and were followed for a further 8 weeks (follow-up period). Those patients who achieved a score between > PASI 50 and PASI <75 after the initial 12 weeks of treatment received Raptiva(R) for a 12-week extended treatment (extended treatment phase). These patients were then observed for an 8-week follow-up period.

In all study periods, the majority of reported adverse events were mild to moderate in severity.

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 cure.

BACKGROUND MATERIAL
For free B-roll, video and other content about Raptiva(R), psoriasis and Serono, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can
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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). 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. Currently, there are approximately 30 ongoing development projects.

In 2004, Serono achieved worldwide revenues of US$2,458.1 million, and a net income of US$494.2 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 16, 2005. 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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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)

May 23, 2005

By: /s/ Stuart Grant

Name: Stuart Grant
Title: Chief Financial Officer