SERONO S A
Form 6-K
April 06, 2005

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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 April, 2005

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_ Ö__ 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_ Ö__

(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

SERONO ANNOUNCES DISCONTINUATION OF ONERCEPT IN MODERATE-TO-SEVERE PSORIASIS AND CANVAXIN™ IN STAGE IV MELANOMA

Geneva, Switzerland - April 6, 2005- Serono (virt-x: SEO and NYSE: SRA) announced today the discontinuation of two phase 3 clinical trial programs; onercept (recombinant tumor necrosis factor binding protein) in moderate-to-severe psoriasis and Canvaxin™ in Stage IV melanoma, licensed from CancerVax. The decision to discontinue these clinical trials is based on the recommendations of two separate independent Data and Safety Monitoring Boards (DSMBs).

Onercept in moderate-to-severe psoriasis

In 2004, Serono initiated three phase 3 clinical trials in moderate-to-severe psoriasis. Investigators have recently reported two patients diagnosed with sepsis, one of whom subsequently died. Sepsis is a recognized potential risk for patients treated with anti-tumor necrosis factor (TNF) therapies. Serono convened a meeting of the independent DSMB to evaluate the available blinded efficacy data at 12 weeks for the two placebo-controlled pivotal trials and data from the first 12 weeks of the open-label trial. It was determined based on these aggregate data that the efficacy response observed for onercept was less than that observed in the earlier phase 2 trial, and with other available treatments. As a consequence of its unfavorable risk-benefit profile, the DSMB recommended to discontinue the clinical development of onercept in moderate-to-severe psoriasis.

Canvaxin™ in Stage IV melanoma

The DSMB for Canvaxin™ which recently completed its planned, second interim analysis of the data in Stage IV melanoma, recommended its discontinuation as the data are unlikely to provide significant evidence of a survival benefit for Canvaxin™ treated patients with Stage IV melanoma versus those receiving placebo.

With regard to the currently on-going phase 3 clinical trial of Canvaxin™ in Stage III melanoma, the DSMB confirmed that this trial should continue. The third interim analysis of the data is expected in the third quarter of 2005. The final analysis of data from this clinical trial will take place after the required number of clinical events will have occurred, which is currently estimated to be around mid-2006.

“We support the recommendation of the two Data and Safety Monitoring Boards”, said Franck Latrille, Senior Executive Vice President, Corporate Global Product Development. “We will continue to develop Canvaxin™ in Stage III melanoma.”

Conference Call
Serono will hold a conference call on Wednesday, April 6, 2005, starting at 15:00 pm Central European Time (9:00 am Eastern Time) during which Serono Management will present a statement on the discontinuation of these clinical trials and answer questions.

To join the telephone conference please dial + 1 866 291 4166 (from the US), 091 610 5600 (from Switzerland), + 44 20 7107 0611 (from the UK) and + 41 91 610 5600 (from elsewhere). Telephone playback will be available one hour after the conference call and until 5.00 pm CET on April 15, 2005. To access this playback please dial the following numbers: 091 612 4330 (from Switzerland), 0207 108 6233 (from the UK), 1 866 416 2558 (from the USA) and +41 91 612 4330 (from elsewhere) and enter the PIN code 943# from a touch tone telephone.

About the DSMB
The DSMB consists of independent experts who are not participating in the clinical trials. Their primary responsibility is to monitor, on a periodic basis, the data emerging from a clinical trial and to provide recommendation to the sponsor on whether a study should continue, be modified or discontinued.

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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, 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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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. 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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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)

April 6, 2005

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