SERONO S A
Form 6-K
April 30, 2003

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 April, 2003

Serono S.A.
(Registrant's Name)

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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).) _____

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(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-_____)

[GRAPHIC OMITTED
SERONO]

Media Release

FOR IMMEDIATE RELEASE

SERONO DISAGREES WITH CPMP OPINION FOR SEROSTIM IN AIDS WASTING IN EUROPEAN UNION

GENEVA, SWITZERLAND, APRIL 30, 2003 - Serono S.A. (virt-x: SEO and NYSE: SRA)

Serono disagrees with the opinion issued by the Committee for Proprietary Medicinal Products (CPMP) on April 25, 2003 that recommends not granting initial marketing authorization for Serostim(R) for the treatment of AIDS wasting in the European Union. In contrast with the CPMP opinion, Serono believes that the data submitted confirm the safety and efficacy of Serostim(R) in the rare condition of AIDS wasting and that the data do justify the therapeutic benefits for patients who have no alternative treatment.

AIDS wasting was designated as a rare condition based on the published criteria of the US Centers for Disease Control and Prevention (CDC)(1). In August 2000 the European Commission granted Serostim(R) orphan designation based on the opinion of the Committee for Orphan Medicinal Products (COMP). This Committee confirmed that the indication of AIDS wasting in the EU should also be in agreement with the CDC disease definition.

The Serostim(R) AIDS Wasting Confirmatory Study (GF9037) was designed to include patients meeting the agreed and official definition of AIDS wasting. The results of this confirmatory trial were positive and demonstrate a highly significant increase of both work output and lean body mass as well as an improvement in quality of life for the patients treated with Serostim(R) as compared to patients treated with placebo. The results of this study were presented at the International AIDS Conference in Barcelona in July 2002.

It is unfortunate that the current CPMP view of AIDS wasting is not aligned with the definition of the orphan drug designation granted in Europe. The CPMP opinion reflects the difficulties in the understanding of rare and continuously evolving diseases and in the assessment of appropriate treatments. The full implementation of the EU Orphan Regulation needs to be improved to ensure access to innovative treatments for rare diseases in Europe. Serono will continue to work with the European Commission, the EMEA and all interested parties to improve the policy continuity from the orphan designation, through clinical development and marketing authorization, to meet patients' unmet medical needs.

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(1) An involuntary weight loss of greater than 10% with intermittent or constant fever and chronic diarrhea, or chronic weakness and fever for more than 30 days in the absence of other causes than HIV that may explain the condition

The CPMP negative opinion marks a sad day for the European patient community suffering from rare diseases, and for all other interested parties. Serono wants to reassure European AIDS wasting patients currently under Serostim(R) therapy both in clinical programs and in national compassionate use schemes, that Serono will continue to work with authorities and patient associations to ensure access to the product in compliance with local regulations.

Serono will review the full details of the current CPMP opinion, and is considering the appropriate next steps.

BACKGROUND

SEROSTIM (R) AIDS WASTING CONFIRMATORY TRIAL

The Serostim(R) AIDS wasting confirmatory trial included more than 700 patients at US, EU and other international trial sites. Following the accelerated approval of Serostim(R) by the FDA, Serono conducted this study to confirm the safety and efficacy of Serostim(R). Patients were randomized into three treatment groups to receive Serostim (R) 6 mg daily, Serostim(R) 6 mg on alternate days or placebo for a 12-week treatment period.

The primary endpoint of the study was to confirm the clinical efficacy of Serostim(R) compared with placebo, based on exercise function change as assessed by cycle ergometer work output from baseline to week 12. The results of the primary endpoint were positive and demonstrated a highly significant increase of work output of 9.9% in the group treated with Serostim(R) 6 mg daily and a decrease of 1% in the placebo group (p