SERONO S A
Form 6-K
September 02, 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 August, 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).) _____

(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

SERONO'S SEROSTIM(R) RECEIVES FULL APPROVAL FROM FDA FOR TREATMENT OF AIDS WASTING

SEROSTIM(R) GRANTED ACCELERATED APPROVAL IN 1996 AS TREATMENT FOR AIDS PATIENTS WITH WASTING OR CACHEXIA, A SERIOUS AND LIFE THREATENING DISEASE

CONFIRMATORY MULTI-CENTER, PLACEBO-CONTROLLED STUDY SUBSTANTIATES PREVIOUS FINDINGS OF INCREASED LEAN BODY MASS AND IMPROVEMENT IN PHYSICAL ENDURANCE

ROCKLAND, MA, AUGUST 29, 2003 - Serono, Inc. announced today that the US Food and Drug Administration (FDA) has granted full approval for Serostim(R) [somatropin (rDNA origin) for injection] which is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.(1)

Serostim(R) received accelerated approval in 1996, a special regulatory status granted by the FDA for approval of a drug that is used to treat patients with serious or life-threatening illnesses, and provides meaningful therapeutic benefit over any existing treatments. Under the terms of the accelerated approval, Serono conducted a multi-center, confirmatory placebo-controlled study with Serostim(R). Data from this trial substantiate previous study findings of increased lean body mass and improvement in physical endurance with Serostim(R). In addition, patients in this study perceived an improvement in their wasting symptoms with Serostim(R) treatment.

"We are very pleased that the FDA has granted full approval for Serostim(R)," said James Sapirstein, Executive Vice President, Metabolic Endocrinology, Serono, Inc. "Wasting continues to be a major concern in the management of HIV and AIDS treatment, even with the benefits of highly active antiretroviral therapy. Serostim(R) makes an important and positive difference in the physical endurance of people experiencing HIV wasting."

HIV-associated wasting is a chronically debilitating and potentially life-threatening condition. It is a metabolic disorder that causes the body to use vital muscle and organ tissue, which is critical for survival, for energy instead of primarily using the

(1) Concomitant antiretroviral therapy is necessary.

body's stored fat. Loss of lean body mass, which consists of muscle tissue, important body organ tissue and blood cells, can lead to increased risk of opportunistic infections, illness, and extreme fatigue and can profoundly diminish a person's quality of life. Serostim(R) was granted orphan drug designation by the FDA in 1991 for this condition.

CLINICAL STUDY OF SEROSTIM IN AIDS WASTING

The full approval of Serostim(R) is based upon a randomized, double-blind, dose-ranging study that confirmed the clinical efficacy of Serostim(R) in the treatment of HIV wasting. The study treated 757 patients with HIV-associated wasting at US, European and other international trial sites. Participants were treated with placebo, Serostim(R) on alternate days (0.1 mg/kg) or Serostim(R) on a daily basis (0.1mg/kg).

The result on the study's primary endpoint of cycle work output was statistically significant for the Serostim(R) daily dose group as compared to

the placebo group (p