SERONO S A
Form 6-K
June 01, 2004

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 June, 2004

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 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 INITIATES PHASE III TRIAL OF SEROSTIM(R) IN HIV-ASSOCIATED ADIPOSE REDISTRIBUTION SYNDROME

STUDY AIMED AT ASSESSING BENEFITS OF RECOMBINANT HUMAN GROWTH HORMONE AS POTENTIAL TREATMENT AND MAINTENANCE THERAPY FOR HIV METABOLIC COMPLICATION

GENEVA, SWITZERLAND AND ROCKLAND, MA, JUNE 1, 2004- Serono, Inc., the US affiliate of Serono (virt-x: SEO and NYSE: SRA), announced today that the company has initiated a Phase III clinical trial of Serostim(R) [somatropin (rDNA origin) for injection] as a potential treatment and maintenance therapy to reduce excess visceral fat accumulation in patients with HIV-associated adipose redistribution syndrome (HARS). HARS is a potentially debilitating medical condition experienced by people being treated for HIV for which there is currently no medical treatment. The visceral adipose tissue accumulations seen in HARS may also be associated with an adverse risk profile.

This multi-center, randomized, double-blind, placebo-controlled study of the safety and efficacy of Serostim(R) in HARS will include approximately 300 patients at 30 clinical trial sites. The study will evaluate the effectiveness of Serostim(R) 4mg administered daily for 12 weeks compared to placebo in reducing abdominal visceral adipose tissue while assessing, among other endpoints, patient reported outcomes. This trial will also evaluate the effect of Serostim(R) 2mg administered on alternate days as a maintenance therapy to sustain reductions in visceral adipose tissue attained during the first 12 weeks of active therapy.

"This trial will build upon Serono's extensive experience with Serostim(R)," said Paul Lammers, MD, MSc, Chief Medical Officer, Serono, Inc. "We are hopeful that it will demonstrate the effectiveness of recombinant human growth hormone for this metabolic complication of HIV."

The results of previous studies suggest that Serostim(R) may be an effective treatment for this indication. Serono has previously reported positive findings of the Serostim(R) for the Treatment of Adipose Redistribution Syndrome (STARS) study, a double-blind, placebo-controlled study, designed to evaluate Serostim(R) as a potential HARS therapy. The study results showed that Serostim(R) 4mg administered daily for 12 weeks decreased visceral adipose tissue and trunk fat as compared to placebo (p