SERONO S A
Form 6-K
October 19, 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 October, 2004

Serono S.A.
(Registrant's Name)

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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

CLINICAL STUDY SHOWS NEED FOR FEWER INJECTIONS TO PREVENT PREMATURE OVULATION DURING THE TREATMENT OF INFERTILITY

First head-to-head clinical study of GnRH antagonists in the treatment of infertility

PHILADELPHIA, PA, OCTOBER 19, 2004 - SERONO (VIRT-X SEO AND NYSE: SRA) - In the first clinical trial to directly compare gonadotropin releasing hormone (GnRH) antagonists, patients using Cetrotide(R) (cetrorelix acetate for injection) required fewer injections compared to patients using Ganirelix Acetate (formerly known as Antagon(TM) Injection) to prevent premature ovulation during infertility treatment. The data were presented today at the 60th Annual Meeting of the of the American Society for Reproductive Medicine (ASRM) by John G. Wilcox, MD, FCOG, Assistant Clinical Professor in the Department of Obstetrics and Gynecology at the University of Southern California School of Medicine and Managing Partner of Huntington Reproductive Center in Pasadena, CA.

"This study shows that hormonal surges can be inhibited with a single injection for the majority of patients until follicles are large enough for oocyte retrieval and subsequent fertilization," said Dr. Wilcox. "Cetrotide(R) offers patients a similar safety profile as well as similar efficacy compared to Ganirelix Acetate, but Cetrotide(R) has the added benefit of significantly fewer injections."

Most of the patients who used Cetrotide(R) (66.7%) required one injection while most of the patients who used Ganirelix Acetate (62.5%) required four or more injections to achieve the same endpoint.

"Cetrotide(R) is an important part of Serono's full portfolio of patient-friendly products designed to make infertility treatment easier," said Bharat Tewarie, MD, MBA, Executive Vice President, Reproductive Health, Serono, Inc. "The ease-of-use it offers demonstrates our commitment to improving the patient experience."

Gonadotropin releasing hormone (GnRH) antagonists are used in the treatment of infertility to prevent the spontaneous release of LH (luteinizing hormone), a hormonal event that impacts the development of eggs. They work by directly blocking the trigger effect of GnRH to stop a possible LH surge before it begins, allowing eggs to reach the level of development needed for fertilization.

Infertility is defined as the inability to achieve pregnancy after one year of regular, unprotected intercourse (six months if the woman is over 35). It affects about 6.1 million Americans, which represents about 10 percent of couples in their childbearing years. The majority of patients who complete treatment ultimately succeed in having a child.

ABOUT THE STUDY

The prospective, open-label, randomized, comparative study was conducted at 16 medical centers in the United States and included 185 infertile patients undergoing ART procedures. A single subcutaneous injection of Cetrotide(R) 3 mg or a daily subcutaneous injection of Ganirelix Acetate 250 mcg was administered in a flexible protocol to prevent premature LH surge when the lead follicle was > 14 mm. Daily Cetrotide(R) 0.25 mg was administered if the criteria for -
recombinant human chorionic gonadotropin (hCG) administration were not met four days after receiving Cetrotide(R) 3 mg. Most women receiving Cetrotide(R) (66.7%) received only a single dose. Of the remaining patients, 89.8% needed

only one additional dose. The overall pregnancy rate for the Cetrotide arm was 51.7% (45/87), and the overall pregnancy rate for the Ganirelix Acetate arm was 48.9% (43/88), with no statistically significant difference between treatment groups. These results, presented at ASRM, represent a final analysis of data.

ADDITIONAL INFORMATION
Side effects may occur with the use of infertility drugs and, therefore, should only be prescribed by physicians who are thoroughly familiar with infertility problems and their management. Ovarian hyperstimulation syndrome (OHSS) with or without vascular and pulmonary complications can occur with the use of infertility drugs. Mild and short lasting injection reactions like reddening, itching and swelling at the injection sites have occurred in women using Cetrotode(R). Nausea and headache have also been reported.

ABOUT SERONO, INC. AND FERTILITY
Serono, Inc., a subsidiary of Serono S.A., is a leader in fertility health, dedicated to developing patient-friendly, innovative products that help people build families. It is the only company to offer a full portfolio of fertility medications for every stage of the reproductive cycle and recombinant versions of three hormones used in the treatment of infertility, including the newly approved Gonal-f(R) RFF Pen (follitropin alfa injection). For more information, please contact Fertility LifeLines(TM), a toll-free educational service that offers customized information and support to people with fertility health concerns, available at 1-866-LETS-TRY (1-866-538-7879).

ABOUT SERONO S.A.
Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R) (interferon beta-1a), Gonal-f(R) (follitropin alfa for injection), Luveris(R) (lutropin alfa for injection), Ovidrel PreFilled Syringe(R)/Ovitrelle(R) (choriogonadotropin alfa injection), Serostim(R) [somatropin (rDNA origin) for injection], Saizen(R) [somatropin (rDNA origin) for injection], Zorbtive(TM) [somatropin (rDNA origin) for injection] and Raptiva(R) (efalizumab). 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. Currently, there are approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US$2,018.6 million, and a net income of US$390.0 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 25, 2004. 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.

Package inserts for Serono's US marketed products are available at www.seronousa.com or by calling 1-888-275-7376.

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FOR MORE INFORMATION, PLEASE CONTACT:

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Bloomberg: SEO VX / SRA US

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)

October 19, 2004

By: /s/ Francois Naef
Name: Francois Naef
Title: Secretary