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SERONO S A
Form 6-K
January 11, 2005

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 January, 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 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

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____)

SERONO

IVAX

Media Release

FOR IMMEDIATE RELEASE

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SERONO AND IVAX TO INITIATE PHASE III CLINICAL TRIAL OF MYLINAX(R) IN MULTIPLE SCLEROSIS

MYLINAX(R) TARGETED TO BECOME FIRST ORAL THERAPY FOR MULTIPLE SCLEROSIS

GENEVA, SWITZERLAND, AND MIAMI, USA - JANUARY 11, 2005 -

Serono (virt-x: SEO and NYSE: SRA) and IVAX Corporation (AMEX: IVX and LSE: IVX.L) announced today that they will initiate a Phase III study with Mylinax(R) (a proprietary oral formulation of cladribine) in the first quarter of 2005. This multi-center, multi-national study is designed to assess the effectiveness of Mylinax(R) in patients with relapsing forms of multiple sclerosis. Endpoints will include assessments of clinical relapses, disability progression and MRI (magnetic resonance imaging) brain scans. It will be a two-year, double-blind, placebo-controlled study involving over 1,200 patients.

"As a leader in multiple sclerosis, we are committed to providing new treatment options that can further improve the quality of the lives of people with multiple sclerosis," said Ernesto Bertarelli, CEO of Serono. "With the initiation of the Phase III program of Mylinax(R), we are getting closer to realizing our objective to bring the first oral disease-modifying treatment to people with multiple sclerosis."

"We are very pleased to have reached this important milestone in the development of Mylinax(R) as a novel therapy for multiple sclerosis," said Dr. Phillip Frost, Chairman and CEO of IVAX Corporation. "The initiation of this Phase III study supports our belief in Mylinax(R) and our choice of Serono as a partner that could help maximize its potential."

Previous clinical trials using a parenteral formulation demonstrated positive effects of cladribine administered via injection in patients with multiple sclerosis. In these trials, reduction in new lesion development in the brain as seen on MRI scans and clinical benefits were observed.

Mylinax(R) is being developed by Serono and IVAX under a worldwide agreement signed in October 2002.

1/3

ABOUT CLADRIBINE

Cladribine is a purine nucleoside analogue that interferes with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are involved in the pathological process of multiple sclerosis. Through its differentiated mechanism of action, Mylinax(R) may offer an alternative option to patients with multiple sclerosis.

ABOUT MULTIPLE SCLEROSIS

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults. Multiple sclerosis affects approximately two million people worldwide. While symptoms can vary, the most common symptoms of multiple sclerosis include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of multiple sclerosis are the most common.

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FOR SERONO

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.

FOR IVAX

This press release contains certain forward-looking statements regarding product development efforts and product performance and other non-historical facts, which are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, among others, that indications from previous clinical trials may not be indicative of future results; that others may develop product formulations that are superior to IVAX' formulations, that Phase III clinical trials for Mylinax(R) may not be commenced or completed on a timely basis or at all, may fail, may not achieve the expected results or effectiveness and/or may not generate data that would support the continued development, approval or marketing of this product for the indications being studied or other indications; and that Mylinax(R) may not become the first oral therapy for multiple sclerosis. In addition to the risk factors set forth above, IVAX' forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, trade buying patterns, patent positions and litigation, among other things. For further details and discussion of these and other risks and uncertainties, see IVAX' Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.

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2/3

ABOUT SERONO

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R), Gonal-F(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R), Zorbitive(TM) and Raptiva(R). 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

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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).

ABOUT IVAX

IVAX Corporation, headquartered in Miami, Florida, discovers, develops, manufactures, and markets branded and brand equivalent (generic) pharmaceuticals and veterinary products in the U.S. and internationally.

In 2003, IVAX had worldwide net revenues of \$1.4 billion and net income of \$121 million. During the first nine months of 2004, IVAX' worldwide net revenues have been \$1.33 billion and net income, \$135 million. IVAX has direct operations in over 36 countries and its products are sold in more than 80. IVAX is listed on the American, London and Warsaw stock exchanges.

Copies of this and other news releases may be obtained free of charge from IVAX' website at www.ivax.com.

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO

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IVAX CORPORATION

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3/3

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)

January 11, 2005

By: /s/ Stuart Grant

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Name: Stuart Grant

Title: Chief Financial Officer