SERONO S A Form 6-K December 07, 2004

SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

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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 December, 2004

Serono S.A.

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(Registrant's Name)

15 bis, Chemin des Mines Case Postale 54 CH-1211 Geneva 20 Switzerland

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(Address of Principal Executive Offices)

1-15096

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(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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule  $101 \, (b) \, (7).$ )

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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- )

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SERONO micromet

Media Release

# FOR IMMEDIATE RELEASE

# SERONO AND MICROMET TO COLLABORATE IN DEVELOPMENT AND COMMERCIALIZATION OF NOVEL ANTI-CANCER DRUG

AGREEMENT FOR MT201, CURRENTLY IN PHASE II CLINICAL TRIALS

GENEVA, SWITZERLAND AND MUNICH, GERMANY - DECEMBER 7, 2004 - Serono (virt-x: SEO and NYSE: SRA) and Micromet (private) have signed an exclusive collaboration and license agreement for the development and commercialization of Micromet's fully human monoclonal antibody MT201 (adecatumumab). MT201 is a pan-carcinoma monoclonal antibody directed against the epithelial cell adhesion molecule Ep-CAM. The product is currently being tested in two multicenter phase II clinical trials for the treatment of prostate and metastatic breast cancer. Ep-CAM, the target antigen for MT201, is overexpressed with high frequency on most human carcinomas, suggesting that it may have therapeutic potential in the treatment of a broad range of cancers, including prostate, breast, colon, lung, stomach, pancreatic, head & neck, and ovarian cancer.

Under the terms of the agreement, Micromet will be responsible for completing the ongoing phase II clinical trials, and Serono will take over further development and commercialization of the product. Effective immediately, Serono will be responsible for all development costs. Micromet will receive an initial license fee of US\$10 million and additional milestone payments of up to US\$138 million if the product is successfully developed and registered worldwide in three or more indications. In addition, Micromet will receive undisclosed royalties based on net sales of the product. Under certain terms and conditions, Micromet may elect to share in the development and commercialization of the product in the US and EU in exchange for a share of profits.

"With its longstanding history and experience in protein based therapeutics, Serono is an excellent partner for MT201," commented Christian Itin, CEO of Micromet. "We are excited to collaborate with Europe's most successful biotechnology company."

"We are committed to the development of novel targeted therapeutics for cancer," said Serono's CEO Ernesto Bertarelli. "MT201 is a promising product with considerable therapeutic potential in the treatment of solid tumours. With this important addition to our pipeline, Serono's portfolio of novel anti-cancer agents is evolving well." Serono is currently evaluating TACI-Ig in two clinical trials for the treatment of B-cell malignancies.

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MT201 has been specifically designed to selectively eliminate tumour cells while leaving healthy tissues largely unharmed. Phase I data have demonstrated an excellent safety profile of MT201, and no MT201 neutralizing antibodies have been observed so far in man. An investigational new drug application (IND) for the product was recently cleared by the United States Food and Drug Administration (FDA) for the initiation of phase II studies in the United States.

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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.

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#### 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), Zorbtive(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.

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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#### ABOUT MICROMET

Micromet AG, a private Munich-based biotechnology company, puts novel concepts in immunotherapy to work. Using proprietary technologies, the Company is building a strong pipeline of innovative drug candidates for the treatment of cancer, inflammation and autoimmune disease. Two candidates are currently in clinical trials. The Company has established a powerful drug development platform based on its BiTE(TM) technology ("Bispecific T cell engagers"), a unique drug format that leverages the outstanding cytotoxic potential of T cells, the most powerful 'killer cells' of the human immune system. In addition, Micromet is exploiting the potential of SCAs (single-chain antibodies) for the development of novel drug candidates under a multi-year strategic collaboration with Enzon Inc. Micromet has integrated infrastructure and expertise in all disciplines of drug design and development. The Company has attracted both top-tier life science investors and corporate drug development partners such as MedImmune, Inc., Enzon, Inc., and now Serono.

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FOR MORE INFORMATION, PLEASE CONTACT:

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#### 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.

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(Registrant)

December 7, 2004 By: /s/ Francois Naef

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Name: Francois Naef Title: Secretary