SERONO S A
Form 6-K
June 26, 2006

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of June**

**Commission File Number 1-15096**

# Serono S.A.

(Translation of registrant s name into English)

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

(Address of principal executive office)

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 o

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): o

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): o

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 o No x

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

# Media Release

## FOR IMMEDIATE RELEASE

### ZYMOGENETICS AND SERONO PRESENT POSITIVE RESULTS OF TACI-IG PHASE 1b TRIAL IN RHEUMATOID ARTHRITIS AT EULAR MEETING

***Phase 2 program to start later this year***

**Seattle, USA and Geneva, Switzerland, June 26, 2006** ZymoGenetics, Inc. (NASDAQ: ZGEN) and Serono (virt-x: SEO and NYSE: SRA*)* today announced favorable results from a Phase 1b clinical trial with TACI-Ig in 73 patients with rheumatoid arthritis (RA), recently presented at the 7th **Annual European Congress of Rheumatology** (EULAR). TACI-Ig is a soluble fusion protein that neutralizes molecules implicated in the pathogenesis of several autoimmune diseases. TACI-Ig appeared to be well tolerated across the full range of dose levels and schedules tested. Clear biologic effect was observed as patients showed schedule and dose dependent decreases in the levels of immunoglobulin (Ig) and serum rheumatoid factor levels. Although this study was not specifically designed to evaluate efficacy, encouraging trends were observed in ACR and DAS 28 scores, commonly used measurements of clinical benefit. Based on these promising results, ZymoGenetics and Serono expect to begin the Phase 2 clinical program of TACI-Ig in patients with RA in the second half of 2006.

In an oral presentation(1), Alain Munafo, Ph.D., Senior Scientific Director of Serono, reported that TACI-Ig appeared to be well tolerated in patients with moderate-to-severe RA. The most common adverse event was a generally mild injection site reaction affecting approximately 40% of the patients. There were no serious adverse events reported. No patients formed detectable antibodies to TACI-Ig, and the patients vaccination immune status did not appear to be compromised by the drug.

TACI-Ig demonstrated clear biological activity, with schedule and dose dependent reductions of immunoglobulin levels in line with the proposed mechanism of action. In a cohort that received seven doses of TACI-Ig over a three-month period, patients showed:

- Reductions of several biomarkers typically found in RA patients, including:
  - IgM, IgA and IgG reductions of 54%, 37% and 21% respectively;
  - Reduction of peripheral blood B-cell levels with a maximum decrease of 30-40%
  - 40-45% reduction of IgM-RF, IgA-RF and IgG-RF

- Trends toward improvement of the ACR and DAS 28 scores commonly used to measure disease severity and effects of treatment.

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(1) TACI-Ig in patients with rheumatoid arthritis (RA): an exploratory, multi-center, double-blind, placebo-controlled, dose-escalating, single and repeat dose phase 1b study (abstract OP0178), 7th Annual European Congress of Rheumatology (EULAR), June 21 - 24, 2006, Amsterdam, Netherlands

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*In a separate poster presentation(2), Ivan Nestorov, Ph.D., Scientific Fellow of ZymoGenetics, reported that there was a well-defined relationship between TACI-Ig exposure and immunoglobulin response. IgM levels were found to be the most responsive to TACI-Ig exposure, followed respectively by IgA and IgG levels. Dosing frequency seemed to play as important a role as dose level in the response of the three biomarkers.*

*The primary objective of the Phase 1b study was to determine the safety and tolerability of TACI-Ig in RA patients and to examine the relationship between TACI-Ig dose and schedule with markers of biologic and disease activity. The trial enrolled adult male and female patients with active, moderate-to-severe RA. Patients received single or multiple doses of either TACI-Ig or placebo for a maximum period of three months.*

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**Abstracts**

**The abstracts and presentation slides are available at www.zymogenetics.com in the What s New section on the home page.**

**Background material**

For free B-roll, video and other content for Serono and its products, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can download print-quality images and receive broadcast-standard video digitally or by tape from this site. Registration and video is free to the media.

**About TACI-Ig**

ZymoGenetics and Serono are developing TACI-Ig for the treatment of autoimmune diseases and B-cell malignancies. TACI-Ig is a soluble receptor that binds to BLyS and APRIL, TNF family cytokines that promote B-cell survival and the production of harmful autoantibodies, which cause certain autoimmune diseases such as systemic lupus erythematosus (SLE). Current data indicates that levels of BLyS and APRIL are elevated in patients with rheumatoid arthritis, SLE and B-cell malignancies. TACI-Ig has been shown to affect several stages of B-cell development and may inhibit the survival of cells responsible for making antibodies. ZymoGenetics is developing TACI-Ig in collaboration with Serono S.A. and is conducting clinical studies in patients with SLE, rheumatoid arthritis and advanced B-cell malignancies, such as multiple myeloma, B-cell non-Hodgkin s lymphoma and chronic lymphocytic leukemia. Commencing July 1, TACI-Ig will be referred to by its International Nonproprietary Name atacicept .

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***Forward-looking Statements***

***For ZymoGenetics***

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of ZymoGenetics. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. ZymoGenetics actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with our unproven discovery strategy, preclinical and clinical development, regulatory oversight, intellectual property claims and litigation and other risks detailed in the company s public filings with the Securities and Exchange Commission, including the company s Annual Report on Form 10-K for the year ended December 31, 2005. Except as required by law, ZymoGenetics undertakes no obligation to update any forward-looking or other statements in this press release, whether as a result of new information, future events or otherwise.*

***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*

(2) Characterizing the relationship between TACI-Ig exposure and IgG, IgM and IgA antibody response in patients with rheumatoid arthritis (RA); (abstract FRI0157), 7th Annual European Congress of Rheumatology (EULAR), June 21 24, 2006, Amsterdam, Netherlands



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The abstracts and presentation slides are available at www.zymogenetics.com in the What s New section on the

*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 February 28, 2006. 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, the outcome of government investigations and litigation 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 ZymoGenetics**

ZymoGenetics creates novel protein drugs with the potential to significantly help patients fight their diseases. The Company is developing a diverse pipeline of potential proprietary product candidates that are moving into and through clinical development. These candidates span a wide array of clinical opportunities that include bleeding, autoimmune diseases and cancer. ZymoGenetics intends to commercialize these product candidates through internal development, collaborations with partners, and out-licensing of patents from its extensive patent portfolio. For further information, visit www.zymogenetics.com.

**About Serono**

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif®, Gonal-f®, Luveris®, Ovidrel®/Ovitrelle®, Serostim®, Saizen®, Zorbtive and Raptiva®. 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, including oncology and autoimmune diseases. Currently, there are more than 25 on-going development projects.

In 2005, Serono, whose products are sold in over 90 countries, achieved worldwide revenues of US$2,586.4 million. Reported net loss in 2005 was US$106.1 million, reflecting a charge of US$725 million taken relating to the settlement of the US Attorney s Office investigation of Serostim. Excluding this charge as well as other non-recurring items, adjusted net income grew 28.4% to US$565.3 million in 2005. 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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**SIGNATURE**

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)

Date June 26, 2006

By: /s/ Stuart Grant
Name: Stuart Grant
Title: Chief Financial Officer