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## Serono Announces Major Milestone in Identifying the Genes Involved in Multiple Sclerosis

### Identification of 80 genes involved in the inflammatory and neurodegenerative pathways of MS provide potential new drug targets

GENEVA, Switzerland and EVRY, France—March 17, 2005: Serono (virt-x: SEO and NYSE: SRA), the world's third largest biotechnology company, announced today that researchers at the Serono Genetics Institute (SGI) have achieved a major milestone in identifying and creating a register of genes involved in multiple sclerosis (MS). For the first time in this disease area, researchers at the SGI have identified 80 genes involved in the inflammatory and neuro-degenerative pathways of MS, based on a 40% genome scan comparing the genetic profile of a total of 1,800 people with MS and healthy individuals in different populations.

"We are excited about this significant step forward in building a complete inventory of genes involved in MS," said Professor Daniel Cohen, Vice-President and Worldwide Head of Genetics at Serono. "The completion of the *MS Whole Genome Scan* in 2006 will lead to a comprehensive catalogue of potential MS drug targets providing a basis for the future development of innovative MS therapies."

"We are dedicated to the task of understanding diseases and developing the treatments of the future," said Ernesto Bertarelli, CEO of Serono. "Through our current marketed products, such as Rebif<sup>®</sup>, our research and development projects and the major findings announced today, Serono is underscoring its commitment to improving the lives of people with MS and will pave the way for innovative treatments."

The understanding of the disease genetics in MS will enhance Serono's drug discovery in identifying proteins that can be used either as targets for drug development or directly as therapeutics. In addition, the knowledge of genetics in MS provides a basis for better designing safer and more effective drugs and enabling physicians to address unmet needs and potentially better match treatments to the individual patient.

This large-scale association study was performed in a French, Swedish and American population, including a total of 900 people with MS and an equivalent number of healthy individuals. Researchers at SGI used the Affymetrix GeneChip technology to scan over 100,000 SNPs (single nucleotide polymorphisms) to identify the genes involved in MS, comparing the genetic profile of cases and controls. The next step is to continue this endeavour, applying next generation GeneChip technology to scan over 500,000 SNPs and thus complete the MS Whole Genome Scan during 2006.

Serono's mission is to discover and develop innovative products to fight debilitating diseases, such as MS, and improve the quality of life of patients. Based on the human genome sequence, this fundamental advance in understanding the genetic roots of MS is a major landmark in the development of more targeted therapies of the future.

#### **About multiple sclerosis**

Multiple sclerosis is a chronic, inflammatory condition of the nervous system and is the most common, nontraumatic, neurological disease in young adults. Multiple sclerosis may affect 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.

#### **About the Serono Genetics Institute**

Founded in 1989, the company joined the Serono Group in 2002 and counts 130 people (90% of them working in Research). The expertise acquired all along these years makes the Serono Genetics Institute a Center of Excellence in Human Genetics. Fully integrated with the global state-of-theart research facilities of Serono, the Serono Genetics Institute is contributing to create a unique biotech approach that brings human genetics into all stages of the discovery and development process, to increase the quality of Serono's therapeutic molecules.

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 more information, please visit www.serono.com.

#### Actelion Pharmaceuticals US, Inc. Announces FDA Approval of Zavesca<sup>®</sup>

Actelion Pharmaceuticals US, Inc. is pleased to announce that Zavesca<sup>®</sup> (miglustat) capsules have been approved by the US Food and Drug Administration (FDA) for the treatment of adults with mild-to-moderate type I Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).

In accordance with an FDA requirement, Zavesca should be prescribed only by physicians who are knowledgeable in the management of patients with

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Gaucher disease. In order to prescribe Zavesca, you will need to sign and fax back the one-page physician statement affirming that you are qualified to manage Gaucher disease patients and that you have reviewed the enclosed educational booklet containing the full prescribing information.

Physicians who prescribe Zavesca need to be aware of the following important safety information:

- Peripheral neuropathy has been reported in patients receiving Zavesca
- Zavesca may cause fetal harm if administered to a pregnant woman
- There is a risk of impaired fertility in men
- Adverse events should be reported by calling 1.866.228.3546

Please review the enclosed booklet and physician statement. If appropriate, please sign the one-page physician statement and return it by fax to CuraScript, the specialty pharmacy managing Zavesca prescriptions, at 1.888.773.7386.

If you have any questions regarding Zavesca, please contact Actelion Medical Information at 1.866.228.3546 or via email, usmedinfo@actelion.com.

Alexander Porter, MD Associate Medical Director Actelion Pharmaceuticals US, Inc. 601 Gateway Boulevard Suite 100 South San Francisco, CA 94080 www.actelion.com

#### First Anniversary and Price Reduction

The Genetic Diagnostic Laboratories at Baylor College of Medicine began offering **Chromosomal Microarray Analysis (CMA)** as a clinical cytogenetic test one year ago. This test is based on array CGH and has proven very successful. The significant volume of testing allows us to announce a price reduction and shorter turnaround times effective immediately. See details at: http://www.bcmgeneticlabs.org/tests/ cyto/cma/html

### **Advantages of CMA**

- Equivalet to telomere FISH with multiple probes per telomere
- Equivalent to all standard FISH tests as a panel
- Detection of atypical presentations of deletion/duplication syndromes
- Detection of duplications superior to metaphase FISH (e.g., 15q11q13 autism)
- Routine detection of relatively nonspecific phenotypes (e.g., Smith-Magenis)
- Detection of findings often missed on karyotype (e.g., deletion 1p36)
- Applicable to fetal demise and postmortem tissue
- Very cost effective relative to data provided

### **Prices and Turnaround Times**

• CMA on blood, tissue, cultured cells, cultured cell pellets

- \$1,500 institutional price
- \$1,500 non-institutional price and payment in full due at submission
- Turnaround time: 5–7 days
- A statement describing test is available for insurance purposes

Significant abnormalities are confirmed by FISH at no additional charge on blood samples and cultured cells. Parental samples are analyzed at no additional charge *if the lab believes it is necessary to clarify polymorphic variants.* 

CMA can be performed on tissue (e.g., fetal demise regardless of cell viability), cultured cells (additional fee and time required if cells cultured by our lab), and cultured cell pellets.

For questions regarding CMA, please contact us at 1-800-411-GENE. A representative will be available to answer your questions regarding any testing provided.

For more information please contact:

Mike Frazier, Director of Client Services/Marketing, Pat Ward, M.S., Director of Clinical Services & Education, Sau Cheung, Ph.D. Director Cytogenetics and CMA Lab.

The "New Products" page is designed to offer you news and information from businesses serving the genetics community. We welcome your submissions. All submissions are subject to review by the Editor. For more information, contact Al Lucchesi, National Accounts Manager, Lippincott Williams & Wilkins, 530 Walnut Street, Philadelphia, PA 19106; phone 215-521-8409; fax 215-521-8411; email alucches@lww.com.

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