Media Release

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MAJOR BREAKTHROUGH TO IMPROVE DETECTABILITY OF MAD COW AND OTHER PRION DISEASES

A paper published in this week's issue of Nature describes a new procedure that may greatly improve the sensitivity of tests for prion diseases such as BSE (mad cow disease) and CJD (Creutzfeldt-Jakob disease)

Geneva, Switzerland, June 13, 2001 –
Serono (SWX: SEO, NYSE: SRA), today announced that researchers at the Serono Pharmaceutical Research Institute (SPRI) in Geneva, led by Dr. Claudio Soto, have developed a new procedure that may greatly improve the sensitivity of current tests used to detect abnormal prion proteins. These are believed to cause fatal neurodegenerative diseases such as bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and Creutzfeldt-Jakob disease (CJD and nvCJD) in humans. A paper describing the research is published in the June 14 edition of *Nature*[1].

Current tests are not able to detect BSE in dead animals under 30 months of age or those recently infected, and there are no tests available for live animals or humans. The new procedure developed by the Serono researchers makes it possible to amplify or multiply abnormal prion proteins up to several hundred times within a day.

"The procedure mimics the replication of abnormal prion proteins in the body in 'fast forward' mode, compressing years of real-life time into a few hours in the laboratory", said Silvano Fumero, Senior Executive Vice President Research & Pharmaceutical Development. "This is a major scientific breakthrough and has potential applications in improving tests for prion diseases, as well as identifying targets against which future drugs could be aimed."

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[1] Gabriela P. Saborio, Bruno Permanne & Claudio Soto, "Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding"; Nature; June 14 2001; **411**: 810-813.

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PROTEIN MISFOLDING CYCLIC AMPLIFICATION

The procedure is termed Protein Misfolding Cyclic Amplification (PMCA). Minute samples of abnormal prion protein (PrP^{sc}) were taken from the brains of scrapie infected hamsters, and mixed with large excess amounts of normal prion protein (PrP^{c}) from disease-free hamsters. This resulted in a rapid conversion of the normal prion protein into many aggregates of the abnormal prion protein. The aggregates were then treated with ultrasound. This cycle of amplification can be repeated many times within a day in a laboratory to produce quantities of the abnormal prion protein which are several hundred times greater than is currently available in the brain tissue of dead animals or humans.

MAJOR SCIENTIFIC BREAKTHROUGHS

This publication demonstrates a number of major scientific breakthroughs:

- The work done by the Serono scientists marks the first time that the abnormal prion protein has been cultivated in vitro, with a greater efficiency than the conversion process that has been postulated to occur in vivo with prion diseases such as BSE and CJD.

- As a result of this research, there is now a very sensitive assay (test) that helps to understand the underlying biology of prions, to identify other factors that may be responsible for the abnormal prion protein conversion, and to identify potential novel drug targets for prion diseases.

Through their continued work in this field, Dr Soto's team may also achieve further significant scientific advances:

- Preliminary experiments suggest in vivo that the abnormal prion protein is infectious. If this data is confirmed, it would strongly support the hypothesis for which Stanley Prusiner won the Nobel Prize in 1997. Dr Soto's team are currently conducting confirmatory experiments that will be published in due course.

- Preliminary experiments using this procedure also suggest that the abnormal prion protein can be detected in the blood of animals. Once again, confirmatory experiments are on-going.

SIGNIFICANT POTENTIAL APPLICATIONS

This work has a number of significant potential applications in the diagnosis of diseases:

- The identification of abnormal prion proteins in the brains of dead cattle under 30 months of age or those recently infected with BSE, which currently escape detection since the present tests are not sensitive enough to detect minute amounts of PrP^{sc} at the earliest stage of the disease.

- The identification of abnormal prion protein in live cattle (symptomatic or pre-symptomatic with BSE), using tissues or biological fluids such as blood.

- The detection of CJD and nvCJD in humans (symptomatic or pre-symptomatic), using spinal fluid or blood.

- This procedure may be applicable to the detection of other protein-misfolding diseases such as Alzheimer's.

COMMERCIAL IMPLICATIONS FOR SERONO

There are many stages involved in bringing this major scientific breakthrough into commercial applications. Serono will explore the opportunities of licensing agreements for this procedure with leaders in the field of diagnostics. These would cover both animal and human tests, using brain tissue, other tissue types and biological fluids such as blood. Serono has already moved to patent the proprietary knowledge and processes resulting from Dr Soto's research .

FURTHER INFORMATION

Please visit Nature.com or Serono.com where you may find:

- The paper published in Nature
- A document of Frequently Asked Questions & Answers
- A Diagram of the Protein Misfolding Cyclic Amplification (PMCA) procedure
- Biography of Dr Soto
- Photographs of Dr Soto's team

For further information about research at the Serono Pharmaceutical Research Institute please visit www.spri.serono.com.

BACKGROUND

The disease mechanism of prion proteins

So-called "normal" prion proteins (PrP^{c}), those with a normal molecular shape, are naturally occurring and are attached to the surface of many cell types in the body. Their function is still unknown. Prions become pathological when their shape changes. Once they have taken on an abnormal shape, these "abnormal" prion proteins (PrP^{sc}) have the ability to replicate themselves. They convert normal prion proteins into abnormal prion proteins, which in turn convert other normal prion proteins, causing a slow but relentless chain reaction. Over time, aggregates of these abnormal prion proteins form plaques in the brain, causing degeneration of tissue and neuronal death, which leads to the disease symptoms.

Current diagnostic tests for BSE

At present, there are a number of companies making diagnostic tests for BSE, including Prionics (Switzerland), Bio-Rad (US, UK), Enfer Scientific (Ireland)). All of the current diagnostic tests are performed post mortem on brain tissue from infected cattle. There are currently no tests available for live animals.

Current tests, which are performed on the brain tissue of animals before they are butchered, are not able to detect BSE in animals younger than 30 months of age or those recently infected, due to the low number of abnormal prion proteins in the early stage of the disease. Efforts thus far have focused on improving the speed and sensitivity of the tests, but the limiting factor remains the inability to detect small amounts of the abnormal prion proteins in brain tissue samples.

Current diagnostic tests for nvCJD

Clinical symptoms can be observed at a late stage in the disease. But currently, the only definite confirmation of vCJD is post mortem analysis of brain tissue. A number of companies have made statements of strategic intent on developing blood screening tests for vCJD patients, including Biorad, Bayer, Roche and Ortho Johnson & Johnson.

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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 April 23, 2001. 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.

About Serono

Serono, headquartered in Geneva, Switzerland, is a global biotechnology leader. The Company has six recombinant products on the market, Gonal-F®, Luveris®, Ovidrel®, Rebif®, Serostim® and Saizen®. In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas. Currently, there are eleven molecules in development.

In 2000, Serono achieved worldwide revenues of US$1.240 billion, and a net income of US$301 million, making it the third largest biotech company in the world based on revenues. The Company operates in 45 countries, and its products are sold in over 100 countries. Bearer shares of Serono S.A., the holding company, are traded on the SWX Swiss Exchange (SEO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

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