



## Media Release

### FOR IMMEDIATE RELEASE

#### **SERONO AND NEWRON ANNOUNCE GLOBAL DEVELOPMENT AND COMMERCIALIZATION AGREEMENT FOR SAFINAMIDE**

**Geneva, Switzerland and Milan, Italy, October 16, 2006** - Serono (virt-X: SEO and NYSE: SRA) and Newron Pharmaceuticals SpA, announced today an agreement under which Newron has granted Serono exclusive worldwide rights to develop, manufacture and commercialise safinamide in Parkinson's disease (PD), Alzheimer's disease, and other cognitive disorders. Newron has recently reported positive results with safinamide from an early Phase III study in Parkinson's disease.

Under the terms of the agreement, Serono will be responsible for all future development, manufacture and commercialisation costs. Serono will make an upfront payment and additional milestone payments to Newron of up to \$200 million based on defined development and commercialization achievements in all major markets. Serono will also pay Newron undisclosed royalties on worldwide net sales. In addition, Newron will have the right to opt for co-promotion with Serono in Italy and Spain. Other details of the financial terms of the agreement were not disclosed.

Luca Benatti, CEO of Newron, said, "Serono has a major presence in the area of CNS and is the right partner to take safinamide on at this late-stage in its development. The significant financial contribution from Serono, together with the co-promotion opportunity, will enable us to further develop Newron as a broader based fully integrated biopharmaceutical company."

Franck Latrille, Senior Executive Vice President Global Product Development, Serono, commented, "This partnership enables us to expand our Neurology portfolio by investing in innovative products to meet significant unmet medical needs, such as Parkinson's and Alzheimer's disease."

Safinamide will be the subject of an extensive clinical development plan undertaken by both companies, with Serono assuming overall leadership of the programme. This will involve Newron completing on-going Phase III studies with safinamide as an add-on therapy to dopamine agonists in early stage PD patients, and with safinamide as an adjunct treatment to Levodopa in mid to late stage PD patients. Serono plans to expand the programme with a series of innovative additional studies aimed at addressing unmet medical needs in the treatment of Parkinson's disease, such as control of non motor symptoms, mainly cognitive impairment and depression, the delay and severity of motor complications and the possibility to delay disease progression.

### **Newron's early Phase 3 Clinical Trial in Parkinson's Disease**

The double blind placebo controlled trial, conducted in Europe, South America and Asia with 270 early stage Parkinson's disease patients being treated with safinamide as an adjunctive treatment to a stable dose of a single dopamine agonist, proved over 24 weeks of treatment to be well tolerated and associated with a clinically relevant and statistically significant improvement in UPDRS part III motor score\* (primary efficacy measure) as well as several secondary endpoints such as responder rates and Activities of Daily Living (ADL) compared to dopamine agonist monotherapy, at a dose of 50 to 100 mg/day. In addition, safinamide showed promising effects on cognition. Compared to patients on dopamine agonist monotherapy, the addition of safinamide indicated a potential improvement in cognitive function.

- Unified Parkinson's Disease Rating Scale (UPDRS) - III motor scale, which provides a semiquantitative evaluation of motor impairment as a means of rating patients severity."

### **About safinamide**

Safinamide is an alpha-aminoamide derivative which is orally administered. Studies have shown that safinamide combines the inhibition of dopamine re-uptake and MAO-B, two key mechanisms involved in the control of dopamine concentration in the brain, and inhibition of glutamate release. Based on the results of prior clinical trials, Newron believes that safinamide, as an adjunctive treatment to dopamine agonists and levodopa, has a competitive advantage over current therapies for Parkinson's disease.

### **About Serono**

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif<sup>®</sup>, Gonal-f<sup>®</sup>, Luveris<sup>®</sup>, Ovidrel<sup>®</sup>/Ovitrelle<sup>®</sup>, Serostim<sup>®</sup>, Saizen<sup>®</sup>, Zorbtive<sup>™</sup> and Raptiva<sup>®</sup>. 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.

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).

### **About Newron Pharmaceuticals**

Newron Pharmaceuticals S.p.A (<http://www.newron.com>) is a research and development company focused on novel therapies for diseases of the Central Nervous System (CNS), particularly pain and Parkinson's disease. Newron is undertaking phase III trials with safinamide, a unique molecule with multiple mechanisms of action, for the treatment of Parkinson's disease. Preliminary results of a six-month phase III trial have demonstrated benefit in motor symptoms and activities of daily living quality, as well as improvement in cognitive function and good tolerability. Phase II trials with safinamide in Restless Leg Syndrome (RLS) have shown promising results. Newron continues to conduct phase II trials with ralfinamide for the treatment of neuropathic pain. Newron's clinical pipeline is supported by a broad portfolio of early stage proprietary compounds generated by its ion channel drug discovery platform. Newron is headquartered in Bresso, near Milan, Italy.

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**Serono's forward-looking statement**

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 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 any government investigations and litigation. Serono is providing this information as of the date of this press release, and 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.

On September 21, 2006 Merck KGaA entered into an agreement with the Bertarelli Family, which owns the majority stake of Serono SA, to purchase their Serono shares. Subject to antitrust review and closing of the purchase, Merck will hold 64.5% of the capital of Serono and 75.5% of the voting rights, for which Merck agreed to pay CHF 1,100 per share in cash. Merck will make a public tender offer under Swiss law for the same price of CHF 1,100 per share. The offer price represents a 20% premium to the share price as of September 20, 2006, and a total equity value of CHF 16.6 billion (approximately EUR 10.6 billion) on a fully diluted basis.

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