

## CLINICAL UPDATE - DEBIO-9902 SR (ZT-1) IMPLANT FOR ALZHEIMER'S DISEASE - First patients enroll in Phase II 'BRAINz' study -

LAUSANNE, Switzerland, February 27, 2007 –Debiopharm Group (Debiopharm), a global independent biopharmaceutical development company specialising in oncology and serious medical conditions, announced its first patient has enrolled in the phase II study with DEBIO-9902 SR implants (formerly ZT-1), the first monthly sustained-release acteylcholinesterase (AChE) inhibitor being developed for Alzheimer's patients. The study will measure the safety and efficacy of DEBIO-9902 SR implants, in comparison to oral donepezil, in a clinical trial named 'BRAINz' (Better Recollection for Alzheimer's patients with ImplaNts of ZT-1).

"This is a promising new therapeutic approach," said David Wilkinson, MARC, Moorgreen Hospital, Southampton, England and Principal Investigator in the United Kingdom. "The DEBIO-9902 SR implant provides a new treatment alternative with the potential for better tolerance through a progressive, steady release of the active compound. This becomes an important factor in terms of compliance and efficacy for Alzheimer's patient who may find taking regular oral medication difficult or distressing."

The phase II, double blind, double dummy clinical trial with DEBIO-9902 SR which will be conducted on three continents, received prompt positive opinions from the ethics committee and regulatory agencies and was approved in the record time of one month. Results are expected during the first half of 2008. The 'BRAINz' study is registered on www.clinicaltrials.gov.

Results of an open label, phase II study with a once daily oral formulation of DEBIO-9902 demonstrated efficacy in mild to moderate Alzheimer (AD) patients, according to the Alzheimer's assessment cognitive sub-scale (ADAS-cog), the Mini mental state examination (MMSE) as well as by the Neuropsychiatric inventory questionnaire (NPI-Q). DEBIO-9902 was safe for doses up to 2mg per day. A prior phase I implant study showed that DEBIO-9902 SR implants were safe up to a dose of 15 mg/month and continuously released the active pharmaceutical ingredient over a period of 28 days.

Debiopharm is seeking a partner for further development and commercialisation of DEBIO-9902.

### About Alzheimer's Disease

Alzheimer's disease (AD) is a progressive brain disorder that gradually destroys a person's memory and ability to learn, reason, make judgments, communicate and carry out daily activities. AD is characterised by the progressive destruction of brain cells leading to a decline in mental

function and eventually, Alzheimer's patients need complete care.

Current estimates show that approximately four million people suffer from AD in the US and 15 million worldwide. Most available treatments produce an increase of the acetylcholine levels by inhibiting AChE, the enzyme responsible for its breakdown. Currently used therapies have significant side-effects which can occur with a frequency of up to 50% for nausea for instance. These treatments generally require complicated titration schemes in order to minimise these cholinergic side-effects, which is a challenge when dealing with memory deficient patients.

An AChE inhibitor with a better tolerance profile than existing treatments and with an easier dosing schedule could improve patient compliance and therefore optimise the patient's treatment.

#### About DEBIO-9902 SR

DEBIO-9902 SR is a novel AChE inhibitor that is transformed non-enzymatically into its active compound, huperzine A (hup A). Hup A has been used in China for centuries to treat distinct disorders such as memory loss, schizophrenia and hypertension, and is widely used in North America and Europe as a food additive to enhance cognition and neuroprotection. The dual mode of action of DEBIO-9902 SR as a N-methyl-D-aspartate receptor antagonist and an AChE inhibitor, positions it as a third generation anti-Alzheimer's product by improving the general condition and cognitive functions of affected patients as well as having the potential of being a neuroprotectant. A compound with neuroprotective properties to complement the cholinergic effects, could potentially reduce the progression of AD.

### **About Debiopharm Group**

Debiopharm Group is a global biopharmaceutical development company that in-licenses promising biologics and small molecule drug candidates. Debiopharm develops its products for global registration and maximum commercial potential for out-licensing to pharmaceutical partners for sales and marketing.

Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

Founded in 1979 and headquartered in Lausanne, Switzerland, Debiopharm has developed three products with global combined sales in excess of \$2.6 billion in 2006. For more information on Debiopharm Group, please visit: www.debiopharm.com.

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