

## ***PRESS RELEASE***

### **FOR IMMEDIATE RELEASE**

**DEBIOPHARM EXERCISES ITS OPTION AND SIGNS  
A LICENSE AGREEMENT WITH THE SHANGHAI INSTITUTE OF MATERIA MEDICA  
FOR THE DEVELOPMENT AND COMMERCIALISATION OF ZT-1**

Lausanne, Switzerland, May 13, 2004 - Debiopharm S.A., the independent drug-development company specialising in oncology, endocrinology, CNS and niche diseases, today announced it exercised its option right by signing a license agreement with the Shanghai Institute of Materia Medica (SIMM), in China, for the development of ZT-1, a novel cholinesterase inhibitor for the treatment of Alzheimer's disease. ZT-1 is a huperzine A (hup A) derivative with a dual pharmacological mechanism of action, that offers potentially neuroprotective properties on top of its cholinergic effects, which could reduce the progression of the disease.

During the development phase, SIMM will supply Debiopharm with predefined amounts of hup A, the starting material of ZT-1. Debiopharm has the exclusive license to develop and commercialise ZT-1 worldwide, however SIMM retains the rights to China. In addition, Debiopharm has put in place strong procurement and back-up strategies to ensure the commercial supply of ZT-1.

Debiopharm started the development of ZT-1 in 2000 and is currently conducting clinical phase II studies with the oral once daily formulation. Debiopharm also has positive results in animals with a sustained release formulation. To this day, Debiopharm has conducted approximately 60 ongoing preclinical studies and seven phase I/phase II clinical studies on ZT-1. Debiopharm is in the process of seeking co-development and commercial partnerships with pharmaceutical companies.

“With the encouraging results on ZT-1 so far, we are confident that there is a place for this molecule for the treatment of patients suffering from Alzheimer's disease,” said Rolland-Yves Mauvernay, President and CEO of Debiopharm. “In addition to the oral daily formulation, market research has also shown that clinicians are prepared to administer an injectable sustained release form of ZT-1.”

Alzheimer's disease is characterised by the degeneration of the neurons responsible for the synthesis of acetylcholine (ACh), a neurotransmitter with a central role in memory and other mental functions. Current treatment for AD in most countries consists in the administration of cholinesterase inhibitors, which increase the amount of ACh at the

neuronal synaptic cleft by inhibiting AChE, the enzyme responsible for the breakdown of ACh. AD is the most common form of dementia affecting elderly people, with a mean duration of around 8.5 years between the onset of clinical symptoms and death. The incidence of AD increases with age, even in the oldest age groups: from 0.5% at 65, it rises to nearly 8% at 85 years of age. Women probably have a higher risk of developing dementia than men, especially at very old ages. Worldwide, some 12 million individuals have AD and by 2025 that number is expected to increase to 22 million.

### **About Debiopharm**

Debiopharm, founded in 1979 in Lausanne, Switzerland, focuses on evaluating compounds with promising *in-vivo* results in animals, to in-license, develop for global registration, and out-license to sales and marketing pharmaceutical partners. Debiopharm's major commercial successes to date are Eloxatin<sup>®</sup>, one of Sanofi-Synthelabo's leading marketed products, Decapeptyl<sup>®</sup>, the leading product of Ipsen in Southern Europe, and Trelstar<sup>®</sup>, with combined sales estimated to be in excess of \$1.8bn in 2004.

Debiopharm is one of an established group of three complementary companies, Debiopharm, Debio R.P. and Debioclinic, with a successful track record in developing, registering and out-licensing innovative therapeutics. Debio R.P. is a leader in polymer-based controlled release technologies that allow certain drugs like proteins, peptides and anti-cancers to be delivered in customised, sustained-release formulation. From its FDA-inspected manufacturing facility in Martigny, Switzerland, Debio R.P. also conducts feasibility studies, formulation selection, optimisation, scale-up and cGMP manufacturing from clinical trial supplies to commercial scale. Debioclinic is a contract research organisation, specialised in oncology and dedicated to clinical development, providing regulatory, biometric and clinical support in line with cGCP.

For more information on Debiopharm, please visit our website at [www.debio.com](http://www.debio.com)

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