**DEBIOPHARM GRANTED EUROPEAN ORPHAN DRUG STATUS FOR DEBIO-0513 (PTR-262) FOR MYASTHENIA GRAVIS**

**Lausanne, Switzerland, September 21, 2006** - The Debiopharm Group (Debiopharm), a global independent biopharmaceutical development company specialising in oncology and serious medical conditions, today announced that it received European orphan drug designation from the Commission of the European Community (EC) for Debio-0513, formerly known as PTR-262, a dual altered ligand peptide analog of the myasthenogenic epitopes of the acetylcholine receptor (AchR) for the treatment of myasthenia gravis (MG).

European orphan drug designation is granted for products intended to treat life-threatening or chronically debilitating conditions affecting no more than 5 in 10,000 persons. Further criteria include the ability of the product to provide significant patient benefit over available treatment, or to fill an unmet medical need where no other treatment exists. The Commission for the EC concluded that DEBIO-0513 meets these requirements for the treatment of MG, a rare disease affecting approximately 0.7 to 1.5 in 10,000 people in Europe. In addition, orphan drug status of DEBIO-0513 in Europe can confer numerous benefits to its development, including clinical protocol assistance and advice, reduced registration fees when filing for product approval and, upon marketing authorisation, marketing exclusivity for a period of up to 10 years.

"Due to its unique mechanism of action, we hope that DEBIO-0513 will become an important novel treatment opportunity for MG sufferers. It has the potential to offer patients benefits such as modifying the progressive course of the disease, preventing relapses, and possibly working in combination with other available treatments. The sparing effect of DEBIO-0513 should decrease the risks usually related to current medications like steroids and other immunosuppressant," said Loïc Maurel, President and CEO of the Debiopharm Group Canadian subsidiary.

**About MG**

The most common form of MG is a chronic autoimmune neuromuscular disorder that is characterized by fluctuating muscular weakness. MG is caused by a defect in the transmission of nerve impulses to muscles. It occurs when normal communication between the nerve and muscle is interrupted at the neuromuscular junction. Normally when impulses travel down the nerve, the nerve endings release acetylcholine (Ach) into the neuromuscular junction, which in turn, binds to the acetylcholine receptors (AchRs) that are activated and generate a muscle contraction. Autoimmune MG is characterized by T-cell mediated autoantibody attacks on the AChRs at the neuromuscular junction, causing muscular weakness and fatigue. Available treatment options include cholinesterase inhibitors, immunosuppressive medication, plasma exchange and thymectomy, all with substantial side effects and which do not specifically target the underlying cause of the disease.

## About DEBIO-0513

DEBIO-0513, discovered at the laboratories of Professors Michael Sela and Edna Mozes at the Weizmann Institute of Science, Rehovot Israel, is a synthetic peptide, which down regulates auto-immune responses associated with myasthenogenic peptides. DEBIO-0513 is derived from the myasthenogenic epitopes of the AChR alpha-subunit, which specifically arrests the autoimmune destruction of AChR.

In preclinical models of MG, treatment by DEBIO-0513 creates a shift in the immune system from the harmful autoreactive T cell population to the T regulatory cells (TH3) , which down-regulates the autoimmune response of MG, resulting in significant improvement of a number of clinical parameters including grip strength and electromyography. Furthermore, in peripheral blood serum derived from MG patients, DEBIO-0513 inhibits the proliferation of T-cell populations that are responsible for myasthenogenic autoimmune mediated reactions and thus the development of MG.

## About The Debiopharm Group

The 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 $2.3 billion in 2005.

For more information on the Debiopharm Group, please visit: www.debiopharm.com


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