THE DEBIOPHARM GROUP AND SIGMA-TAU SIGN R&D AND COMMERCIAL AGREEMENT FOR ISTAROXIME IN ACUTE HEART FAILURE SYNDROMES

Lausanne, Switzerland, June 14, 2006 – The Debiopharm Group (Debiopharm), a global independent biopharmaceutical development company specialising in oncology and serious medical conditions, and sigma-tau Industrie Farmaceutiche Riunite SpA (sigma-tau), a leading Italian pharmaceutical group, announced the signature of a research and development (R&D) and commercialisation license agreement for istaroxime, a first-in-class luso-inotropic agent in clinical phase II for the treatment of acute heart failure syndromes.

Istaroxime was identified, patented and developed up to phase I by sigma-tau. Under the terms of the agreement, Debiopharm has the right to develop and commercialise istaroxime worldwide except in Italy and has an option to acquire similar rights on istaroxime follow-on compounds. Debiopharm will pay an upfront license fee and milestones to sigma-tau and will fund the future clinical development costs for the compound. Upon Debiopharm's completion of the phase II clinical development program, sigma-tau may exercise its semi-exclusive rights to market istaroxime in Spain and France and exclusive rights in Portugal. Royalties will accrue to both Debiopharm and sigma-tau according to a specific contractual mechanism.

"Istaroxime is just the type of molecule that Debiopharm favours; a promising innovative product in a disease area with an unmet need. Together with sigma-tau, I am hopeful that we will very quickly be able to offer patients a unique, more targeted new treatment for systolic and diastolic dysfunction," said Rolland-Yves Mauvernay, President and CEO of The Debiopharm Group.

"Istaroxime is an innovative drug which represents an important achievement of sigma-tau research. Thanks to this agreement with Debiopharm, sigma-tau will be able to reinvest into the development of other molecules of its pipeline," said Claudio Cavazza, Chairman and founder of sigma-tau.

About Istaroxime

Istaroxime is an innovative luso-inotropic agent which combines an inotropic (stimulation of myocardial contractility during systole) and lusitropic (improvment of diastolic relaxation) effect through an original dual mode of action. Istaroxime modulates calcium cycling through inhibition of the Na^+K^+-ATPase and activation of the sarcoplasmic reticulum Ca-ATPase, SERCA2a.

The efficacy and safety of istaroxime have been investigated in a variety of *in vitro* and *in vivo* models. In animal models istaroxime displays an interesting hemodynamic profile suitable for a drug addressed to the treatment of heart failure: it increases myocardial contractility without increasing heart rate and oxygen consumption, it improves ventricular relaxation and lowers preload. Moreover, istaroxime showed a good safety profile: it does not induce chronotropic response, does not prolong QT intervals and demonstrated a good tolerability in safety studies.
In the first-in-man study, conducted on congestive heart failure (CHF) patients with left ventricular dysfunction and treated with different doses of Istaroxime, a dose-dependent increase of the recorded myocardial contractility parameters was demonstrated, without increase in heart rate and without signs of arrhythmogenesis.

About acute congestive heart failure
Heart Failure (HF) is an increasingly common condition associated with high morbidity and mortality. Congestive heart failure (CHF) occurs at some time during most cases of severe heart disease. This pathophysiological state is produced by a variety of clinical syndromes, from acute heart failure to chronic heart failure. Acute decompensation in patients with CHF is one of the most frequent indications for hospitalisation in the US and represents about the 75% of the expenses for HF treatment. The general principles of pharmacological therapy include vasodilatation, control of sodium and fluid retention, and inotropic support of depressed ventricular function.

Intravenous inotropes are mainstay therapy in patients with acute exacerbation of heart failure when hemodynamic support is needed. Presently, Phosphodiesterase (PDE) inhibitors, catecholaminergic agents, and inodilators are the only classes of inotropes commonly used in such situations, but they can all elicit serious adverse effects, negatively impacting morbidity and mortality.

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

The Debiopharm Group 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, the Debiopharm Group has developed three products with global combined sales in excess of $2.2 billion in 2005.

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

About sigma-tau

Sigma-tau was founded at the end of the 1950's and is the second largest Italian pharmaceutical group. The 2005 Group's revenues amount to 674 million euros (US$ 850 million). It employs 2,400 people, 400 of whom work in R&D. Since its creation, the Group has made significant investments in R&D activities. The Group focuses on the following therapeutic areas: cardiovascular, metabolism, central and peripheral nervous system, immunology and oncology. Particular significance in the latter area has "Gimatecan", a novel oral anticancer compound. A major agreement was signed in 2003 with the Swiss multinational drug company Novartis, which acquired the worldwide development and marketing rights for Gimatecan from sigma-tau.

Currently, sigma-tau's portfolio includes 48 projects in several therapeutic areas; clinical trials are being conducted in 32 different indications; 16 proprietary molecules are under investigation, 13 of which are NCEs (New Chemical Entities). Sigma-tau is particularly proud of its R&D efforts in the area of "Rare Diseases" which is being intensively developed by its US subsidiary, sigma-tau Pharmaceuticals, Inc.

The Group, headquartered in Pomezia (Rome), has subsidiaries in France, Switzerland, the Netherlands, Germany, the UK, the USA (Gaithersburg, Maryland), as well as in Spain and Sudan, where the Group runs two production facilities. Finally, sigma-tau has recently established cooperations in China for the worldwide development of an anti-malarial drug deriving from Chinese Traditional Medicine.

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