

PRESS RELEASE

Clinical Update – Debio 0614 (istaroxime) in Acute Heart Failure - Presentation of Phase IIa Efficacy Results -

Lausanne, Switzerland, and Pomezia, Italy - April 2, 2008 - Debiopharm Group (Debiopharm), a global independent biopharmaceutical development specialist focusing on serious medical conditions, particularly oncology and cardiology, and sigma-tau Industrie Farmaceutiche Riunite SpA (sigma-tau), a leading Italian pharmaceutical group, today presented positive efficacy results of a phase IIa Horizon-HF study with Debio 0614 (formerly PST2744), also known as istaroxime, in development for the treatment of acute heart failure. Data showed that Debio 0614 is able to significantly reduce pulmonary congestion in patients admitted with worsening heart failure and left ventricular dysfunction. These findings were presented at the 57th American College of Cardiology (AAC) Annual Meeting in Chicago, by Mihai Gheorghiade, Professor of Medicine and Surgery at Northwestern University, Chicago and chair of the steering committee of the study.

The results of the study demonstrated that in patients with decompensated heart failure, Debio 0614 improves hemodynamics and diastolic function, without adversely affecting neurohormones or renal function. In this randomized, double-blind, placebo-controlled, multicenter trial, 120 patients were admitted with worsening heart failure, with a left ventricular ejection fraction below 35% and a pulmonary capillary wedge pressure above 20 mmHg. In 30 patients who received three doses of Debio 0614 over six hours, a statistically significant decrease of pulmonary wedge pressure ($p < 0.03$ for all doses) was observed, with a reduction of the left ventricular diastolic volume ($p = 0.02$ for the highest dose) and an increase in cardiac index ($p = 0.04$ for the highest dose), compared to patients treated with placebo.

“Debio 0614 is a novel intravenous agent combining inotropic and lusitropic properties. Its innovative mechanism of action allows for improving systolic and diastolic functions without causing significant arrhythmias or ischemia or increasing of myocardial oxygen consumption,” said Kamel Besseghir, CEO of Debiopharm S.A.

“Compared to available inotropes, known to be associated with increase of heart rate, hypotension and increase in atrial or ventricular arrhythmias, Debio 0614 demonstrated a rapid improvement of pulmonary capillary wedge pressure, associated with an apparent increase in systolic blood pressure and a trend to decrease heart rate, that makes this agent a promising therapy for the acute heart failure patients with low output stage,” added Paolo Carminati, R&D Director of sigma-tau.

Acute heart failure and Debio 0614

Acute decompensated heart failure (ADHF) syndromes represent a significant public health burden, resulting in 1 million patients hospitalised annually in the US with a post discharge event rate (readmissions/deaths) of 35% at 60 days.

Debio 0614 is a first in class luso-inotropic agent with calcium cycling modulating properties. It was discovered and developed up to phase IIa by sigma-tau and is currently being developed by Debiopharm for the treatment of acute heart failure syndromes with low output stage. It inhibits the Na⁺K⁺ ATPase pump, also known as the sodium-potassium pump and

restores the SERCA2 ATPase activity (Sarcoplasmic Reticulum Calcium ATPase 2 activity). The combined mechanism of action allows for cytosolic calcium accumulation during systole (inotropic response), as well as rapid sequestration of calcium during diastole and myocardial relaxation (lusitropic response).

Previously conducted phase I-II studies resulted in a good safety and tolerability profile of the drug.

About Debiopharm Group

Debiopharm Group is a global biopharmaceutical development specialist 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 \$2.65 billion in 2007.

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

About sigma-tau Group

Sigma-tau Group is a leading research-based Italian pharmaceutical company with a consolidated 2007 turnover of approximately €671 million (US\$ 980 million) and over 2500 employees worldwide. The therapeutic areas in which sigma-tau Group focuses its Research and Development include cardiovascular disease, metabolism, neurology, oncology and immunology, totalling 48 projects. Over 30 indications are explored in clinical trials with 24 molecules of which 17 are proprietary and the majority of them (14) are NCEs. Sigma-tau Group has operating subsidiaries throughout Europe and the U.S. and is active in every major pharmaceutical market. For additional information about sigma-tau Group, please visit www.sigma-tau.it

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