



THE DEBIOPHARM GROUP TO INITIATE CONFIRMATORY PHASE III TRIAL FOR SANVAR® IN ESOPHAGEAL VARICEAL BLEEDING

Lausanne, Switzerland, June 1, 2006 – The Debiopharm Group, a global independent biopharmaceutical development company specialising in oncology and serious medical conditions, announced today its initiation of a confirmatory Phase III study for Sanvar® in the United States (US), for the treatment of acute esophageal variceal bleeding (EVB) secondary to portal hypertension. The US Food and Drug Administration (FDA) has reviewed the protocol for this study under the Special Protocol Assessment (SPA) process. Previous Phase III trials for Sanvar® in this indication were conducted in Europe.

EVB is a frequent complication of late stage liver cirrhosis that affects approximately 750,000 patients per year worldwide. Survival is directly related to effective, early control of the bleeding episode, with one in five patients dying from the condition. Sanvar® works to reduce the bleeding by reducing portal hypertension. The new Sanvar® study seeks to confirm results, in US patients, of earlier trials that demonstrated that the early use of Sanvar® with endoscopic treatment improves the control of bleeding and prevents re-bleeding episodes in these patients.

During this multicenter, single-arm, open-label study in the US, Sanvar® will be administered for five days in 85 patients with acute EVB due to portal hypertension. The steering committee members include Professors Roberto Groszmann and Guadalupe Garcia-Tsao from Yale University, as well as Norman Grace from Brigham & Women's Hospital.

“We are very proud to conduct this study with a renowned group of experts in the field of portal hypertension in the US,” said Loïc Maurel, CEO of the Debiopharm Group Canadian subsidiary. “Sanvar® would be the first FDA approved product for EVB in the US.”

About Sanvar®

Sanvar® (vapeotide acetate) is a synthetic octapeptide analogue of the naturally occurring somatostatin hormone. It has similar pharmacological properties to native somatostatin but exhibits a longer duration of action. It is the only somatostatin analog to demonstrate statistically significant benefits in the early treatment of EVB in association with endoscopic therapy in a placebo controlled clinical study (Calès et al. *New England Journal of Medicine*, 2001). Survival with hemostasis at 5 days was achieved significantly ($p=0.021$) more often with Sanvar® than with placebo. In patients with control of bleeding at day 5, Sanvar®

significantly (p=0.006) increased hemostasis and survival through day 42. Sanvar[®] has been granted orphan drug status in the US and received an approvable letter from the FDA in 2004.

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.

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