

# PRESS RELEASE

# Sanvar<sup>®</sup> (Debio 8609) for esophageal variceal bleeding - Debiopharm submits response to the FDA -

**Lausanne, Switzerland, November 4, 2008** - Debiopharm Group (Debiopharm), a global biopharmaceutical development specialist that focuses on serious medical conditions and particularly oncology, announced today that Debiovision Inc., its Canadian affiliate, filed its Complete Response to the approvable letter received from the United States (U.S.) Food and Drug Administration (FDA) for Sanvar<sup>®</sup>, or Debio 8609 (vapreotide acetate). The immediate release formulation of Sanvar<sup>®</sup>, a somatostatin analogue, is used in the treatment of acute esophageal variceal bleeding (EVB).

"This is an important step towards completing the U.S. registration of our drug. Sanvar<sup>®</sup> has demonstrated therapeutic benefit in the control of acute variceal bleeding prior to endoscopic treatment, an indication for which, to this day, no product has been approved by the FDA," said Rolland-Yves Mauvernay, president and founder of Debiopharm Group.

"Last summer, we completed a confirmatory phase III study in the U.S. Our study took place in over 20 centers and enrolled 103 patients including 70 that qualified for the intention-totreat (ITT) analysis. Debioclinic S.A., the Group's French affiliate, participated with the statistical analysis of our study. The results of this study were an important component of the Complete Response and were submitted to the FDA on September 30<sup>th</sup>," added Jacques Guertin, president and CEO of Debiovision Inc.

Debiopharm has already signed license agreements for the sales and marketing of Sanvar<sup>®</sup>, with several commercial partners that include Salix Pharmaceuticals in the U.S., Ranbaxy Laboratories Ltd in India, EMS Sigma Farma in Brasil, LG Life Sciences in Korea, Tzamal Bio-Pharma Ltd in Israel, and Medical Futures in Canada.

# **About Sanvar**<sup>®</sup>

Sanvar<sup>®</sup> is used prior to endoscopic intervention to control haemorrhage and prevent rebleeding during the critical five days following the onset of bleeding. EVB is a life threatening condition and the mortality rate is high (about 15% to 25%) in the first six weeks following the haemorrhage. EVB is the cause of about 70% of gastro-intestinal bleeding in patients suffering from liver cirrhosis.

Sanvar<sup>®</sup> (vapreotide 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 analogue to have demonstrated 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). Control of bleeding with survival at five days was achieved more often with Sanvar<sup>®</sup> (p=0.021) than with placebo. Additional Phase III trials have been completed in Europe in this indication. Sanvar<sup>®</sup> can be stored at room temperature, an advantage over other products requiring refrigeration, allowing immediate administration, a key benefit in a life-threatening situation. The product has been granted orphan drug status in the U.S., where there is currently no FDA approved treatment for this indication.

### **About Debiopharm Group**

Debiopharm Group is a global biopharmaceutical development specialist that in-licenses promising biologics and small molecule drug candidates. It 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.

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