



## **DEBIOPHARM AND SALIX PHARMACEUTICALS SIGN LICENSE AGREEMENT FOR SANVAR<sup>®</sup>**

**Lausanne, Switzerland, and Raleigh, NC, US, September 5, 2006** - The Debiopharm Group (Debiopharm), a global independent biopharmaceutical development company specialising in oncology and serious medical conditions, and Salix Pharmaceuticals, Ltd. (NASDAQ:SLXP) today announce the signing of an exclusive license agreement granting Salix the right to sell, market and distribute, in the United States (US), SANVAR<sup>®</sup> IR (immediate release formulation) developed by Debiopharm for the treatment of acute esophageal variceal bleeding (EVB). The product is currently undergoing a confirmatory Phase III trial, in the US for the treatment of EVB secondary to portal hypertension. The US Food and Drug Administration (FDA) has reviewed the protocol under the Special Protocol Assessment (SPA) process. In addition to royalty payments on the sales of the product, under the terms of the agreement Salix will pay up to \$14 million in up-front and regulatory and sales performance milestone payments to Debiopharm.

Commenting on the announcement, Bill Forbes, Pharm. D., Vice President, Research and Development, and Chief Development Officer, Salix, stated, “EVB is a life-threatening and frequent complication of late-stage liver cirrhosis. Survival is directly related to early control of bleeding and Sanvar works to reduce bleeding by reducing portal hypertension. There is no approved treatment for EVB in the US at this time. Currently a multicenter trial is being conducted in the US at several major gastro-enterology centers. It is anticipated that the study, will confirm the results of trials conducted earlier in Europe by Debiopharm, that demonstrated that the early use of SANVAR<sup>®</sup> with endoscopic treatment improves the control of bleeding and prevents re-bleeding episodes in patients with portal hypertension.”

Carolyn Logan, President and Chief Executive Officer, stated, “Salix’s licensing-in of SANVAR<sup>®</sup> is the latest demonstration of our commitment to providing gastroenterologists and

their patients with innovative and effective products. Additionally, this acquisition demonstrates our continuing success in executing our strategy to identify emerging opportunities worldwide in order to expand our product portfolio. If SANVAR<sup>®</sup> is granted marketing approval by the FDA in the time frame we anticipate, we look forward to being able, by the end of 2007, to offer patients in the US the first product approved for this serious complication of late-stage liver cirrhosis.”

“We are thrilled to have a dedicated gastroenterology company like Salix as a partner for SANVAR<sup>®</sup> in the US. We are confident that their therapeutic focus along with their expertise in sales and marketing will help develop the full potential of SANVAR<sup>®</sup> in the important US market” said Loic Maurel, President and Chief Executive Officer of the Debiopharm Group Canadian subsidiary

### **About SANVAR<sup>®</sup>**

SANVAR<sup>®</sup> (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 (Cales et al. New England Journal of Medicine, 2001). Survival with hemostasis at 5 days was achieved significantly (p=0.021) more often with SANVAR<sup>®</sup> than with placebo. In patients with control of bleeding at day 5, SANVAR<sup>®</sup> (p=0.006) increased hemostasis and survival through day 42. 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. It has been granted orphan drug status in the US, where EVB affects less than 200,000 patients per year and received an approvable letter from the FDA.

### **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](http://www.debiopharm.com)

### **About Salix**

Salix Pharmaceuticals, Ltd., headquartered in Raleigh, North Carolina, develops and markets prescription pharmaceutical products for the treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete any required development and regulatory submission of these products, and market them through the Company's 150-member gastroenterology specialty sales and marketing team. Salix markets Colazal<sup>®</sup> (balsalazide disodium) Capsules 750 mg, Xifaxan<sup>®</sup> (rifaximin) tablets 200 mg, Visicol<sup>®</sup> Tablets (sodium phosphate monobasic monohydrate, USP, sodium phosphate dibasic anhydrous, USP), OsmoPrep<sup>™</sup> Tablets (sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP), Moviprep<sup>®</sup> (PEG 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid for oral solution), Azasan<sup>®</sup> (azathioprine 75mg and 100mg tablets, USP), Anusol-HC<sup>®</sup> 2.5% (hydrocortisone Cream USP), Anusol-HC<sup>®</sup> 25 mg Suppository (Hydrocortisone Acetate), Proctocort<sup>®</sup> Cream (Hydrocortisone Cream USP) 1% and Proctocort<sup>®</sup> Suppositories (Hydrocortisone Acetate Rectal Suppositories, 30 mg). Granulated mesalamine is under development.

For full prescribing information on Salix products, please visit [www.salix.com](http://www.salix.com).

### **Debiopharm Contacts**

Loïc Maurel  
President & CEO, Debiovision Inc.  
The Debiopharm Group  
Tel.: +1 514 842 99 76  
Fax: +1 514 842 54 30  
[лмаурел@debiovision.com](mailto:лмаурел@debiovision.com)

### **Additional Media Contacts In London**

Maitland Noonan Russo  
Brian Hudspith  
Tel: +44 (0)20 7379 5151  
[bhudspith@maitland.co.uk](mailto:bhudspith@maitland.co.uk)

Jeff Skinner  
Associate Director, BD&L, Debiovision Inc.  
The Debiopharm Group  
Tel.: +1 514 842 99 76  
Fax: +1 514 842 54 30  
jskinner@debiovision.com

**Salix Contacts**

Adam C. Derbyshire  
Senior Vice President and  
Chief Financial Officer  
919-862-1000

**In New York**

Noonan Russo, A division of  
Euro RSCG Life PR  
Wendy Lau  
Account Supervisor  
Tel: +1 212-845-4272  
Fax: +1 212-845-4260  
wendy.lau1@eurorscg.com

Mike Freeman  
Executive Director, Investor  
Relations and Corporate  
Communications  
919-862-1000