

## **Helsinn Healthcare SA Suspends Enrollment of New Patients in Becatecarin (XL-119) Phase III Clinical Trial Program in Biliary Tract Tumors.**

Lugano, Switzerland, November 16, 2006 -- Helsinn Healthcare SA, today announced that it has suspended enrollment of new patients in the becatecarin (XL-119) phase III clinical trial program in biliary tract tumors. Despite some evidence of becatecarin activity, preliminary analysis of the phase III data by an Independent Data Monitoring Committee (IDMC) indicated that the comparator agent 5-fluorouracil (5-FU) demonstrated a greater than expected survival benefit, making it statistically improbable that the final study results could achieve the planned objectives of the trial. In addition, the number and severity of serious adverse events has been lower in the 5-FU arm. Helsinn therefore decided to suspend enrollment of new patients pending further review.

"Certainly, we are disappointed with this recent development. Although becatecarin appears to have provided benefit to some biliary tract tumors patients in this trial, it was surprising that 5-FU performed substantially above the trial design expectations", said Dr. Sergio Cantoreggi, Helsinn's Head of Research & Development. "As we are in the process of collecting and analyzing all relevant data, our primary focus remains the safety and the optimal treatment of the patients. Therefore we are suspending the enrollment of new patients, but becatecarin will continue to be available to currently-enrolled patients who are experiencing clinical benefit."

### **About Becatecarin**

Becatecarin is a small molecule, anticancer compound for the treatment of hepatobiliary duct tumors, a rare and aggressive form of cancer with a high medical need and very limited survival. Becatecarin was granted the Orphan Drug designation in the USA and in EU.

## **About HELSINN HEALTHCARE**

HELSINN HEALTHCARE SA is a privately owned pharmaceutical group with headquarters in Switzerland. HELSINN's core business is the licensing of pharmaceuticals in niche therapeutic areas. The company's business strategy is to in-license early-stage new chemical entities and complete their development from the performance of pre-clinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELSINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELSINN's cGMP facilities and supplied worldwide to its customers. For more information about HELSINN, please visit [www.helsinn.com](http://www.helsinn.com).

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