

## **HELINN GROUP IS REINFORCING ITS CANCER SUPPORTIVE CARE PIPELINE**

**The Company has entered the Phase III clinical program for both its investigational medications anamorelin, in non-small cell lung cancer-associated anorexia/cachexia, and netupitant + palonosetron oral fixed-dose combination in chemotherapy-induced nausea and vomiting (CINV)**

**Lugano, Switerland, September 26, 2011** - Helsinn, the Swiss pharmaceutical Group, global leader in the segment of the prevention of chemotherapy-induced nausea and vomiting (CINV) with the second generation 5-HT<sub>3</sub> receptor antagonist palonosetron, is working very hard in reinforcing its cancer supportive care pipeline.

The company last Friday presented at the 2011 European Multidisciplinary Cancer Congress (EMCC), in Stockholm, Sweden, its Phase III clinical program for both its investigational medications anamorelin, in non-small cell lung cancer-associated anorexia/cachexia, and netupitant + palonosetron oral fixed-dose combination in chemotherapy-induced nausea and vomiting (CINV).

“We at Helsinn have always been very attentive to the quality of life of the patient. Hence our decision to concentrate our R&D efforts on a medical area with many, if not too many, unmet needs,” Dr. Riccardo Braglia, CEO of the Helsinn Group stated. “We have decided to focus and expand our pipeline of products in the oncology field, and in particular in the cancer supportive care arena where our company is consolidating its worldwide leadership. Therefore, we are excited to commence the final stages of development of our promising drugs in this important yet underserved area,” he said.

Helsinn’s pivotal Phase III clinical program of anamorelin for the treatment of anorexia/cachexia in patients with advanced non-small cell lung cancer includes two pivotal Phase III studies to be run in parallel, named ROMANA-1 and ROMANA-2.

Each is a randomized, double-blind, placebo controlled, multicenter global trial that is expected to enroll up to 477 patients, designed to measure the difference in the change in lean body mass and muscle strength in patients with advanced NSCLC-associated weight loss and evaluate pharmacokinetic and additional safety measures.

The Phase III clinical studies investigating the netupitant + palonosetron fixed-dose combination in chemotherapy-induced nausea and vomiting are designed to assess efficacy and safety of the combination and will enrol up to 2,600 patients in about 250 study centres in 18 countries worldwide.

For more information regarding the ongoing clinical studies, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

## About Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and the USA.

Helsinn has a large product development capability ranging from early optimization phase, preclinical phase and throughout all phases of clinical development and a proven expertise in oncology and cancer supportive care, pain and inflammation, and gastroenterology.

Helsinn's business model is focused on the licensing of pharmaceuticals and medical devices in therapeutic niche areas. The Group in-licenses early to late stage new chemical entities, completes their development from the performance of pre-clinical/clinical studies and Chemistry, Manufacturing and Control (CMC), development to the filing for and attainment of their market approval worldwide.

Helsinn's products are out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how, and assisted and supported with a full range of product and scientific management services, including commercial, regulatory, financial, legal and medical marketing advice.

The active pharmaceutical ingredients and the finished dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers.

For more information about Helsinn Group, please visit the website: [www.helsinn.com](http://www.helsinn.com)

For further information please contact:

**Paola Bonvicini**

Head of Communication & Press Office

Helsinn Healthcare SA

Ph: +41 91-985-21-21

[info-hhc@helsinn.com](mailto:info-hhc@helsinn.com)