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Helsinn Announced to have Initiated Global Pivotal Phase III Clinical Program to Evaluate Anamorelin (ONO-7643/RC-1291) in Non-Small Cell Lung Cancer-Associated Anorexia/Cachexia

Helsinn, a Swiss-based pharmaceutical company, announced on 23 August 2011 (Swiss local time) that its US subsidiary, Helsinn Therapeutics, has enrolled the first patient in the company's pivotal Phase III clinical program of anamorelin HCI, which is positioned as the final clinical stage, for the treatment of anorexia/cachexia in patients with advanced non-small cell lung cancer (NSCLC).

Attached is the press release made by Helsinn for your information.
In Japan, phase II clinical study is now being implemented under the license agreement agreed in October 2006*.

*Ono entered into an exclusive license agreement with Helsinn to develop and commercialize anamorelin (ONO-7643) in Japan, Korea and Taiwan. The compound is in clinical development by Helsinn Therapeutics in Europe and the U.S.

Helsinn Therapeutics Initiates Global Pivotal Phase III Clinical Program to Evaluate Anamorelin in Non-Small Cell Lung Cancer-Associated Anorexia/Cachexia

Lugano Switzerland, August 23rd 2011 - Helsinn, a Swiss-based pharmaceutical company, announced today that its US subsidiary, Helsinn Therapeutics, has enrolled the first patient in the company's pivotal Phase III clinical program of anamorelin HCl for the treatment of anorexia/cachexia in patients with advanced non-small cell lung cancer (NSCLC).

The anamorelin clinical program 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. In addition, patients will have the option of continuing treatment in a 12-week safety extension study called ROMANA-3.

The primary efficacy endpoints of ROMANA-1 and 2 include a measure of difference in the change in lean body mass and muscle strength in patients with advanced NSCLC-associated weight loss. Pharmacokinetic and additional safety measures will also be evaluated.

"We're very pleased to begin the final stages of testing in this important yet underserved area of cancer care," commented Dr. Riccardo Braglia, Chief Executive Officer of Helsinn Group. "Helsinn is committed to helping patients maintain their strength and energy while they undergo cancer treatment. The development of anamorelin solidifies our commitment to developing new supportive care therapies for patients in their fight against cancer."

"In the U.S. and much of the rest of the world, there are no approved treatments for cancer-related cachexia even though it affects a majority of cancer patients, including up to sixty percent* of those with lung cancer," commented Dr. John Friend, Senior Vice President, Research and Development. "Earlier clinical studies suggest anamorelin may help address the significant loss of weight and physical function experienced by many patients undergoing treatment for cancer. We look forward to confirming this in the ROMANA clinical program."

About Anamorelin and Ghrelin

Anamorelin HCl is an orally administered ghrelin receptor agonist and has been previously studied in approximately 500 subjects, including four completed Phase II trials involving 361 patients with cancer. Complete results from Phase II studies are expected to be published in the near future.

Ghrelin is a hormone that is predominantly produced in the stomach. As the first identified "hunger" hormone, administration of ghrelin rapidly stimulates appetite, which may lead to increased food intake and body weight, as well as other physiologic activities including increasing lean body mass and stimulating gastric emptying.

About Cancer-related Cachexia

Cachexia is a common yet life-threatening consequence of advanced cancer. The condition causes a decline in lean muscle mass, reduced strength and a decrease in physical function that can begin early in the course of a patient's cancer. In addition, it results in a compromised metabolism, making chemotherapy less tolerable. Up to 80 percent of advanced cancer patients experience cachexia and it is the cause of death in 20 to 40 percent[*] of these patients. There are no approved treatments for cancer-related cachexia in the United States or in much of the world.

About the Helsinn Group

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

[*] National Cancer Institute

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