

Helsinn initiates two new global Phase III studies with anamorelin

- **Helsinn committed to anamorelin which is being evaluated for weight loss and anorexia in patients with advanced non small cell lung cancer (NSCLC) and cachexia**
- **ONO has submitted application for manufacturing and marketing approval of anamorelin in Japan**

LUGANO, Switzerland, March 7, 2019: Helsinn Group, a Swiss pharmaceutical group focused on building quality cancer care products, today announces that the first patient has now been dosed in the new global Phase III program to evaluate anamorelin for the treatment of weight loss and anorexia in patients with advanced NSCLC with cachexia. Cancer cachexia is a multifactorial syndrome that involves loss of muscle mass and body weight, and is often accompanied by anorexia/loss of appetite.

Anamorelin is an orally active selective ghrelin receptor agonist which activates multiple pathways involved in the positive regulation of appetite and body weight.

The Phase III program consists of two 24-week double-blind randomized placebo-controlled multiregional confirmatory trials with identical study design. The primary efficacy endpoint will be measured at week 9 and will be based on the concomitant occurrence of a clinically relevant improvement of both body weight and a validated PRO (5-item Anorexia Symptoms Scale score) in alive patients at Day 64.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, said: “I am excited that the new Phase III program with anamorelin is taking off. Several clinical studies have clearly indicated that anamorelin had demonstrated an effect in weight loss and anorexia, two major components of cancer-cachexia, and Helsinn is fully committed to continue all the necessary development activities to bring this agent to cancer patients. Cancer cachexia remains an area of largely unsatisfied medical need with no safe and effective pharmacologic treatments available. Anamorelin could represent an innovative treatment for this currently high unmet cancer supportive care.”

“We’re delighted also that Ono Pharmaceutical Co., Ltd., our Japanese partner, has recently submitted an application for the manufacturing and marketing approval of anamorelin (ONO-7643) in Japan, a step we believe brings this promising therapy closer to the patients that need it.”

Anamorelin is an investigational agent not approved in any country.

Anamorelin in Japan

The application in Japan is mainly based on the results from the following two studies conducted in Japan in patients with cancer-cachexia:

- Phase II multi-center, placebo-controlled, randomized, double-blind, parallel group study in patients with non-small cell lung cancer (ONO-7643-04 study),
- Phase III multi-center, open-label, uncontrolled study in patients with colorectal, gastric or pancreatic cancer (ONO-7643-05 study).

In accordance with a license agreement with Ono Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd. has exclusive rights to develop and commercialize anamorelin in Japan, South Korea, and Taiwan.

About Anamorelin

Anamorelin is a selective, novel, orally active ghrelin receptor agonist. Ghrelin is an endogenous peptide primarily secreted by the stomach. Upon binding to its receptor, ghrelin stimulates multiple pathways in the positive regulation of body weight, muscle mass, appetite and metabolism. Anamorelin has shown effects in increasing body weight, and muscle mass, as well as appetite in patients with cancer cachexia and is expected to be the first treatment for this patient population.

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

To learn more about Helsinn Group please visit www.helsinn.com

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