October 31, 2014

ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp

Helsinn Group, Switzerland, announced new data on Fatigue from Phase III Trial (ROMANA 1) of Anamorelin/ONO-7643 in patients with Cancer Anorexia-Cachexia Syndrome (CACS) associated with Non-Small Cell Lung Cancer at 2014 Chicago Multidisciplinary Symposium in Thoracic Oncology

Helsinn Group ("Helsinn") announced on October 30, 2014 (Switzerland local time) that anamorelin/ONO-7643, a ghrelin receptor agonist, increased lean body mass and body weight, reduced fatigue and improved symptoms compared to placebo in the Phase III trial (ROMANA 1) in patients with cancer anorexia-cachexia syndrome (CACS) associated with non-small cell lung cancer.

In accordance with the license agreement entered into October 2006, ONO PHARMACEUTICAL CO.,LTD. has exclusive rights to develop and commercialize anamorelin/ONO-7643 in Japan, South Korea and Taiwan, and is currently conducting a Phase II trial in patients with cancer cachexia associated with non-small cell lung cancer.

Attached is the press release distributed by Helsinn for your information.

HELSINN
Building quality cancer care together

For Medical Press

HELSINN GROUP

New Data on Fatigue from ROMANA 1, a Pivotal Phase III Study of Anamorelin in Advanced NSCLC Patients with Cachexia Presented at 2014 Chicago Multidisciplinary Symposium in Thoracic Oncology

In ROMANA 1, a pivotal Phase III study, anamorelin was shown to increase lean body mass and body weight, reduce fatigue and improve health-related quality of life in patients with advanced NSCLC cachexia.

Lugano, Switzerland, October 30, 2014--Helsinn Group, the Company focused on building quality cancer care, announces that anamorelin, its investigational novel once-daily ghrelin receptor agonist for the treatment of cancer anorexia-cachexia syndrome (CACS), delivered significant improvements in lean body mass [LBM; one of two primary endpoints] in ROMANA 1, a pivotal 12-week Phase III study in non-small cell lung cancer (NSCLC) patients,

The results underscore the potential for treatment with anamorelin to support the care of patients with CACS, a poorly-understood and debilitating condition that affects a majority of advanced cancer patients but for which existing treatment approaches are limited.

In the ROMANA 1 trial, over the course of the study, patients treated with anamorelin demonstrated an increase in body weight along with improvements in patient symptoms and concerns, such as appetite, early satiety and fatigue.

Dr. Philip Bonomi, Director of Hematology-Oncology at Rush University Medical Center in Chicago stated “Weight loss is a dominant feature of advanced lung cancer, and there are no consistently effective treatments for this problem. The recently completed randomized study shows that treatment with anamorelin was associated with increased lean body mass and total body weight in advanced stage non-small cell lung cancer patients who had been losing weight. Along with weight loss, reduced appetite and fatigue cause considerable distress for many lung cancer patients and their

concerned loved ones. While taking anamorelin, patients also reported significantly improved appetite and less fatigue than patients taking placebo."

Riccardo Braglia, Helsinn Group CEO, commented: "The data show that, in patients with advanced non-small cell lung cancer, anamorelin can significantly improve lean body mass and body weight and alleviate some of the most debilitating symptoms of cancer anorexia-cachexia syndrome that are among the most important factors in preserving the best possible quality of life for patients with this disease. Anamorelin offers the potential of a novel treatment in advanced NSCLC patients with CACS, for whom getting the most out of every day is crucial."

Methodology:

ROMANA 1 (NCT01387269) was one of two international, double-blind, Phase III trials evaluating the efficacy and safety of anamorelin in NSCLC. Patients with unresectable Stage III/IV NSCLC, ECOG score of 0-2 and cachexia (≥5% weight loss within six months or BMI <20 kg/m^2), were randomized (2:1) to 100 mg anamorelin or placebo, given daily orally for 12 weeks. Patients were permitted to receive chemotherapy while on study. Co-primary endpoints were change from baseline over 12 weeks in LBM (measured by DXA) and in handgrip strength. Secondary endpoints included change in body weight and quality of life outcomes assessed by the FAACT (Functional Assessment of Anorexia/Cachexia Therapy) and FACIT-F (Functional Assessment of Chronic Illness Therapy–Fatigue) questionnaires. Safety assessments included lab values and adverse events.

ROMANA 1 results

Anamorelin significantly increased LBM compared with placebo (median change from baseline of 1.10 kg [95% CI 0.76; 1.42] vs -0.44 kg [95% CI -0.88; 0.20]; p<0.0001). Body weight also increased with anamorelin vs placebo (2.20±0.3 vs 0.14±0.4 kg; p<0.0001). Differences between treatment groups relating to handgrip strength were not statistically significant. Over the 12-week treatment period, FAACT scores were significantly higher in the anamorelin arm than in the placebo arm (change from baseline of 4.12±0.8 vs 1.92±0.8; p=0.0004); scores were also higher at all time points after treatment was started. For fatigue, FACIT-F scores deteriorated progressively in the placebo arm during the course of the study but remained stable in the anamorelin arm. The difference between treatment groups was significant at the end of the treatment

period. Changes from baseline in FACIT-F scores at week 9 were 0.33±0.9 vs -1.50±1.0 (p=0.0331) for anamorelin vs placebo, respectively and at week 12 were 0.48±1.0 vs -2.10±1.0 (p=0.0244).

The most frequent drug-related adverse events included hyperglycemia and nausea, affecting 5.3% and 3.8% of anamorelin treated patients, respectively. Drug-related serious adverse events affected less than 1% of patients.

Notes for editors:

About Cancer-anorexia-cachexia syndrome

Cancer anorexia-cachexia syndrome (CACS), characterized by decreased body weight, mainly lean body mass (LBM), is a common, poorly-understood and debilitating condition in patients with cancer, that frequently occurs in patients with advanced NSCLC, for which existing treatment approaches are limited.

NSCLC

Non-small cell lung cancer accounts for roughly 85% of all lung cancer cases. Lung cancer, which has some of the poorest survival rates of any cancers, is the most common form of cancer globally.

About anamorelin and ghrelin

Anamorelin HCl is an investigational selective, novel, orally active ghrelin receptor agonist that is under evaluation for the treatment of Cancer Anorexia-Cachexia in NSCLC patients. Ghrelin is an endogenous peptide secreted by the stomach. Upon binding to its receptor, ghrelin stimulates multiple pathways in the positive regulation of body weight, lean body mass, appetite and metabolism.

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the United States and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

About the Helsinn Group

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing preclinical and clinical studies and associated manufacturing

activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge. Helsinn supports these partners by providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics (U.S.), Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn's products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers

Further information on Helsinn Group is available at www.helsinn.com

For more information please contact:

Helsinn Group

Paola Bonvicini

Head of Communication & Press Office

Tel: +41 91-985-21-21

info-hhc@helsinn.com

For media / external inquiries

Consilium Strategic Communications

Mary-Jane Elliott / Jessica Hodgson / Matthew Neal /Laura Thornton

Tel: +44 (0)203 709 5700

Helsinn@consilium-comms.com