

HEL SINN GROUP SIGNS EXCLUSIVE AGREEMENTS WITH MUNDIPHARMA FOR DISTRIBUTION AND LICENCE OF ANAMORELIN IN BRAZIL AND ACROSS KEY MARKETS IN THE MIDDLE EAST AND NORTH AFRICA

The exclusive agreement builds on our existing partnerships in the area of cancer supportive care across multiple global territories

Lugano, Switzerland and Singapore, 11 February, 2015 – Helsinn, the Swiss Group focused on building quality cancer care, and Mundipharma, today announce that they have entered into distribution and license agreements for the exclusive rights to ***anamorelin*** in Brazil and across key markets in the Middle East and North Africa.

Under the terms of the new agreements, Helsinn retains all international development as well as regulatory and clinical development activities and the supply of *anamorelin* for commercial use. Mundipharma will obtain the rights to marketing, promotion, distribution and sales of *anamorelin* in the designated territories.

Anamorelin is a novel, once-daily, orally active ghrelin receptor agonist under investigation for the treatment of cancer anorexia-cachexia syndrome (CACS) in patients suffering from non-small cell lung cancer (NSCLC), an area with no truly effective treatment in the market. Also known as the wasting syndrome, CACS characteristics like reduced appetite/food intake and unintended weight loss (mainly due to muscle loss) are leading to early deaths of cancer patients. It is estimated that over 50% of late-stage cancer patients suffer from cancer anorexia-cachexia.¹

By mimicking ghrelin, the so-called “hunger hormone” secreted by the gastrointestinal tract, ***anamorelin*** has been shown to improve appetite and lean body mass in NSCLC patients who are suffering from CACS. The drug was also lauded by the European Society for Medical Oncology (ESMO) in the “*ESMO 2014 Wrap-Up: What should be remembered?*” as one of the

¹ K.C.H. Fearon et al (Sep 2002). *Cancer cachexia*. Int J Cardiol 85 (1): 73–81. PMID 12163211

top innovations in oncology of 2014. The Guest Associate Editor mentioned that “The results from the phase III ROMANA 1 and 2 studies in NSCLC (1483O_PR) demonstrated significant benefits with *anamorelin* in body mass, body weight and patients’ symptoms and concerns about anorexia-cachexia. These findings suggest that *anamorelin* has the potential to improve the lives of a significant number of cancer patients.”^{2, 3}

Riccardo Braglia, CEO of Helsinn Group, said: “This partnership is another step in what we foresee as a long and successful collaboration with Mundipharma. We believe that *anamorelin* will be established as an important advancement in the management of cancer anorexia-cachexia. With a clear potential to improve Lean Body Mass, patients can be stronger and able to tolerate more treatments, ultimately resulting in a better quality of life.”

Raman Singh, President of Mundipharma Asia Pacific, Latin America, Middle East and Africa, said: “We are excited to further expand our partnership with Helsinn and supplement our portfolio of products for supportive care of patients with cancer. This partnership will help us in our mission to alleviate the burden of disease and treatment related secondary effects for cancer patients in the key markets where we operate.”

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.

Anamorelin is administered orally at 100mg, once daily. In phase II trials, *anamorelin* was shown to increase body weight compared with placebo and to improve patient-reported

² ESMO 2014. Anamorelin Shown to Improve Appetite and Body Mass in Patients with Cancer Anorexia-Cachexia. <http://bit.ly/17fh0dE>

³ ESMO 2014 Wrap Up: What should be remembered? <http://bit.ly/1Bu3oGu>

symptoms, including appetite.⁴

Anamorelin recently completed phase III trials (the ROMANA program) in NSCLC patients with cachexia. In ROMANA 1 and ROMANA 2, *anamorelin* increased respect to placebo body weight, lean body mass, improved patient's symptoms and concerns related to anorexia/cachexia and was generally well tolerated.⁵

About the Helsinn Group

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 USA 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.

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing pre-clinical/clinical studies as well as 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. Helsinn has built a large product portfolio of cancer care products with the alliance of over 65 global partners. 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

⁴ Garcia JM, Friend J, Allen S. Therapeutic potential of anamorelin, a novel, oral ghrelin mimetic, in patients with cancer-related cachexia: a multicenter, randomized, double-blind, crossover, pilot study. *Support Care Cancer*. 2013;21(1):129–137.

⁵ Temel J, et al, *Annals of Oncology*, Volume 25, Supplement 4, 2014 (Abstract 1483O_PR)

About Mundipharma

Mundipharma's global network of companies are privately owned entities covering the world's pharmaceutical markets. Mundipharma provides patients across 6 continents with a growing portfolio of 19 products in 5 therapeutic areas, which include moderate-to-severe pain, consumer healthcare, oncology, respiratory disease, rheumatoid arthritis, antiseptics and laxatives. Mundipharma is a prime example of a company that consistently delivers high quality products while standing by the values that represent the company. Our mission is to alleviate the suffering of patients and to substantially improve their quality of life.

For more information, please visit: www.mundipharma.com.sg

For more information please contact:

Helsinn Group

Paola Bonvicini
Head of Communication & Press Office
PH +41 91-985-21-21
info-hhc@helsinn.com

Mundipharma Pte Ltd

Stephenie Vasko
Head of Communications Asia Pacific, Middle East, Africa & Latin America
PH+65 6303 9732
stephenie.vasko@mundipharma.com.sg
www.mundipharma.com.sg

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