

HELSINN GROUP SIGNS EXCLUSIVE AGREEMENT WITH MUNDIPHARMA FOR DISTRIBUTION AND LICENCE OF ANAMORELIN IN CHINA, HONG KONG AND MACAO

*This exclusive agreement broadens Helsinn's existing partnerships for **anamorelin** in the area of cancer supportive care across multiple global territories*

Lugano, Switzerland and Singapore, 26 March, 2015 – Helsinn, a Swiss Group focused on building quality cancer care, and Mundipharma, today announce that they have entered into a distribution and license agreement for the exclusive rights to **anamorelin** in China, Hong Kong and Macao.

Under the terms of the new agreement, 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 in patients suffering from non-small cell lung cancer (NSCLC), an area of significant unmet medical need. Cancer Anorexia-Cachexia is a multifactorial syndrome defined by an ongoing loss of skeletal muscle mass, the inability to be fully reversed by conventional nutritional support and a progressive functional impairment¹. In addition to its physical impact, Cancer Anorexia-Cachexia has also a marked psychological implication that contributes to decreased quality of life for both patients and their families². By mimicking ghrelin, the so-called “hunger hormone” secreted by the gastrointestinal tract, **anamorelin** has been shown to improve lean body mass and appetite in NSCLC patients who are suffering from Cancer Anorexia-Cachexia.

¹ Fearon K et al., Definition and classification of cancer cachexia: an international consensus. *Lancet Oncol* 2011;12:489–95

² Vaughan VC et al., Cancer cachexia: impact, mechanisms and emerging treatments. *J Cachexia Sarcopenia Muscle* 2013;4:95–109

The drug was also commented by the European Society for Medical Oncology (ESMO) in the “*ESMO 2014 Wrap-Up: What should be remembered?*” as one of the 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 (14830_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.*”^{3,4}

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** could be established as an important advancement in the management of cancer anorexia-cachexia. Anamorelin offers the potential for a new approach of treating this multifactorial clinical condition which can be devastating for patients and caregivers. Anamorelin has been shown in two large-scale clinical studies to improve lean body mass, potentially enabling patients to tolerate more treatments, and to alleviate their symptoms and concerns, ultimately helping them get more out of every day.”

Mr Raman Singh, President, Mundipharma Asia, Latin America, Middle East and Africa, said: “Improving the quality of patients’ lives has always been one of our core commitments, and the eventual launch of anamorelin in China seeks to provide healthcare professionals and patients with the effective support they need as patients undergo treatment. Our continued partnership with the Helsinn Group helps us further this goal, with their excellence in innovation and cancer supportive care.”

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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

³ ESMO 2014. Anamorelin Shown to Improve Appetite and Body Mass in Patients with Cancer Anorexia-Cachexia. <http://bit.ly/17fh0dE>

⁴ ESMO 2014 Wrap Up: What should be remembered? <http://bit.ly/1Bu3oGu>

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 symptoms, including appetite.⁵

Anamorelin recently completed phase III trials (the ROMANA program) in NSCLC patients with cachexia. In ROMANA 1 and ROMANA 2, ***anamorelin*** increased, in respect to placebo, body weight, lean body mass, improved patients' symptoms and concerns related to anorexia/cachexia and was generally well tolerated.⁶

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 around 70 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

⁵ 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.

⁶ Temel J, et al, *Annals of Oncology, Volume 25, Supplement 4, 2014 (Abstract 1483O_PR)*

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

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

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