



# HELSINN GROUP AND GEN ILAÇ ESTABLISH A COLLABORATION FOR ANAMORELIN IN TURKEY

Exclusive distribution and licensing agreement signed for the commercialization of Helsinn's compound currently in development for the treatment of cancer anorexia-cachexia syndrome in non-small cell lung cancer (NSCLC) patients

**Lugano, Switzerland, June 30<sup>th</sup>, 2014** – Helsinn Group, the company focused on building quality cancer care, today announces that rights to anamorelin, its innovative ghrelin receptor agonist, have been granted in Turkey to GEN IIaç.

Anamorelin is a cutting-edge novel, oral, once-daily drug in development for the treatment of cancer anorexia-cachexia syndrome ("CACS"). Current phase III studies are designed to assess safety and efficacy in increasing body weight, lean body mass, muscle strength, and patients' quality of life. The studies' focus is non-small cell lung cancer and is near completion.

Under the terms of the agreement, Helsinn will retain all the development activities (Chemistry, Manufacturing and Controls, preclinical and clinical) and the supply of anamorelin for commercial use. GEN IIaç will be responsible for regulatory approval as well as commercial activities within their territory.

Riccardo Braglia, CEO of Helsinn Group, said: "We are delighted to be taking our first significant steps into Turkey for anamorelin with a company with the reputation and reach of GEN Ilaç. Medicines like anamorelin, which target therapy areas of significant unmet need such as CACS, will help to improve the quality of life for patients living with cancer and help us deliver on our goal of becoming the world's leading cancer supportive care company."

Abidin Gülmüs, CEO of GEN Ilaç added: "We are proud of our reputation as one of Turkey's leading speciality pharma companies and we are excited to have a successful partnership with Helsinn. We look forward to providing anamorelin to oncologists for the treatment of patients who are suffering from CACS."

#### **Notes to editors**

### About anamorelin and ghrelin

Anamorelin HCI is a selective, novel, orally active ghrelin receptor agonist and has been previously studied in approximately 500 subjects, including four completed phase II trials over 300 patients with cancer. Anamorelin is currently being tested in two phase III studies,





ROMANA 1 and ROMANA 2 evaluating anamorelin HCI for the treatment of anorexia-cachexia syndrome in patients with advanced non-small cell lung cancer (NSCLC). The two studies enrolled approximately 477 patients each in over 15 countries, with sites in North America, Europe, Russia, Australia and the Middle East. Patients who complete ROMANA 1 or 2 have the option of continuing treatment in the ROMANA 3 safety extension study.

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.

#### About cancer anorexia-cachexia Syndrome (CACS)

Cancer anorexia-cachexia is a multifactorial syndrome that cannot be fully reversed by conventional nutritional support, and in which reduced food intake and altered metabolism contribute to loss of muscle mass and reduction in body weight. Patients with CACS have reduced quality of life, physical disability and shortened survival. CACS is often under-recognized despite of its frequency (more than 50% of cancer patients develop cachexia) and its strong implications, such as reduction of treatment tolerance, response to therapy and shortened survival. With no present standard of care and limited efficacy of current approaches, there is a need of a multimodal treatment for this multifactorial condition.

#### **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

## About Gen Ilaç

Gen Ilaç is a leading specialty pharmaceutical company headquartered in Ankara, Turkey, and represents innovative pharmaceutical and biotechnology companies, serving the medical community and patients in specific therapeutic areas of Neurology, Oncology, Hematology, Endocrinology and Nephrology. The company has long term collaborations with a number of international companies including Biogen Idec, Ipsen, Onyx, Gentium and many others. Gen Ilac is taking a leading role in Turkey bringing novel treatment options to patients with difficult to treat or rare conditions.

www.genilac.com.tr

For more information, please contact:

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