



## **Helsinn and Italfarmaco reinforce their alliance through the grant of rights to phase-III ghrelin receptor agonist Anamorelin in Italy**

*Helsinn Group grants exclusive distribution and licensing rights to Italfarmaco for the commercialization of its compound currently in development for the treatment of anorexia-cachexia syndrome related to non-small cell lung cancer (NSCLC)*

### **Lugano, Switzerland, December 18, 2013**

- Helsinn Group is pleased to announce that exclusive distribution and licensing rights to its innovative ghrelin receptor agonist, anamorelin, in Italy, San Marino and Vatican City have been granted to its long-established partner Italfarmaco.

Anamorelin is an innovative first-in-class, once daily oral drug currently in phase III for the treatment of anorexia-cachexia in NSCLC. Cancer anorexia-cachexia syndrome is a severe multifactorial condition that involves systemic inflammation, reduced food intake and altered metabolism, which contribute to the loss of muscle mass and body weight. This leads to diminished quality of life, functional impairment and decreased survival.

In Phase II trials anamorelin showed its capability to improve appetite and increase lean body mass, with a positive impact on the quality of life of cancer patients, as well as a positive safety and tolerability profile.

“Italy is one of the major pharma markets worldwide, and Italfarmaco is one of the most relevant Italian pharmaceutical groups, with a sound expertise in oncology/supportive care, among other fields. Our companies share a common view on the importance to safeguard and preserve patients’ quality of life and we are very happy to extend our fruitful and friendly relationship. Anamorelin will certainly play a significant synergic role within Italfarmaco’s therapeutic assets,” said Riccardo Braglia, Helsinn Group CEO.

Helsinn will retain all development tasks (CMC, preclinical and clinical) and supply of anamorelin for commercial use. The Swiss Group will also be responsible for the regulatory and clinical development while Italfarmaco will undertake all the commercial activities within Italy, San Marino and Vatican City. “We are very excited for this new promising asset, which perfectly fits to our existing portfolio and



long time expertise in the supportive care arena. Italfarmaco is looking forward to making Anamorelin available to Italian patient population suffering from such a debilitating disease”, commented Francesco De Santis, President of the Italfarmaco Group.

#### **About Anamorelin and Ghrelin**

Anamorelin HCl is a selective, novel, orally active ghrelin receptor agonist and has been previously studied in approximately 500 subjects, including four completed phase II trials dosing 361 patients with cancer. Anamorelin is currently being tested in two phase III studies, ROMANA 1 and ROMANA 2 evaluating anamorelin HCl for the treatment of anorexia-cachexia syndrome in patients with advanced non-small cell lung cancer (NSCLC). The two studies enroll 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, also known as the “hunger hormone”, is a multiacting peptide secreted by the stomach. Upon binding to its receptor, ghrelin stimulates multiple pathways in the 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 systemic inflammation, 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 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 privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and 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 therapeutic niche areas. Helsinn is an



important player in cancer supportive care. Helsinn Group in-licenses early-to-late stage new chemical entities, completes their development through the performance of pre-clinical /clinical studies and Chemistry, Manufacturing, and Control (CMC) development, and files and attains their market approvals worldwide. Helsinn's products are out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how whom Helsinn assists and supports by providing a full range of product and scientific management services, including commercial, regulatory, financial, legal, and medical marketing advice. The active pharmaceutical ingredients and the finished products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland and supplied worldwide to its customers. Further information on Helsinn Group is available at [www.helsinn.com](http://www.helsinn.com).

#### **About Italfarmaco Group**

Italfarmaco is a multinational pharmaceutical group headquartered in Italy, with operations in Spain, Portugal, Greece, France, Nordic Countries, Turkey, Russia, Morocco, Chile, Peru, Colombia and the United States. Italfarmaco is focused on

development, manufacturing and commercialization of prescription drugs, with high therapeutic content, in the fields of oncology/supportive care, women health, thrombosis, and CNS.

Italfarmaco is very well known for its commitment in R&D, with a number of new chemical entities in clinical stage of development. The group owns modern, sophisticated industrial plants, devoted to the GMP production of oral solids and injectables (in Milan) and oral liquids (in Madrid), where it manufactures its proprietary drugs at the highest standards of quality. Further information on Italfarmaco Group is available at [www.italfarmaco.com](http://www.italfarmaco.com).

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