

## Helsinn and Chugai Pharma Marketing Enter into Agreement for Rights of Anamorelin, Currently in Development for Treatment of Anorexia-Cachexia Syndrome Related to Non-Small Cell Lung Cancer in Top EU Markets

*Swiss Pharma Group Helsinn seals an alliance with Japanese company Chugai by granting exclusive distribution & licensing rights to commercialize its innovative phase III ghrelin receptor agonist in Germany, France, Benelux, UK and Ireland*

**Lugano, Switzerland and Tokyo, Japan, November 12, 2013** - Swiss-based Helsinn group has granted Chugai Pharma Marketing Ltd., a wholly-owned subsidiary of Chugai Pharmaceutical Co., Ltd., exclusive commercialization rights to their innovative ghrelin receptor agonist, anamorelin, for the three major European pharma markets.

Anamorelin is a new first-in-class, oral, once daily drug, currently in phase III for the treatment of anorexia-cachexia in NSCLC, a detrimental multifactorial disorder that affects over 50% of people with cancer and in which systemic inflammation, reduced food intake and altered metabolism contribute to loss of muscle mass and reduction of body weight leading to reduced quality of life, functional impairment and decreased survival.

Phase II trials have highlighted how anamorelin can improve appetite, increase lean body mass and have a positive impact on the quality of life of patients with cancer suffering from anorexia-cachexia. A good safety and tolerability profile was also shown. Phase II data have recently been presented at the ECCO/ESMO 2013 meeting in Amsterdam while the phase III clinical trial program (ROMANA 1, 2 & 3) that started in Q3 2011 is proceeding as expected.

“We are extremely pleased of this new, important collaboration with Chugai and we are very confident it will be significantly fruitful for both parties. This milestone is an additional recognition of anamorelin’s promising clinical development in the cancer supportive care arena”, said Riccardo Braglia, Helsinn Group CEO. “We are confident that our product can improve the quality of life of cancer patients in these European countries”, he concluded.

Under the terms of the agreement, Helsinn will retain all development activities (CMC, preclinical and clinical) and supply of anamorelin for commercial use. In addition, Helsinn will be responsible for the regulatory and clinical development whilst Chugai Pharma Marketing will undertake all the commercial actions within Germany, France, Benelux, UK and Ireland.

“This alliance is a result of our shared vision with Helsinn to introduce an important new treatment to reduce the burden of anorexia-cachexia syndrome in cancer patients. Anamorelin will give physicians a totally new option that could potentially change the way they treat patients with advanced cancer in the future. It is Chugai’s commitment and dedication to bring innovative medicines to patients, and we are confident that Anamorelin’s novel mechanism of action and strong

supporting data will lead to a successful introduction of this medicine to patients and physicians.” said John Halls, Managing Director of Chugai Pharma Marketing.

### **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 Chugai Pharma Marketing**

Chugai Pharma Marketing Ltd. is the headquarters of all Chugai's commercial activities throughout Europe and co-ordinates the European marketing operations through subsidiaries located in the UK, France, and Germany. Products which are currently marketed in those countries include "RoActemra<sup>®</sup> (tocilizumab)", a humanized anti-human IL-6 receptor monoclonal antibody, "Granocyte<sup>®</sup> (lenograstim)", a G-CSF preparation, and "Antepsin<sup>®</sup> (sucralfate)", an antiulcer agent (marketed in the UK and Ireland).

### **About Chugai**

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and Ukima is conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research was established in Singapore in January 2012 for conducting research focusing on the generation of new antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2012 of Chugai totaled 391.2 billion yen and the operating income was 76.4 billion yen. We are aiming at the consolidated revenue of 416.0 billion yen and operating profit of 77.5 billion yen in IFRS core basis, in 2013.

Additional information is available on the Internet at <http://www.chugai-pharm.co.jp/english>.

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