

December 1, 2015

# HELSINN ANNOUNCES EUROPEAN MEDICINES AGENCY ACCEPTANCE OF MARKETING AUTHORIZATION APPLICATION FOR ANAMORELIN HCL

(Lugano, Switzerland, November 30, 2015 [Switzerland local time])- Helsinn announced that the European Medicines Agency (EMA) accepted for review, the marketing authorization application (MAA) for anamorelin HCI, a novel, orally active selective ghrelin receptor agonist under development for the treatment of anorexia, cachexia, or unintended weight loss in non-small cell lung cancer (NSCLC) patients.

In accordance with the license agreement entered into October 2006, ONO PHARMACEUTICAL CO.,LTD. has exclusive rights to develop and commercialize anamorelin HCL / ONO-7643 in Japan, South Korea and Taiwan, and is currently conducting a Phase II trial in patients with cancer cachexia associated with non-small cell lung cancer in Japan.

Attached is the press release distributed by Helsinn for your information.

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# HELSINN ANNOUNCES EUROPEAN MEDICINES AGENCY ACCEPTANCE OF MARKETING AUTHORIZATION APPLICATION FOR ANAMORELIN HCL

**Lugano, Switzerland,** November 30, 2015: Helsinn, the Swiss pharmaceutical Group focused on building quality cancer care, today announced that the European Medicines Agency (EMA) accepted for review, the marketing authorization application (MAA) for anamorelin HCI, a novel, orally active selective ghrelin receptor agonist under development for the treatment of anorexia, cachexia, or unintended weight loss in non-small cell lung cancer (NSCLC) patients.

Riccardo Braglia, Chief Executive Officer of Helsinn Group commented, "With this EMA submission, we are one step closer to bringing this new and potentially effective treatment to market, meaning that the quality of life for patients with non-small cell lung cancer who suffer from anorexia, cachexia, could soon improve. Anamorelin is part of our pipeline of products dedicated to cancer supportive care, all of which address areas of significant unmet medical need."

#### About anamorelin and ghrelin

Anamorelin HCI is a novel, orally active ghrelin receptor agonist under development for the treatment of anorexia, cachexia, or unintended weight loss in NSCLC patients.

Ghrelin is an endogenous peptide primarily 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 an investigational agent that has not yet been approved by any regulatory authority.

The information discussed in this release is not intended to convey conclusions about its efficacy and safety.

#### **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 high ethical standards whom Helsinn assists and supports by providing a full range of product and scientific management services, including commercial, regulatory, 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.

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