

# **Helsinn Grants Specialised Therapeutics Australia (STA) Rights to Anamorelin, a First-in-Class Compound to Treat Cachexia-Anorexia Related to Non-Small Cell Lung Cancer (NSCLC)**

*Helsinn Healthcare SA and STA reinforce their Cancer Supportive Care Alliance in Australia and New Zealand with a Distribution and License Agreement for the innovative phase III ghrelin receptor agonist*

**Lugano, Switzerland and Melbourne, Australia, October 15th, 2012** – Melbourne biopharmaceutical company Specialised Therapeutics Australia (STA) has been granted exclusive commercialisation rights to a new drug for the treatment of NSCLC cachexia-anorexia. This condition is a serious multifactorial disorder which involves muscle wasting and metabolic impairment and commonly affects patients with advanced cancer. STA has reached agreement with Swiss pharmaceutical company Helsinn Healthcare to in-license the novel ghrelin receptor agonist anamorelin for both Australia and New Zealand.

This further collaboration follows on from STA's successful Australian commercialisation of Helsinn's second-generation 5-HT<sub>3</sub> antagonist, Aloxi<sup>®</sup> (palonosetron), as well as STA in-licensing Helsinn's new fixed dose combination compound, netupitant-palonosetron, for the prevention of chemotherapy-induced nausea and vomiting. Under the terms of the latest agreement, Helsinn will retain all development activities (CMC, preclinical and

clinical) and supply of anamorelin for commercial use. STA will be responsible for regulatory/clinical development and commercial activities within Australia and New Zealand.

Anamorelin is a first-in-class therapy being developed for the treatment of cachexia-anorexia in NSCLC, suitable for once daily oral administration. Previous phase II trials have demonstrated an improvement in appetite, an increase in lean body mass and improved quality of life in patients with cancer cachexia-anorexia. These trials have also demonstrated a good safety and tolerability profile (Helsinn data on file).

There are currently no approved treatments for cancer-related cachexia-anorexia in Australia, the EU or in the US.

Regional Director of Palliative Care for Barwon Health in Victoria, and a principal investigator for the phase III anamorelin registration trial, Associate Professor Peter Martin, described cachexia-anorexia as “a massive issue of concern” for clinicians, cancer patients and their families. He said it was not uncommon for patients to lose 5-10% of their body weight, and in extreme cases it can be significantly higher. “Cachexia-anorexia is an issue right from diagnosis” Associate Professor Martin said. “Anamorelin has produced some very encouraging data in placebo-controlled phase II studies, and we look forward to seeing a compound that is capable of successfully treating this serious condition.”

STA CEO Mr. Carlo Montagner said anamorelin was an important addition to the company’s expanding oncology portfolio, and specifically the company’s supportive care business.

“Our mission is to expand our portfolio to include treatment options which not only treat cancer, but address concerns related to this disease and improve the quality of life for all cancer patients,” Mr. Montagner said. “There are currently no approved or effective drugs to treat muscle wasting and more generally cachexia-anorexia in cancer patients. This condition affects a significant number of Australian and New Zealand patients with advanced cancers and severely diminishes their quality of life, and potentially compromises treatment.”

The anamorelin phase III clinical trial program (ROMANA 1, 2 & 3) began in Q4 2011 and will complete enrolment in the second half of 2013. It is anticipated that a New Drug Application will be filed with the FDA in mid-2014. Immediately

thereafter, a submission for Australian regulatory approval will be lodged with the Therapeutic Goods Administration (TGA).

Helsinn Group Chief Executive Officer, Dr. Riccardo Braglia said he was extremely pleased to strengthen the existing STA/Helsinn alliance with the latest anamorelin agreement.

“STA has been achieving great results as our commercial partner for our antiemetic franchise, placing themselves as one of our best performing partners in the world. Together we will now strive to reach even better outcomes for Australian and New Zealand cancer patients fighting cachexia and anorexia.”

### **About Anamorelin and Ghrelin**

Anamorelin HCl is an orally administered ghrelin receptor agonist and has been previously studied in approximately 500 subjects, including four completed phase II trials dosing 361 patients with cancer. Complete results from phase II studies are expected to be published in the near future.

Anamorelin is currently being tested in two phase III studies, ROMANA 1 and ROMANA 2, running in parallel are evaluating anamorelin HCl for the treatment of anorexia-cachexia in patients with advanced non-small cell lung cancer (NSCLC). The two studies will 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 is a hormone that is predominantly produced in the stomach. As the first identified “hunger” hormone, administration of ghrelin rapidly stimulates appetite, which may lead to increased food intake and body weight, as well as other physiologic activities including increasing lean body mass and stimulating gastric emptying.

### **About Cancer-related Cachexia-anorexia**

Cachexia-anorexia is a common yet life-threatening consequence of advanced

cancer. The condition causes a decline in lean muscle mass, reduced strength and a decrease in physical function that can begin early in the course of a patient's cancer. In addition, it results in a compromised metabolism, making chemotherapy less tolerable.<sup>1</sup> Up to 80 percent of advanced cancer patients experience cachexia-anorexia and it is the cause of death in 20 to 40 percent of these patients.<sup>2</sup> There are no approved treatments for cancer-related cachexia-anorexia in the United States or in much of the world.

## **About the Helsinn Group**

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and the United States. 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 Specialised Therapeutics Australia Pty Ltd**

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical companies worldwide to provide acute care therapies for high unmet medical needs to people living in

Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology and infectious disease.

Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nab paclitaxel) and ALOXI® (palonosetron) respectively, and has recently licensed from the Helsinn Group a fixed-dose combination product (in both oral and intravenous forms) containing netupitant, a neurokinin-1 (NK1) receptor antagonist, and Aloxi® (palonosetron), a serotonin-3 (5-HT<sub>3</sub>) receptor antagonist.

STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at [www.specialisedtherapeutics.com.au](http://www.specialisedtherapeutics.com.au)

**References:**

1. von Haehling, S et al. J Cachexia Sarcopenia Muscle, 2010; 1(1): 1-5.
2. U.S.A. National Cancer Institute Physician Data Query: [www.cancer.gov](http://www.cancer.gov)

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