

# Specialised Therapeutics Australia Extends Collaboration with Swiss Helsinn Group

**Melbourne, Australia and Lugano, Switzerland, 10 August 2011:** Melbourne bio-pharmaceutical company Specialised Therapeutics Australia plans to further expand its oncology portfolio, to include a new product for the prevention of chemotherapy-induced nausea and vomiting (CINV).

The Australian company has signed a letter of intent with its Swiss partner, Helsinn Group, to in-license Helsinn's new compound for the prevention of chemotherapy induced nausea and vomiting. The arrangement covers the development of a fixed-dose combination product (in both oral and intravenous forms) containing netupitant, a neurokinin-1 (NK<sub>1</sub>) receptor antagonist, and Aloxi® (palonosetron), a serotonin-3 (5-HT<sub>3</sub>) receptor antagonist.

This further collaboration follows the successful Australian launch in November last year of the second generation 5-HT<sub>3</sub> antagonist, Aloxi®, which is listed on the Pharmaceutical Benefits Scheme (PBS).

Aloxi® has been available internationally after being registered by Helsinn Group in the USA in 2003 and Europe in 2005, and is indicated for the prevention of nausea and vomiting induced by cytotoxic chemotherapy. It is successfully marketed in over 50 countries, with annual sales in 2010 in excess of \$500M worldwide.

Under the terms of the agreement, Helsinn will manufacture the new product in the group's plant located in Ireland and will also be responsible for the supply of the product for clinical and commercial use in Australia.

STA will be responsible for regulatory/clinical development and commercial activities within Australia and New Zealand. It is anticipated approval submissions will be lodged with the Therapeutic Goods Administration in 2014 following the successful completion of the Phase III registration program.

STA chief executive officer Mr Carlo Montagner said his company would pay an

upfront payment to Helsinn, as well as milestone and royalty payments.

Given the promising data from the phase I and II studies, he said he was optimistic this new product would further establish both STA and Helsinn as market leaders in oncology patient supportive care.

Riccardo Braglia, CEO of Helsinn Group said the company is very proud that the existing successful collaboration with STA for Aloxi® is now extending to netupitant-palonosetron fixed dose combination. He added that the strength of the two companies will enable Australian patients to have additional treatments for CINV now and in the future.

Ends.

For further information please contact Emma Power at Monsoon Communications on (03) 9620 3333 or 0419 149 525.

## **About Netupitant**

Netupitant is a highly selective NK<sub>1</sub> receptor antagonist, an antiemetic that works by blocking the action of Substance P, an endogenous neurotransmitter contained in high concentrations in the vomiting centre of the brainstem that can stimulate the vomiting reflex. The fixed-dose combination of netupitant and palonosetron has entered Phase III for the prevention of acute and delayed nausea and vomiting following both highly and moderately emetogenic chemotherapy.

## **About Palonosetron (Aloxi®, Onicit®, Paloxi®)**

Aloxi® (palonosetron hydrochloride) is a second generation 5-HT<sub>3</sub> receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting in cancer patients. Aloxi® has a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. In clinical trials and clinical practice, Aloxi® demonstrates unique long-lasting action in the prevention of CINV. A single intravenous dose of Aloxi® provides better protection from CINV than first-generation 5-HT<sub>3</sub> receptor antagonists.

Aloxi® is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions

(incidence  $\geq$  2 percent) in trials with Aloxi® were headache (9 percent) and constipation (5 percent), and they were similar to the comparators. Palonosetron has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi®, Onicit®, and Paloxi® in more than 50 countries world-wide. Aloxi® is the leading brand in the USA and in Japan within the CINV Day of Chemo segment, and it is steadily growing in the European markets. For more information about palonosetron, please visit the website: [www.aloxi.com](http://www.aloxi.com)

### **About Helsinn Group**

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and USA. Helsinn's business model is focused on the licensing of pharmaceuticals and medical devices in therapeutic niche areas. The Group in-licenses early to late stage new chemical entities, completes their development from the performance of pre-clinical/clinical studies and Chemistry, Manufacturing and Control (CMC), development to the filing for and attainment of their market approval 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, and assisted and supported with 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 dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers. For more information about Helsinn Group, please visit the website: [www.helsinn.com](http://www.helsinn.com)

### **About Specialised Therapeutics Australia, Pty Ltd**

Specialised Therapeutics Australia Pty Ltd (STA) was established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Australasian market. Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nab paclitaxel) and ALOXI® (palonosetron) respectively, and has recently licensed GLIOLAN® (5-aminolevulinic acid, 5-ALA) for intraoperative visualisation of malignant glioma. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.

