

Specialised Therapeutics and Helsinn Group Announce a PBS Listing for ALOXI® (Palonosetron) in Australia

Melbourne, Australia and Lugano, Switzerland 1st November 2010: A world leading anti-nausea/anti-vomiting drug for cancer patients undergoing chemotherapy will be available in Australia on the Pharmaceutical Benefits Scheme (PBS) from November 1st 2010.

Aloxi® (palonosetron hydrochloride) is a new therapy to prevent acute and delayed nausea and vomiting which can occur in cancer patients undergoing chemotherapy.

The drug is licensed in Australia by Specialised Therapeutics Australia Pty Ltd (STA) following an agreement with Swiss Pharmaceutical Company, The Helsinn Group.

This agreement grants STA the exclusive license and distribution rights for Aloxi® in Australia and New Zealand.

Specialised Therapeutics Australia chief executive officer Mr Carlo Montagner said thousands of Australian cancer patients would now benefit from Aloxi® and its listing on the PBS.

“Aloxi® is a leading antiemetic. Many of the international medical community regards this as the first choice anti-nausea drug for cancer patients following treatment,” he said.

“This PBS listing ensures Australian cancer patients affordable access to this leading treatment.”

“It enables a better quality of life for cancer patients and adds to our portfolio of leading oncology medications.”

Mr Montagner said Aloxi® was highly regarded by the world’s cancer

organisations. It is the only drug of its class specifically recommended by the European Society of Medical Oncology (ESMO), and the Multinational Association of Supportive Care in Cancer (MASCC), for moderately emetogenic chemotherapy³.

Aloxi® is a second generation 5-HT₃ receptor antagonist, which is differentiated to older 5-HT₃ antagonists by its higher receptor binding affinity and longer duration of its activity^{1,2}.

A single intravenous dose of Aloxi® is given on the day of chemotherapy, and has been shown to be effective for up to five days¹.

Aloxi® has been available in the USA since 2003, and is indicated in Australia for the management of nausea and vomiting associated with cytotoxic chemotherapy.

Today the product is approved in 63 countries, with annual sales last year of over 400 million US dollars.

Mr Montagner added: "The Helsinn Group has done a first class job of developing Aloxi®.

Helsinn Group chief executive officer Dr Riccardo Braglia said he looked forward to co-operating with STA on the Australian launch.

"We are delighted to sign this new agreement with STA and look forward to initiating a successful co-operation for Aloxi® in Australia," he said.

"STA has demonstrated a commitment to grow products in the specialist oncology market, while the patients and the medical community in Australia will enjoy the benefits of an innovative antiemetic like Aloxi®."

Aloxi® is PBS approved for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

For further information please contact:

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About ALOXI®

Palonosetron (palonosetron hydrochloride) is a second generation 5-HT₃ Receptor Antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. Palonosetron demonstrates, in clinical trials and clinical practice, a unique long-lasting action in the prevention of CINV. The product has shown to be effective in preventing both acute and delayed CINV in patients receiving moderately emetogenic chemotherapy (MEC). A single intravenous dose of palonosetron provides better protection from CINV than first-generation 5-HT₃ receptor antagonists throughout a 5-day post-chemotherapy period. Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions in CINV trials with palonosetron 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 60 countries world-wide. Palonosetron, marketed as Aloxi®, is the leading brand in the USA within the CINV Day of Chemo segment, and it is steadily growing in the European markets. In Australia, Aloxi® is PBS listed for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. For more information about palonosetron, please visit the website: www.aloxi.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 and ALOXI (palonosetron) respectively. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.

<http://www.specialisedtherapeutics.com.au>.

About Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and 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 sold directly through the Group's subsidiaries or 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. Helsinn is the worldwide licensor of palonosetron, a second generation 5-HT₃ receptor antagonist, for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer and of post-operative nausea and vomiting (PONV), and of the original nimesulide, a non-steroidal anti-inflammatory drug (NSAID) distributed in more than 50 countries worldwide.

Helsinn, with a workforce of around 450 employees in Switzerland, Ireland and USA, reported a 2009 turnover of over CHF 305.6 million, covering 85 countries worldwide, with over 20% of this turnover invested in R&D.

For more information about Helsinn Group, please visit the website: www.helsinn.com

- Leading anti-nausea/anti-vomiting drug available November 1st
- PBS listed for Australian cancer patients

References:

1. Aloxi product Information
2. Wong E, et al Br J Pharmacol 1995; 114: 851-859.
3. www.mascc.org

