

# 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 chemotherapy<sup>3</sup>.

Aloxi® is a second generation 5-HT<sub>3</sub> receptor antagonist, which is differentiated to older 5-HT<sub>3</sub> antagonists by its higher receptor binding affinity and longer duration of its activity<sup>1,2</sup>.

A single intravenous dose of Aloxi® is given on the day of chemotherapy, and has been shown to be effective for up to five days<sup>1</sup>.

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:

Emma Power at Monsoon Communications on 03 9620 3333 or 0419 149 525.

## **About ALOXI®**

Palonosetron (palonosetron hydrochloride) is a second generation 5-HT<sub>3</sub> 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-HT<sub>3</sub> 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](http://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-HT<sub>3</sub> 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](http://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](http://www.mascc.org)

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# **Celgene Acquires Abraxis BioScience and Leading Anti-Cancer Drug Abraxane**

Melbourne 20 October 2010: Celgene Corporation (NASDAQ: CELG) today announced it has completed its acquisition of Abraxis BioScience, Inc. The transaction adds Abraxane® (nanoparticle albumin-bound paclitaxel) to the company's existing portfolio of leading cancer products and offers another significant scientific platform that may drive future development.

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## **Abraxis Bioscience and Specialised Therapeutics Announce Approval to Market ABRAXANE® for Metastatic Breast Cancer in New Zealand**

**Los Angeles, Calif. and Melbourne Australia - July, 2010** - Abraxis BioScience, Inc. (NASDAQ:ABII), a fully integrated, global biotechnology company, and Specialised Therapeutics Ltd. today announced that MEDSAFE, the New Zealand Medicines and Medical Devices Safety Authority, has approved for marketing ABRAXANE® (nanoparticle albumin-bound paclitaxel) for the

treatment of metastatic breast cancer after failure of anthracycline therapy.

Abraxis BioScience granted exclusive marketing rights to Specialised Therapeutics for ABRAXANE in New Zealand. Specialised Therapeutics will commence distribution when reimbursement of Abraxane is approved through the New Zealand pharmaceutical reimbursement authority, Pharmac. ABRAXANE is currently fully reimbursed for “Metastatic breast cancer after failure of prior therapy” in Australia under the Pharmaceutical Benefits Scheme.

“In the U.S. and Australia ABRAXANE has rapidly become the taxane treatment of choice in its approved indication,” said Patrick Soon-Shiong, M.D., Executive Chairman of Abraxis BioScience. “We are pleased to provide this new treatment option for women in New Zealand with metastatic breast cancer.”

“Abraxane offers a safer and more efficacious taxane therapy for New Zealand women with metastatic breast cancer. Discussions with Pharmac will commence shortly and we hope to make Abraxane available as soon as an agreement with Pharmac is reached” said Carlo Montagner, CEO of Specialised Therapeutics.

With the approval in New Zealand, ABRAXANE is now approved in 41 countries.  
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### **About ABRAXANE**

ABRAXANE is a solvent-free chemotherapy treatment option for metastatic breast cancer which was developed using Abraxis BioScience’s proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin, a naturally-occurring human protein. By wrapping the albumin around the active drug, ABRAXANE can be administered to patients at higher doses, delivering higher concentrations of paclitaxel to the tumor site than solvent-based paclitaxel. ABRAXANE is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast, non-small cell lung, malignant melanoma, pancreatic and gastric.

The U.S. Food and Drug Administration approved ABRAXANE for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) in January 2005 for the treatment of breast cancer after failure

of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. For the full prescribing information for ABRAXANE please visit <http://www.abraxane.com>.

### **About nab-Driven Chemotherapy**

Abraxis BioScience has developed a proprietary nanoparticle albumin-bound (nab) technology which leverages albumin nanoparticles for the active and targeted delivery of chemotherapeutics to the tumor. This nab-driven chemotherapy provides a new paradigm for penetrating the blood-stroma barrier to reach the tumor cell. The proposed mechanism of delivery of this nab-driven chemotherapy is thought to be by targeting a previously unrecognized tumor-activated, albumin-specific biologic pathway with a nanoshell of the human blood protein albumin. This nano-shuttle system is believed to activate an albumin-specific (Gp60) receptor-mediated transcytosis path through the cell wall of proliferating tumor cells, using caveolin-1 activated caveolar transport. Once in the stromal micro-environment, the albumin-bound drug may be preferentially localized by a second albumin-specific binding protein, SPARC, a protein secreted into the stroma by tumor cells. The resulting collapse of stroma surrounding the tumor cell may thus enhance the delivery of the nab-chemotherapeutic to the intracellular core of the tumor cell itself.

### **IMPORTANT SAFETY INFORMATION**

The use of ABRAXANE has not been studied in patients with hepatic or renal dysfunction. In the randomized controlled trial, patients were excluded for baseline serum bilirubin >1.5 mg/dL or baseline serum creatinine >2 mg/dL.

ABRAXANE can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with ABRAXANE.

Men should be advised to not father a child while receiving treatment with ABRAXANE. It is recommended that nursing be discontinued when receiving ABRAXANE therapy. ABRAXANE contains albumin (human), a derivative of human blood.

Caution should be exercised when administering ABRAXANE concomitantly with known substrates or inhibitors of CYP2C8 and CYP3A4.

ABRAXANE therapy should not be administered to patients with metastatic breast cancer who have baseline neutrophil counts of less than 1,500 cells/mm<sup>3</sup>. It is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE. Patients should not be retreated with subsequent cycles of ABRAXANE until neutrophils recover to a level >1,500 cells/mm<sup>3</sup> and platelets recover to a level >100,000 cells/mm<sup>3</sup>. In the case of severe neutropenia (<500 cells/mm<sup>3</sup> for 7 days or more) during a course of ABRAXANE therapy, a dose reduction for subsequent courses is recommended.

Sensory neuropathy occurs frequently with ABRAXANE.

If grade 3 sensory neuropathy develops, treatment should be withheld until resolution to grade 1 or 2 followed by a dose reduction for all subsequent courses of ABRAXANE. Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients in the randomized trial. These events included chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary embolism, and hypertension.

In the randomized metastatic breast cancer study, the most important adverse events included alopecia (90%), neutropenia (all cases 80%; severe 9%), sensory neuropathy (any symptoms 71%; severe 10%), asthenia (any 47%; severe 8%), myalgia/arthralgia (any 44%; severe 8%), anemia (all 33%; severe 1%), infections (24%), nausea (any 30%; severe 3%), vomiting (any 18%; severe 4%), diarrhea (any 27%; severe <1%), and mucositis (any 7%; severe <1%).

Other adverse reactions have included ocular/visual disturbances (any 13%; severe 1%), fluid retention (any 10%; severe 0%), hepatic dysfunction (elevations in bilirubin 7%, alkaline phosphatase 36%, AST [SGOT] 39%), renal dysfunction (any 11%; severe 1%), thrombocytopenia (any 2%; severe <1%), hypersensitivity reactions (any 4%; severe 0%), cardiovascular reactions (severe 3%), and injection site reactions (<1%). During postmarketing surveillance, rare occurrences of severe hypersensitivity reactions have been reported with ABRAXANE.



### **About Specialised Therapeutics, 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 therapies, ABRAXANE and ALOXI (palonosetron). Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.

### **About Abraxis BioScience, Inc.**

Abraxis BioScience is a fully integrated global biotechnology company dedicated to the discovery, development and delivery of next-generation therapeutics and core technologies that offer patients safer and more effective treatments for cancer and other critical illnesses. The company's portfolio includes chemotherapeutic compound (ABRAXANE®), which is based on the company's proprietary tumor targeting technology known as the nab® platform. The first FDA approved product to use this nab® platform, ABRAXANE, was launched in 2005 for the treatment of metastatic breast cancer and is now approved in 41 countries. The company continues to expand the nab® platform through a robust clinical program and deep product pipeline. Abraxis trades on the NASDAQ Global Market under the symbol ABII. For more information about the company and its products, please visit <http://www.abraxisbio.com>.

### **FORWARD-LOOKING STATEMENTS**

The statements contained in this press release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the clinical development plan, and the timing and scope of clinical studies and trials, for ABRAXANE and the global commercialization of ABRAXANE. Because these forward-looking statements involve risks and uncertainties, there are important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, the fact

that results from pre-clinical studies may not be predictive of results to be obtained in other pre-clinical studies or future clinical trials; delays in commencement and completion of clinical studies or trials, including slower than anticipated patient enrollment and adverse events occurring during the clinical trials; decisions by regulatory authorities regarding whether and when to approve ABRAXANE for various indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of; unexpected safety, efficacy or manufacturing issues with respect to ABRAXANE; the need for additional data or clinical studies for ABRAXANE; regulatory developments (domestic or foreign) involving the company's manufacturing facilities; the market adoption and demand of ABRAXANE, the costs associated with the ongoing launch of ABRAXANE; research and development associated with the nab® technology platform; the impact of pharmaceutical industry regulation; the impact of competitive products and pricing; the availability and pricing of ingredients used in the manufacture of pharmaceutical products; the ability to successfully manufacture products in a time-sensitive and cost effective manner; the acceptance and demand of new pharmaceutical products; and the impact of patents and other proprietary rights held by competitors and other third parties. Additional relevant information concerning risks can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2009 and in other documents it has filed with the Securities and Exchange Commission.

The information contained in this press release is as of the date of this release. Abraxis assumes no obligations to update any forward-looking statements contained in this press release as the result of new information or future events or developments.

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# **PBS Change for Leading Breast Cancer Drug ABRAXANE®**

Melbourne, 7 June 2010: Melbourne pharmaceutical company Specialised Therapeutics Australia (STA) wishes to announce a change in the Pharmaceutical Benefits Scheme (PBS) listing for its lead product ABRAXANE® (nanoparticle albumin-bound paclitaxel).

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# **Study Shows Leading Breast Cancer Drug ABRAXANE®**

# **Increases Survival Time for Advanced Pancreatic Cancer**

MELBOURNE, May, 2010: An international study of world-leading breast cancer drug ABRAXANE® (nanoparticle albumin-bound paclitaxel) has shown promising results for patients with advanced pancreatic cancer when used in combination with Gemcitabine.

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## **ABRAXANE® in Focus at International Conference**



**CANCER DRUG ABRAXANE® IN FOCUS AT INTERNATIONAL  
CONFERENCE**

*Delegates to hear trial results for future possible ABRAXANE indications including lung cancer and melanoma*

**Melbourne: 27 May 2010:** World leading advanced breast cancer drug ABRAXANE® (nanoparticle albumin-bound paclitaxel) will be in focus at a leading international medical conference in Chicago next week.

Specialised Therapeutics Australia Pty Ltd (STA), which markets the drug in Australia, says its lead product will be showcased in 31 abstracts at the American Society of Clinical Oncology (ASCO) Conference, which begins in Chicago on June 4.

All presentations will highlight interim or final results for trials with ABRAXANE in several types of cancers, including breast, non-small cell lung, melanoma, ovarian, head and neck, pancreatic and bladder cancer.

Specialised Therapeutics Australia chief executive officer Mr Carlo Montagner said while the drug was currently only approved for metastatic breast cancer, trials around the world into the use of ABRAXANE in other cancer types were “extremely encouraging”.

He indicated Specialised Therapeutics Australia will submit the new data, when available, to the Therapeutic Goods Administration for approval of ABRAXANE in other cancers.

Among ASCO presenters will be world renowned cancer authority Dr Mark Socinski, from the University of North Carolina Lineberger Comprehensive Cancer Centre.

Dr Socinski will present the tumour response rates for the pivotal Phase 3 registration trial of ABRAXANE on 1052 lung cancer patients globally.

The major global study, which included Australian patients, trialled ABRAXANE in combination with Carboplatin, compared with solvent-based paclitaxel and Carboplatin, as a first line therapy in advanced non-small cell lung cancer.

Mr Montagner said he expected strong international interest in this presentation and other ABRAXANE abstracts, with the world’s first nanoparticle drug approved in over 36 countries.

He said that most recently, delegates at the American Association for Cancer Research in Washington were told the drug may have further potential in patients with triple-negative breast cancers when used in combination with Bevacizumab<sup>1</sup>.

*nab*-paclitaxel plus bevacizumab was shown to inhibit tumour growth by 100%, and reduced the incidence of lymph node and lung metastases by 50% and 87% respectively.

Mr Montagner added: “As these pivotal clinical trials around the world advance, we look forward to potentially bringing a new treatment option to patients with these difficult to treat cancers. It may be several years before we have approval for these new indications, however we are extremely encouraged by these results and look forward to presenting them to global medical experts at the ASCO conference.”

**Ends.**

### **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. ABRAXANE is the first of such therapies. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.

### **About ABRAXANE**

In Australia, ABRAXANE is currently approved and reimbursed by the Pharmaceutical Benefits Scheme (PBS) for the treatment of metastatic breast cancer after failure of prior therapy which includes an anthracycline.

ABRAXANE has also been granted orphan drug designation by the Therapeutic Goods Administration for the treatment of pancreatic cancer. Orphan drug status is granted to drugs used to treat relatively rare diseases such as pancreatic cancer and may allow for priority evaluation by the TGA.

ABRAXANE is approved for metastatic breast cancer in over 35 countries including the U.S., Canada, European Union and China, and more than 60,000 cancer patients have received ABRAXANE therapy in the past five years.

Additionally, ABRAXANE is currently under Phase III investigation for the treatment of the following cancers: non-small cell lung, malignant melanoma, and metastatic pancreatic.

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option for metastatic breast cancer<sup>2</sup>. Developed using Abraxis BioScience's proprietary *nab*<sup>(TM)</sup> technology platform, ABRAXANE is a nanoparticle protein-bound chemotherapy agent. ABRAXANE combines paclitaxel with albumin, a naturally-occurring human protein, to deliver the drug and eliminate the need for solvents in the administration process. Nanoparticle technology allows ABRAXANE to deliver a 49% higher dose compared to regular solvent-based paclitaxel without compromising safety and tolerability<sup>2,3</sup>.

In a randomised Phase III study of metastatic breast cancer patients, ABRAXANE demonstrated nearly double the overall tumour response rate compared to solvent-based paclitaxel<sup>2,3</sup>. Anthracycline pre-treated patients lived significantly longer<sup>4</sup>.

The tolerability with ABRAXANE and solvent-based paclitaxel was comparable, despite the 49% greater dose of paclitaxel administered as ABRAXANE<sup>2,3</sup>. Neutropenia was lower with ABRAXANE compared to solvent-based paclitaxel, although there was an increase in incidence of grade 3 peripheral neuropathy with ABRAXANE. However the median time to improvement, from grade 3 peripheral neuropathy to grade 2 or lower, was 22 days. No adverse events were reported that were not already known for paclitaxel<sup>2,3</sup>.

**FOR MORE INFORMATION PLEASE CONTACT EMMA POWER AT MONSOON COMMUNICATIONS ON (03) 9620 3333 OR 0419 149 525.**

## **References:**

- 1 .Ran S et al.** Abstract AACR 2010: 3852,
  - 2. Abraxane Product Information**
  - 3.** Gradishar WJ et al. J Clinical Oncology 2005; 23:7794-7803
  - 4.** Vukelja SJ et al. Abstract ASCO 2008;26:1082
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# **ABRAXANE® Meets Primary Endpoint in Phase 3 Trial for Advanced Non-Small Cell Lung Cancer**

LOS ANGELES and MELBOURNE - March 18, 2010: An international lung cancer trial has shown positive results in those patients treated with the leading breast cancer drug ABRAXANE in combination with carboplatin.

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## **Today Tonight Channel 7: March**



# 2010

The following story appeared on Channel 7's current affairs program Today Tonight in March 2010. Click to view.



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## **ABRAXANE® Granted Orphan Drug Status for Pancreatic Cancer by Therapeutic Goods Administration**

Melbourne, February 2010: A leading Australian breast cancer drug, ABRAXANE® (nanoparticle albumin-bound paclitaxel), has been granted orphan drug status by the Therapeutic Goods Administration (TGA) for pancreatic cancer.