# Specialised Therapeutics to License Brain Tumour Visualisation Drug GLIOLAN® in Australia & NZ

Melbourne, Australia and Hamburg, Germany, 17 June 2011: A new drug which aids neurosurgeons to better visualise and operate on high grade glioma, a type of brain tumour which has a poor prognosis, has been in-licensed by Melbourne bio-pharmaceutical company Specialised Therapeutics Australia Pty Ltd (STA).

STA has signed a binding term sheet with German company photonamic GmbH and Co. KG to in-license the drug Gliolan. The drug is used in brain surgery to selectively induce fluorescence in brain tumour cells to assist surgeons in defining and resecting gliomas.

An article published in The Lancet Oncology medical journal indicated complete resection of the malignant brain tumour tissue was achieved in 65% of patients receiving Gliolan, compared to 36% of patients in the control arm. Additionally, 6-month progression-free survival was achieved in 41% of patients receiving Gliolan compared to 21.1% of patients who received surgery without the use of the drug.<sup>1</sup>

The drug is already approved for use in 27 countries, including the United Kingdom, France and Germany. STA plan to lodge an application later this year with the Therapeutic Goods Administration to have the drug formally approved for widespread use in Australia.

Announcing the plan, STA chief executive officer Mr Carlo Montagner said STA would be responsible for marketing and clinical/regulatory development of the product in Australia and NZ. Photonamic would receive a confidential upfront payment, as well as milestone and royalty payments.

"The widespread adoption of Gliolan in Europe as a result of the Phase III randomised study published in The Lancet clearly demonstrates that patients significantly benefit from its use during surgery," Mr Montagner said.

"Australian neurosurgeons will welcome the opportunity to access Gliolan.

"For our part, we have made clear our strategy of building Specialised Therapeutics Australia through the acquisition and growth of specialist medicines that offer unique clinical benefits to patients.

"Gliolan is an excellent fit in our growing portfolio and we look forward to driving its growth."

Photonamic managing director, Mr Ulrich Kosciessa, said Gliolan which has recently been approved in Korea was now widely available and phase III trials of the drug had demonstrated "extremely positive" data.

"We anticipate similar results when the drug is used on patients with malignant gliomas in Australia and New Zealand," he said. "We are delighted this drug is now being made available in Australia."

Gliolan is used in adult patients with malignant glioma. Gliolan helps surgeons to visualise brain tumours more clearly during surgery which enables improved complete resection of the malignant tissue in the brain.

The active substance in Gliolan is 5-aminolevulinic acid, a natural biochemical precursor of heme, which is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). <sup>2</sup>

Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue which enables the surgeon to literally see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.<sup>2</sup>

Gliolan was first approved in Europe in 2007 and is marketed by medac in Europe, Africa, South America and Asia (excepting Japan and Korea).

## **References:**

1. Stummer W, Pichlmeier U, Meinel T, et al., Fluorescence-guided surgery

- with 5-aminovulinec acid for resection of malignant glioma: a randomised controlled multicentre phase III trial, Lancet Oncol, 2006;7:392-401
- 2. European Public Assessment Report Gliolan; http://www.ema.europa.eu/docs/en\_GB/document\_library/EPAR\_-\_Summar y for the public/human/000744/WC500021786.pdf

## About Gliolan®

The active substance in Gliolan is 5-aminolevulinic acid. It is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue. This enables the surgeon to see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.<sup>2</sup>

## 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\* (nanoparticle albumin-bound paclitaxel) and ALOXI\* (palonosetron) respectively. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australasia and other regional markets.

## About photonamic GmbH and Co KG

photonamic GmbH and Co KG was established in 2003 to develop photosensitizers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed 5-ALA for the fluorescence guided resection of glioblastoma (Gliolan) and for the photodynamic therapy of skin lesions (Alacare). Both products are approved in Europe and will further be developed for the global market. photonamic is based in Hamburg, Germany.

- Phase III study shows 6-month progression-free survival is doubled in patients receiving Gliolan<sup>®</sup> (5-aminolevulinic acid, 5-ALA)
- Drug improves visualisation and resection of brain tumour cells

## World Leading Breast Cancer Drug Now Available in New Zealand

Melbourne, Australia and Auckland, New Zealand - 21 February 2011 - New Zealand women now have access to a leading breast cancer drug ABRAXANE. (nanoparticle albumin-bound paclitaxel) for the treatment of metastatic breast cancer after failure of anthracycline therapy.

The drug, ABRAXANE, uses novel nanoparticle technology to deliver the chemotherapeutic agent to the tumour site and has been shown to prolong patient survival times with overall fewer side effects compared with traditional solvent-based chemotherapy treatments. <sup>13</sup>

Some of the side effects of traditional solvent-based chemotherapy treatments include serious solvent-related anaphylactic events, which can be fatal in some patients.

ABRAXANE is now available to patients in New Zealand via Specialised Therapeutics and will be distributed by Healthcare Logistics, based in Auckland.

Currently ABRAXANE is not subsidised in New Zealand, however a reimbursement application has been submitted to Pharmac, the Pharmaceutical

Management Agency of New Zealand, for review. A decision is expected later this year.

ABRAXANE is fully reimbursed for Metastatic breast cancer after failure of prior therapy in Australia under the Pharmaceutical Benefits Scheme (PBS).

Specialised Therapeutics CEO Mr Carlo Montagner said ABRAXANE had rapidly become a standard of care in Australia and the US for the treatment of metastatic breast cancer.

"We are pleased to provide this new treatment option for women in New Zealand with metastatic breast cancer," he said.

"We are hopeful that reimbursement approval will provide all women in New Zealand with metastatic breast cancer the option of a safer and more efficacious taxane therapy". <sup>2,3</sup>

International Phase III registration trials of Abraxane for metastatic pancreatic and melanoma cancers are currently enrolling patients, with results expected in the next two to three years.

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

## **About Specialised Therapeutics**

Specialised Therapeutics is a bio-pharmaceutical company primarily established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Australasian market. Currently Specialised Therapeutics 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.

## **About ABRAXANE**

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option for metastatic breast cancer.<sup>1</sup>

In Australia, ABRAXANE is currently listed on the PBS for the treatment of metastatic breast cancer after failure of prior therapy.

Developed using Celgene's proprietary nanoparticle albumin-bound (nab)(TM) technology platform, ABRAXANE is a nanoparticle protein-bound chemotherapy agent. ABRAXANE combines paclitaxel with albumin, a naturally-occurring human protein, to deliver the drug, eliminating 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>12</sup>

## **About nab-Driven Chemotherapy**

nab technology leverages albumin nanoparticles for the active and targeted delivery of chemotherapeutics to the tumour. This nab-driven chemotherapy provides a new paradigm for penetrating the blood-stroma barrier to reach the tumour cell. The proposed mechanism of delivery of this nab-driven chemotherapy is thought to be by targeting a previously unrecognised tumour-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 localised by a second albumin-specific binding protein, SPARC, a protein secreted into the stroma by tumour cells. The resulting collapse of stroma surrounding the tumour cell may thus enhance the delivery of the nab-chemotherapeutic to the intracellular core of the tumour cell itself.

ABRAXANE is approved for metastatic breast cancer in 41 countries including the U.S., Canada, European Union, Japan and China, and more than 100,000 cancer patients have received ABRAXANE therapy in the past five years.

In a randomised Phase III study of metastatic breast cancer patients, ABRAXANE demonstrated a significant improvement in response rate and progression free survival compared to solvent-based paclitaxel, while anthracycline pre-treated

patients lived significantly longer.5

The tolerability with ABRAXANE and solvent-based paclitaxel was comparable, despite the 49% greater dose of paclitaxel administered as ABRAXANE. Neutropaenia 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. 1-2

In Australia, ABRAXANE has also been granted orphan drug designation by the Therapeutic Goods Administration (TGA) 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. Additionally, ABRAXANE is currently under Phase III investigation for the treatment of the following cancers: non-small cell lung, malignant melanoma, and metastatic pancreatic.

Contraindications and side effects:

Like all medications, ABRAXANE may cause side effects.

ABRAXANE should not be used in patients who have baseline neutrophil counts of  $<1.5 \times 109$  /L.

In patients who have exhibited hypersensitivity reactions to paclitaxel or albumin, patients should not be treated with ABRAXANE. ABRAXANE is contraindicated during pregnancy and lactation.

For further information please refer to www.specialisedtherapeutics.com.au for the New Zealand ABRAXANE Product Information.

## References:

- 1. Abraxane Product Information
- 2. Gradishar WJ et al. J Clinical Oncology 2005;23:7794-7803
- 3. Gradishar WJ et al. J Clinical Oncology 2009; 27(22): 3611-19
- 4. Irizarry LD et al. Community Oncology 2009;6(3):132-134

## 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<sub>\*</sub> (palonosetron hydrochloride) is a new therapy to prevent acute and delayed nausea and vomiting which can occur in cancer patients undergoing chemotherapy<sub>1</sub>.

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<sub>\*</sub> 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<sub>®</sub> and its listing on the PBS.

"Aloxi<sub>"</sub> 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<sub>3</sub>.

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>12</sup>.

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

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<sub>\*</sub>.

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<sub>\*</sub>."

Aloxi<sub>\*</sub> 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

## **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

· 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

## 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.

## 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. -END-

## **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 microenvironment, 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/mm3. 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/mm3 and platelets recover to a level >100,000 cells/mm3 In the case of severe neutropenia (<500 cells/mm3 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).

# 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.

# 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.

# 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.