ABRAXANE® Demonstrates Significant Improvement in Progression-Free Survival Compared to Standard Chemotherapy in Advanced Melanoma Patients

MELBOURNE, Australia – October 25, 2012 – Specialised Therapeutics Australia Pty Ltd today announced that abstracts for the upcoming Society for Melanoma Research meeting have been published online in the organization's official journal. The publication includes an abstract reviewing results from a phase III metastatic melanoma study with ABRAXANE® (nanoparticle albumin-bound paclitaxel).

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)

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.

GLIOLAN® Granted Orphan Drug Status by the Therapeutic Goods Administration

Melbourne, Australia April 2012: A drug which aids neurosurgeons to better visualise and more completely remove malignant brain tumours has been granted orphan drug status by the Therapeutic Goods Administration (TGA).

The drug, Gliolan, is currently in-licensed by Melbourne biopharmaceutical company, Specialised Therapeutics Australia (STA) and is currently only available to neurosurgeons via the federal government's Special Access Scheme (SAS).

Gliolan has been granted orphan drug designation for photodynamic diagnosis of gliomas that are glioblastoma multiforme (GBM) (malignant) on preoperative imaging, and intended for gross macroscopic resection of all visible tumour. STA will lodge an application for TGA approval later this year. Orphan drug designation also means TGA application fees are waived.

STA chief executive officer, Mr Carlo Montagner, said orphan drug status is an important milestone as the company progressed plans to register the drug with the TGA.

"After we submit our documentation for registration by the TGA, approval for Gliolan could take 12 to18 months. We look forward to making this product broadly available to patients as it has been shown to significantly improve

outcomes in glioma patients."

Gliolan is administered to patients three hours prior to surgery and causes cancerous tissue to glow fluorescent red during brain surgery. This enables improved visualisation of the boundary between healthy and diseased brain tissue, and aids the surgeon to more thoroughly remove the tumour. International studies have shown the use of Gliolan during surgery has nearly doubled the rate of achieving a complete resection, which has resulted in a doubling of the number of patients without progression of their brain cancer six months after their surgery.[1]

The pivotal Phase III registration study published in The Lancet Oncology medical journal reported 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. This resulted in 6-month progression-free survival being achieved in 41% of patients receiving Gliolan compared to 21.1% of patients who received surgery without the use of the drug.[1]

Gliolan has been accessed via the SAS and used in five brain tumour (high grade glioma) operations to date in Australia, at the Royal Melbourne Hospital and the Wesley Hospital in Brisbane.

The drug has been approved for use in 29 countries since 2007, including the United Kingdom, France, Germany, and Korea. Gliolan is used in adult patients with malignant glioma. The active substance in Gliolan, 5-aminolevulinic acid, is a photoreceptive compound which is predominantly absorbed by highly proliferative cells in the body and converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX).[2]

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 visualise the tumour more clearly during brain surgery and to remove it more completely and accurately, sparing healthy brain tissue.[2]

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

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.[2]

Like all medications Gliolan may cause side effects. Gliolan should not be used in patients with hypersensitivity to 5-ALA or porphyrins, in cases of acute or chronic porphyria, or in pregnancy. Cardiac disorders, gastrointestinal disorders and skin and subcutaneous disorders are all reported as being uncommon.

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 negotiating the rights to several more important therapeutic agents for release in Australasia and other regional markets.

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_1) receptor antagonist, and Aloxi® (palonosetron), a serotonin-3 (5-HT_3) receptor antagonist.

This further collaboration follows the successful Australian launch in November last year of the second generation 5-HT_3 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_1 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_3 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_3 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 ≥ 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

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

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 visulisation 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.

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. [1-3]

Some of the side effects of traditional solvent-based chemotherapy treatments include serious solvent-related anaphylactic events, which can be fatal in some patients[4].

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”. [2,3]

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.[1]

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.[1-2]

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,[1-2] 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.[1-2] 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[1]:

Like all medications, ABRAXANE may cause side effects.

ABRAXANE should not be used in patients who have baseline neutrophil counts of <1.5 x 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
5. Vukelja SJ et al. ASCO 2008 Abstract 1082

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.

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.