

Updated Pancreatic Cancer Data Presented at International Cancer Conference



Melbourne, January 2014 - A leading breast cancer drug, ABRAAXANE® (nanoparticle albumin-bound paclitaxel), has been shown to extend overall survival (OS) for patients with metastatic pancreatic cancer when used in combination with current standard of care, gemcitabine, with some patients surviving longer than three years.¹

The updated OS data from the pivotal Phase III Metastatic Pancreatic Adenocarcinoma Clinical Trial (MPACT)^{1,2} of ABRAAXANE in combination with gemcitabine, was presented at the recent American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Conference in San Francisco by Australian Oncologist, Professor David Goldstein.

Professor Goldstein, who is based at the Prince of Wales Hospital in New South Wales, said that the data was “extremely encouraging” and paved the way for ABRAXANE to be used as a first-line therapy in the treatment of pancreatic cancer.

“Importantly, this large multinational trial in metastatic pancreatic cancer has demonstrated important three year survival rates, with 4% of patients in the ABRAXANE plus gemcitabine arm alive after three years, compared to none in the gemcitabine alone arm, and a near 30% improvement in survival outcomes,” he said.

“This cancer is the fourth most common cancer in Australia for both men and women³ and typically patients diagnosed with metastatic pancreatic cancer have a median life expectancy of approximately three to six months. These patients have very limited treatment options as there have been no new medications approved for metastatic pancreatic cancer in nearly seven years.

Data from this important study shows that ABRAXANE when used in conjunction with standard of care gemcitabine can substantially improve OS, with predictable and manageable side effects.”

The MPACT study was conducted at a number of sites internationally, including 20 sites in Australia, and involved 861 patients, of which 120 were Australian.

The median survival benefit in the updated analysis was extended in the ABRAXANE + gemcitabine arm with a 2.1 month OS improvement compared to gemcitabine alone (OS; median 8.7 months vs 6.6 months; HR=0.72; $p<0.0001$).¹ This compares favourably with the 1.8 months improvement previously reported in the New England Journal of Medicine (OS; median 8.5 months vs 6.7 months; HR=0.72; $p<0.00001$).²

The Chief Executive Officer of Australian biopharmaceutical company, Specialised Therapeutics Australia (STA), Mr Carlo Montagner, said ABRAXANE is currently approved in the United States and Europe as a first-line therapy in combination with gemcitabine for patients with metastatic pancreatic cancer.

He said a submission to the Therapeutic Goods Administration (TGA) for the regulatory approval of ABRAXANE (in combination with gemcitabine) for first-line

treatment of locally advanced unresectable or metastatic adenocarcinoma of the pancreas was made in 2013. An application for a Pharmaceutical Benefits Scheme (PBS) listing for this indication has also been submitted with the Pharmaceutical Benefits Advisory Committee (PBAC) and will be reviewed at the March 2014 meeting.

Mr Montagner commented: “We are extremely pleased with these results presented at the ASCO GI conference and look forward to a TGA approval for ABRAXANE and a subsequent PBS listing for Australian patients with this difficult to treat cancer.”

ABRAXANE is currently TGA approved for the treatment of metastatic breast cancer and first-line Non Small Cell Lung Cancer (NSCLC).⁴

About the MPACT Study²

The MPACT study was a Celgene-sponsored, open-label, randomised, international study of 861 patients with metastatic pancreatic cancer. Patients were randomised to receive either ABRAXANE plus gemcitabine (125 mg/m² followed by 1000 mg/m² gemcitabine for 3 weeks followed by a week of rest) or gemcitabine alone (1000 mg/m² administered weekly for 7 weeks followed by a week of rest followed by cycles of weekly administration for 3 weeks followed by one week of rest).

The primary endpoint for the study was overall survival. Secondary endpoints were progression-free survival and overall response rate determined by independent radiological review. Other endpoints included progression-free survival and overall response rate determined by investigator, and the safety and tolerability of this combination in this patient population.

About Advanced Pancreatic Cancer

Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is approximately 5% and is less than 2% for those with advanced disease.³ There are two main types of pancreatic cancer – adenocarcinomas,

which account for approximately 90% of all pancreatic cancer, and neuroendocrine tumours. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers. However, pancreatic cancer is the fourth most common cause of cancer death for men and women in Australia, and the ninth most commonly diagnosed cancer in Australia.⁴

About ABRAXANE®

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option approved for the treatment of metastatic breast cancer and NSCLC.⁴

ABRAXANE is indicated for the treatment of metastatic carcinoma of the breast after failure of anthracycline therapy. ABRAXANE, in combination with carboplatin, is indicated for the first-line treatment of NSCLC in patients who are not candidates for potentially curative surgery and/or radiation.⁴

In Australia, ABRAXANE is currently listed on the PBS for the treatment of metastatic breast cancer and HER2 positive breast cancer in combination with trastuzumab. ABRAXANE is not listed on the PBS for the indication of NSCLC.

ABRAXANE is approved for metastatic breast cancer in over 40 countries including the U.S., Canada, European Union, Japan and China, and more than 180,000 cancer patients have received ABRAXANE therapy in the past five years.

ABRAXANE is currently in various stages of investigation for the treatment of the following cancers: metastatic melanoma, adjuvant pancreatic cancer, bladder cancer, ovarian cancer, and expanded applications for breast cancer.

Developed using the proprietary *nab*[™] 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 eliminates 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.^{4,5}

Contraindications and Side Effects⁴:

Like all medications, ABRAXANE may cause side effects.

ABRAXANE should not be used in patients who have baseline neutrophil counts of $<1.5 \times 10^9$ /L.

Patients who have exhibited hypersensitivity reactions to ABRAXANE or human albumin should not be treated with ABRAXANE.

ABRAXANE is contraindicated during pregnancy and lactation.

Most common side effects ($\geq 1/10$) caused by ABRAXANE include; neutropenia, anaemia, leucopenia, thrombocytopenia, lymphopenia, anorexia, peripheral neuropathy, hypoaesthesia, paraesthesia, nausea, diarrhoea, vomiting, constipation, stomatitis, alopecia, rash, arthralgia, myalgia, fatigue, asthenia, pyrexia. This is not a full list of all the side effects.

Before prescribing or for further information regarding ABRAXANE and potential side effects, physicians should review the ABRAXANE Product Information at www.specialisedtherapeutics.com.au

Patients should consult their oncologist or the ABRAXANE Consumer Medicine Information available at www.specialisedtherapeutics.com.au

ABRAXANE® is a registered trademark of Celgene Corporation.

ABRAXANE® is under license from Celgene Corporation and distributed by STA in Australia and New Zealand.

About Specialised Therapeutics Australia Pty Ltd

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical companies worldwide to provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

- Study shows ABRAXANE plus gemcitabine combination therapy further extends overall survival benefit
- First Phase III trial in metastatic pancreatic cancer to report three year survival rates¹
- New standard of care for patients with metastatic pancreatic cancer

References:

1. Goldstein D et al. Oral Abstract # 178. Updated survival from a randomized phase III trial (MPACT) of nab-Paclitaxel plus gemcitabine versus gemcitabine alone for patients (pts) with metastatic adenocarcinoma of the pancreas. ASCO GI 2014.
 2. Von Hoff DD et al. Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine. N Engl J Med 2013; 369(18):1691-703.
 3. Cancer in Australia. An Overview 2012. Australian Institute of Health and Welfare (AIHW)
 4. ABRAXANE Product Information
 5. Gradishar WJ et al. J Clinical Oncology 2005;23:7794-7803
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**Melbourne Biopharmaceutical
Company Named First Corporate
Sponsor of International Medical
Aid Organisation**



Melbourne, June 2013 Melbourne biopharmaceutical company Specialised Therapeutics Australia has become the first corporate sponsor of an international charitable organisation which enables medical and surgical specialists to impart their expertise to colleagues in developing countries.

The company has become the inaugural donor for the Specialists Without Borders (SWB) organisation, an Australian based non-profit entity established in 2005 to provide specialist medical and allied health teaching in developing countries.

The specialist teaching from some of Australasia's leading academic doctors, covers areas such as trauma surgery, orthopaedics, neurosurgery, anaesthetics, urology, radiology, oncology, paediatrics, perinatal health and psychiatry.

Announcing the \$50,000 donation, STA co-founders Carlo Montagner and Bozena Zembrzuski said this funding would immediately assist a specialised teaching seminar to be undertaken in Malawi and Zimbabwe in September 2013, with expansion of the teaching programme into Asia in 2014. STA will also provide communications and marketing support to SWB as part of its sponsorship.

20 Australian doctors and five select medical students will travel to each location for one week of teaching. Supported by four major Australian universities, the

organisation has pioneered innovative teaching techniques in medicine and surgery and is rapidly becoming a valued medical teaching resource in developing countries. SWB has recently completed a five-year teaching module in Rwanda.

Ms Zembrzuski said these intensive teaching programs in developing countries were designed to empower local communities and reduce poverty by educating local doctors in cutting-edge medical developments and techniques which are often commonplace in the western world.

“STA is committed to improving health outcomes not only for Australians but for people in more remote parts of the world who may not have access to the same facilities and top-level expertise we are lucky enough to enjoy,” she said.

“We hope this donation plays a part in helping SWB make real inroads in these developing countries, with the ultimate goal that doctors in these areas are equipped to give high class care to their own communities.”

Working in full partnership with local communities and health care services, SWB co-ordinates an international body of medical specialists committed to providing medical education which enables sustainable health care solutions.

SWB chairman Dr Paul Anderson said all Australian doctors involved in the mission covered their own airfare and accommodation expenses.

“We are extremely pleased to accept this generous contribution from STA and are committed to ensuring these funds will help educate our colleagues in other parts of the world,” Dr Anderson said.

“We can make a real difference. And it is this kind of support that will enable us to further develop and continue to provide programs addressing areas of high need in terms of medical education in the third world.

“Every trip we make brings us closer to achieving our goals of helping these communities help themselves with improved medical care and high class training.”

About Specialised Therapeutics Australia

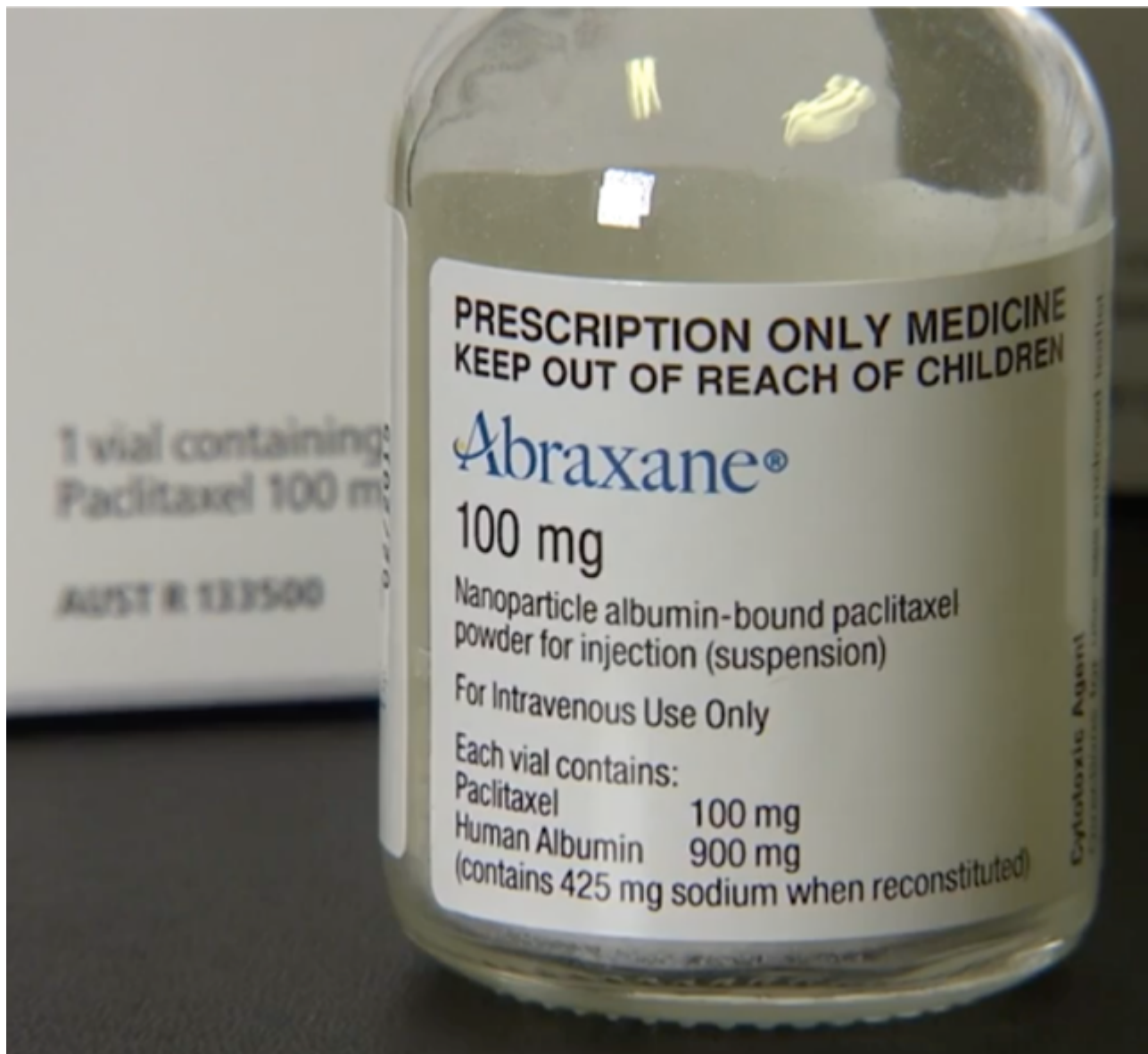
Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical companies worldwide to provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

About Specialists Without Borders

Specialists Without Borders (SWB) is an Australia-based non-profit organisation contributing towards sustainable medical education in developing countries. SWB recognises the vital importance of information-sharing through the participation in global health, education and aid networks and works within the context of the United Nations Millennium Development Goals (MDGs) towards a more just, stable and secure world.

Through SWB, groups of international medical specialists volunteer their time to lead training seminars in developing countries. Each seminar is undertaken in full partnership with local communities, hospitals, health departments, medical schools and universities. Projects include, where possible, the upgrading of facilities and the provision of educational materials and textbooks to enhance medical learning and practice.

ABRAXANE Meets Primary Endpoint of Overall Survival Improvement in Phase III Advanced Pancreatic Cancer Study



Melbourne, November 2012 Specialised Therapeutics Australia (STA) is pleased to announce that the phase III, randomised, international study of ABRAXANE® (nanoparticle albumin-bound paclitaxel) in combination with gemcitabine in treatment-naïve patients with advanced pancreatic cancer met its primary endpoint of overall survival.

This is now the fourth disease in which ABRAXANE has demonstrated positive phase III results, including difficult to treat diseases where other taxanes have shown limited activity.

In the MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial) study, a Celgene-sponsored, open-label, randomised, international study, 861 metastatic pancreatic cancer patients were randomised to receive either ABRAXANE plus gemcitabine (125 mg/m² followed by 1000 mg/m² gemcitabine for 3 weeks followed by a week of rest) or gemcitabine alone (1000 mg/m² administered weekly for 7 weeks followed by a week of rest followed by cycles of weekly administration for 3 weeks followed by one week of rest).

The primary endpoint for the study was improvement in overall survival. Secondary endpoints included evaluation of progression-free survival, objective tumour response and the safety and tolerability of the ABRAXANE/gemcitabine combination in this patient population.

The safety profile of ABRAXANE in combination with gemcitabine observed in the study was comparable with other ABRAXANE clinical trials in pancreatic cancer.

A late-breaker abstract has been submitted to the American Society of Clinical Oncology's (ASCO) 2013 Gastrointestinal Cancers Symposium being held in San Francisco on January 24-26, 2013, after which more details will be made available.

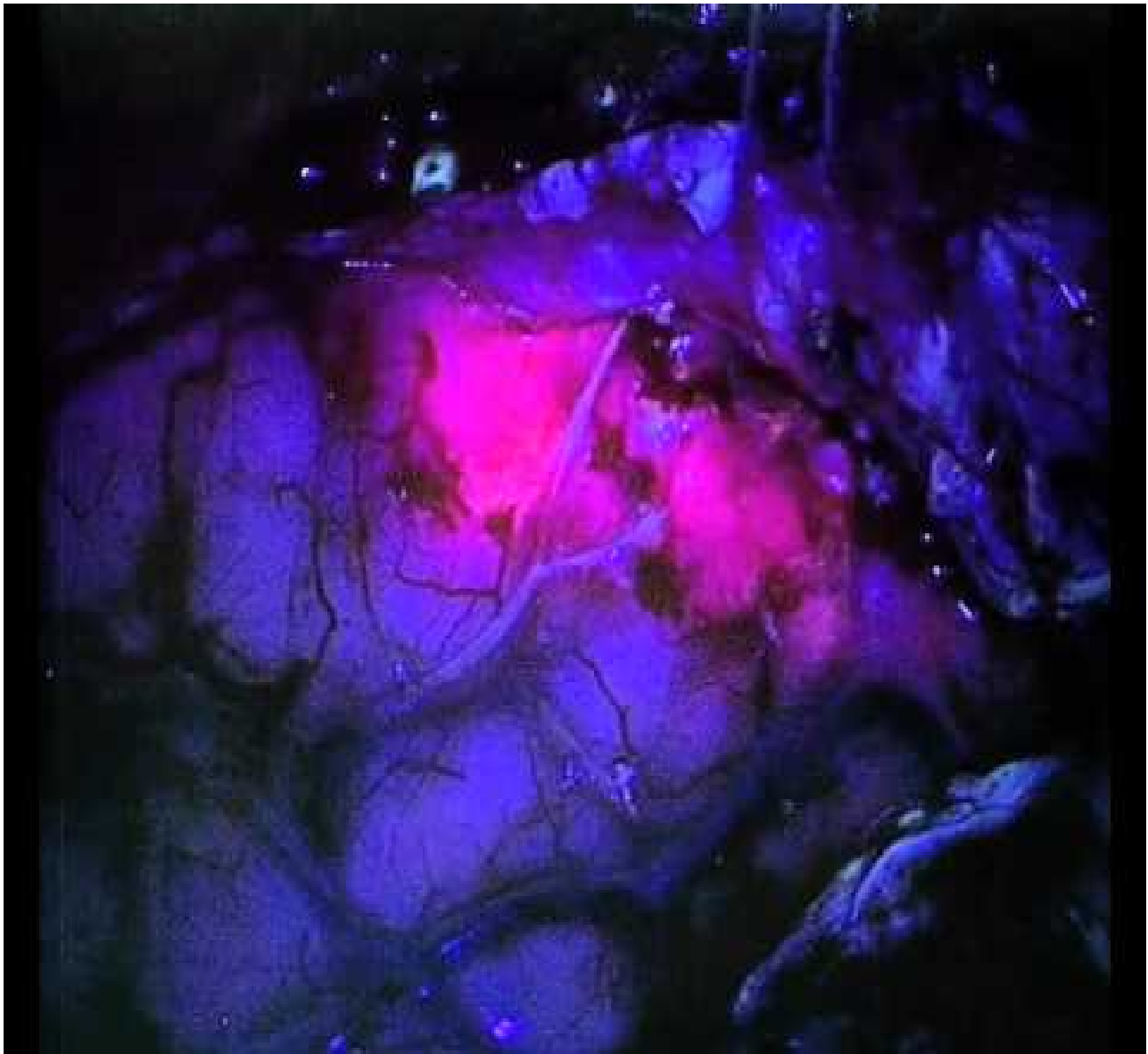
Australia contributed the second highest number of patients to this study with 120 patients enrolled. Combined with over 450 patients with advanced pancreatic cancer who have accessed ABRAXANE via STA's compassionate access program, substantial local clinical experience with ABRAXANE has been generated in this disease.

Based on the results of the MPACT study, STA look forward to submitting an application in 2013 to the Therapeutic Goods Administration and Pharmaceutical Benefits Advisory Committee for regulatory and PBS approval.

Please note these results are from an investigational phase III study. ABRAXANE is not currently approved for the treatment of advanced pancreatic cancer in Australia.

Before prescribing ABRAXANE please refer to the [Abraxane Product Information](#).
For further information please contact STA on 1300 798 820.

Royal Melbourne Hospital: First Public Hospital in Australia to Adopt New Technology for Brain Tumour Surgery



Melbourne, Australia May 2012: Patients with an aggressive form of brain tumour, glioblastoma multiforme (GBM), have been given access to a new brain tumour visualisation drug, Gliolan[®] (5-aminolevulinic acid), at The Royal Melbourne Hospital.

In 2011, The Royal Melbourne Hospital trialled the drug with great success, and is expected to treat up to an additional 25 patients.

Gliolan causes brain tumours, known as gliomas, to become fluorescent during surgery. This enables neurosurgeons to better visualise these tumours and more completely remove them. Gliolan is given to the patient as a drink three hours before surgery. During surgery, a specially modified neurosurgical microscope fitted with a blue operating light is used, which causes cancerous tissue to glow fluorescent red whilst normal brain tissue appears blue.

Associate Professor Kate Drummond, a neurosurgeon at The Royal Melbourne Hospital, was the first surgeon in Victoria to use Gliolan.

“Gliolan has made a positive difference to how we can treat our patients with this aggressive form of brain cancer,” A/Professor Drummond said.

“We have found the drug to be a very useful tool during neurosurgery because it can highlight difficult to see pockets of brain tumour tissue.”

“This assists us to more thoroughly remove these difficult to treat brain tumours, providing patients with better outcomes.”

The Royal Melbourne Hospital was the first hospital in Australia to approve the use of Gliolan for patients with GBM. At present it is the only hospital in Victoria to offer this new treatment and it will now become a standard treatment for people with GBM which is able to be surgically removed.

International studies have shown that the use of Gliolan during surgery has nearly doubled the rate of achieving complete removal of the tumour, which has resulted in a doubling of the number of patients without progression of their brain cancer six months after their surgery.¹

Gliolan is in-licensed by Melbourne biopharmaceutical company, Specialised Therapeutics Australia (STA).

STA chief executive officer Mr Carlo Montagner said: “Neurosurgeons at The Royal Melbourne Hospital can now use Gliolan to assist them when performing extremely complex brain surgery. Our ultimate aim is for Gliolan to become widely available in hospitals right around Australia to improve outcomes for all GBM patients.”

Gliolan is not yet approved but has been granted orphan drug designation by the Therapeutic Goods Administration (TGA). STA will be filing for regulatory approval later this year. Prior to TGA approval, Gliolan is being made available to Australian neurosurgeons through the federal government’s Special Access Scheme.

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

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.

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.

Gliolan is under license from photonamic GmbH and Co. KG.

- The Royal Melbourne Hospital to treat more patients with brain tumour drug Gliolan[®]
- Twice as many patients are without progression of their brain cancer six months after surgery with Gliolan

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.

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 Bevacizumab¹.

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 cancer². Developed using Abraxis BioScience's proprietary *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 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^{2,3}.

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^{2,3}. Anthracycline pre-treated patients lived significantly longer⁴.

The tolerability with ABRAXANE and solvent-based paclitaxel was comparable, despite the 49% greater dose of paclitaxel administered as ABRAXANE^{2,3}. 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^{2,3}.

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