Study Shows Leading Breast Cancer Drug ABRAXANE® Increases Survival Time for Advanced Pancreatic Cancer

Patients Receiving 125mg/m^2 ABRAXANE in Combination with Gemcitabine Demonstrated:

- Median Survival of 12.2 Months
- 50 per cent Response Rate
- 68 per cent Disease Control
- Decrease in CA19-9 Tumour Biomarker in 100 Percent of Patients Treated

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.

Abraxis BioScience, Inc. (NASDAQ:ABII) announced findings from the phase I/II study, which showed patients' overall survival time almost doubled, and levels of a major tumour marker were decreased by more than 20 per cent in all trial patients.

Specialised Therapeutics Australia Chief Executive Officer Mr Carlo Montagner, said: "As we advance our pivotal Phase III registration trials of ABRAXANE in pancreatic cancer and melanoma, we look forward to potentially bringing a new treatment option to patients with these difficult to treat cancers. While approval may be several years away, we are extremely encouraged by these results."

The study showed that in 44 patients treated at the recommended dose of 125 mg/m^2 nab-paclitaxel plus gemcitabine (1000 mg/m^2), the median overall survival (OS) time was 12.2 months, a doubling of survival compared to the historical

control of gemcitabine administered alone.

This combination of *nab*-paclitaxel and gemcitabine also resulted in a confirmed overall response rate in 50 percent of patients treated, and a disease control rate (CR, PR and stable disease for 16 weeks or longer according to RECIST criteria) of 68 percent.

In the overall study (n=67), three patients achieved a complete response.

The findings were included in a keynote address by Daniel Von Hoff, M.D., "Epithelium and Stroma: Double Trouble," during the "Progress in Pancreatic Cancer" session on April 18 at the 101st Annual Meeting of the American Association for Cancer Research (AACR) being held in Washington, D.C.

"The results of this study demonstrate that the combination of *nab*-paclitaxel and gemcitabine at the recommended dose of 125 mg/m^2 *nab*-paclitaxel has substantial antitumour activity," Mr Von Hoff said.

" One hundred percent of the patients in the 125 mg/m^2 *nab*-paclitaxel arm (n=44) tested for the serum carbohydrate antigen CA 19-9 demonstrated a greater than 20 percent decrease in levels of the tumour marker, a degree of decrease which has been shown to be correlated with improved overall survival.[1-3]"

The biomarker CA19-9 is a tumour-associated antigen that has been shown to be highly specific and sensitive for pancreatic cancer; approximately three-quarters of all pancreatic cancer patients have elevated baseline serum CA19-9 level at baseline.[4]

Of the 54 patients in the trial interrogated for CA 19-9, 69 percent had a greater than 70 percent decrease in levels of the biomarker, which correlated to a median overall survival of 15.6 months in this subset.

The updated survival data follow interim data from the Phase I/II pancreatic clinical trial presented at the 45th Annual Meeting of the American Society of Clinical Oncology. The combination of *nab*-paclitaxel (125mg/m^2) and gemcitabine (1000 mg/m^2) is now the treatment arm of a randomized Phase 3 clinical trial that is currently enrolling patients.

Pancreatic cancer is particularly difficult to treat because many patients are diagnosed after their disease has progressed. More than 2000 cases of pancreatic cancer are diagnosed in Australia every year [5]; fewer than five per cent of patients survive longer than five years [5].

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 global Phase III investigation including Australia for the treatment of the following cancers: non-small cell lung (NSCLC), malignant melanoma, and metastatic pancreatic. It was recently announced that the global Phase III NSCLC trial achieved its primary endpoint and the results will be presented at the American Society of Clinical Oncology meeting in Chicago on June 7.

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option for metastatic breast cancer[6]. 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 [6,7].

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 [7]. Anthracycline pre-treated patients lived significantly longer [7].

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

Contraindications and side effects[6]:

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.

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.

Most common side effects (≥1/10) caused by ABRAXANE include; neutropenia, anemia, leucopenia, thrombocytopenia, lymphophenia, anorexia, peripheral neuropathy, hypoaesthesia, paraethesia, nausea, diarrhoea, vomiting, constipation, stomatitis, alopecia, rash, arthralgia, myalgia, fatigue, asthenia, pyrexia.

For further information regarding ABRAXANE and potential side effects, physicians should review the ABRAXANE Product Information and patients should consult their oncologist or the ABRAXANE Consumer Medicine Information available on www.specialisedtherapeutics.com.au.

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.

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