ABRAXANE® Meets Primary Endpoint in Phase 3 Trial for Advanced Non-Small Cell Lung Cancer

ABRAXANE® (nanoparticle albumin-bound paclitaxel), Carboplatin Combination Demonstrated Superiority to Taxol plus Carboplatin in 1st Line 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.

Biopharmaceutical companies Abraxis Bioscience Inc (NASDAQ: ABII) and Specialised Therapeutics Australia Pty Ltd (STA) announced that the extensive trial, conducted at 102 sites globally, including Australia, which enrolled 1052 patients suffering advanced non-small cell lung cancer (NSCLC), met its primary efficacy endpoint as assessed by an independent radiologist review.

Researchers found those patients treated with ABRAXANE and carboplatin combination demonstrated a significant improvement in overall tumour response rate compared with patients treated with a standard chemotherapy combination containing TAXOL and carboplatin.

The Phase 3 trial was led by principal investigator Mark Socinski, M.D., at the University of North Carolina Lineberger Comprehensive Cancer Center, and is recognised as one of the largest NSCLC clinical studies to be conducted.

“This is exciting news for lung cancer patients and has important implications not only in late stage cancer but also in earlier stages of the disease,” Socinkski said.

Professor Michael Boyer of Royal Prince Alfred Hospital, Sydney, was the

Australian lead investigator.

The data will be submitted for consideration as a late breaking presentation at the upcoming American Society of Clinical Oncology (ASCO) meeting to be held in June in Chicago.

CEO and founder of Specialised Therapeutics Australia Mr Carlo Montagner said this was positive news for the many Australians who continue to be affected by this disease.

“We are extremely pleased with the results from this Phase 3 study, which included several Australian treatment sites, showing the superiority of ABRAXANE over a commonly used drug combination in Australia,” he said.

“Subject to further data analysis, we anticipate filing to the TGA in 2011 for what will be the second indication for ABRAXANE in Australia.”

NSCLC is the most common form of lung cancer, accounting for approximately 85% of all lung cancer cases.

National lung cancer statistics indicate it is the fourth most commonly diagnosed cancer in Australia, with over 8000 new cases annually. [1]

Study Design

Patients in the study were randomised to two treatment arms: patients in Arm A received ABRAXANE 100 mg/m^2 weekly plus carboplatin AUC 6 on Day 1 of a three-week treatment cycle; patients in Arm B received Taxol 200 mg/m^2 every 3 weeks plus carboplatin AUC 6 on Day 1 of a three-week treatment cycle. The primary study endpoint was independently-assessed tumour response rate, as defined by Response Evaluation Criteria in Solid Tumours (RECIST) criteria. Secondary study endpoints included: safety and tolerability; disease control rate and duration of response; progression-free survival (PFS); patient survival. Assessments of ABRAXANE efficacy correlated with specific tumour biomarkers, including secreted protein acidic and rich in cysteine (SPARC).

About ABRAXANE

In Australia, ABRAXANE is currently approved and listed on the PBS for the treatment of metastatic breast cancer after failure of prior therapy, which includes an anthracycline.

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 3 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[1]. Developed using Abraxis BioScience's 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 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 3 study of metastatic breast cancer patients, ABRAXANE demonstrated nearly double the overall tumour response rate compared to solvent-based paclitaxel[3]. Anthracycline pre-treated patients lived significantly longer[3].

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[2]:

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, 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.

References:

1. AIHW (Australian Institute of Health and Welfare) Incidence and prevalence of chronic diseases 2006
2. ABRAXANE® Product Information

3. Gradishar WJ et al. J Clinical Oncology 2005;23:7794-7803

Contact:

Emma Power
Monsoon Communications
(03) 9620 3333
0419 149 525