ABRAXANE® Granted Orphan Drug Status for Pancreatic Cancer by Therapeutic Goods Administration

Leading Breast Cancer Drug To Be Investigated In Pancreatic Cancer, Melanoma

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.

The drug has been available in Australia since last February from Melbourne based pharmaceutical company Specialised Therapeutics Australia Pty Ltd, primarily for patients with metastatic breast cancer [1].

From May 2009, it has been listed on the Pharmaceutical Benefits Scheme (PBS) for metastatic breast cancer after failure of prior therapy which includes an anthracycline.

ABRAXANE is now regarded as a leading treatment for this disease, prolonging survival rates, with fewer reactions and greater patient convenience as compared to solvent-based paclitaxel in the phase III registration trial[1-2].

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.

Specialised Therapeutics' Chief Executive Officer, Mr Carlo Montagner, said this was an important step in bringing new treatment options for pancreatic cancer patients, with Phase II data presented at the 2009 American Society of Clinical Oncology annual meeting indicating ABRAXANE is active in pancreatic cancer [3].

"As we advance our pivotal Phase III clinical trials of ABRAXANE in lung, pancreatic cancer and melanoma, we look forward to the potential of bringing a new treatment option to patients with these difficult to treat cancers," Mr

Montagner said.

“If the Phase III studies meet their efficacy targets, we expect ABRAXANE to be approved and generally available for lung, pancreatic and melanoma cancers in the next few years.

“People currently undergoing treatment for these diseases should direct any questions about the ongoing trials to their physicians.”

ABRAXANE is the first solvent-free taxane available as a treatment option to cancer patients. Because ABRAXANE is solvent free, it eliminates the risk of solvent-related hypersensitivity reactions and potentially fatal anaphylaxis [1,2,4-].

It is also the first nanoparticle drug to be approved by the Therapeutic Goods Administration.

A Phase III trial of ABRAXANE has begun in pancreatic cancer patients at 21 sites around the country, with hospitals now recruiting trial participants.

This international study will evaluate whether ABRAXANE plus gemcitabine has greater activity versus gemcitabine alone as a first line therapy for advanced metastatic pancreatic cancer.

Pancreatic cancer and metastatic melanoma can be particularly hard to treat cancers. 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].

Melanoma is an aggressive form of skin cancer that strikes approximately 12,000 Australians every year [5].

Metastatic melanoma is the leading cause of skin cancer death. A Phase III trial of ABRAXANE versus a standard drug regimen in first line metastatic melanoma has also begun in Australia, with results expected in the next two years.

The Non-Small Cell Lung Cancer Phase III registration trial was completed in 2009 and the results will be presented later this year.

For further information please contact Emma Power at Monsoon Communications on 03 9620 3333 or 0419 149 525.

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 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 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[1,2].

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]. Anthracycline pre-treated patients lived significantly longer[6].

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[1]:

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. ABRAXANE Product Information
2. Gradishar WJ et al. J Clinical Oncology 2005;23:7794-7803

3. Von Hoff D et al. ASCO 2009; Abstract 4525
4. Irizarry LD et al. Community Oncology 2009; 6(3):132-134
5. AIHW (Australian Institute of Health and Welfare) & AACR (Australasian Association of Cancer Registries) 2008. Cancer in Australia: an overview, 2008. Cancer series no. 46. Cat. no. CAN 42. Canberra: AIHW.
6. Vukelja SJ et al. ASCO 2008; Abstract 1082