PBS Change for Leading Breast Cancer Drug ABRAXANE®

More Australian women to potentially have access to leading breast cancer drug

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).

From 1 July, Abraxane will be available via PBS Authority to patients with 'Metastatic breast cancer after failure of prior therapy.'

STA chief executive officer Mr Carlo Montagner said the change would enable more Australian women to access the drug, which is now regarded as a leading treatment for this disease, prolonging survival rates, with overall fewer adverse reactions and greater patient convenience. [1,2]

"We are extremely pleased the Pharmaceutical Benefits Advisory Committee has made this change to the PBS listing of ABRAXANE" he said.

"It paves the way for a greater number of patients to be treated with this therapy. Until now, only those patients with metastatic breast cancer who had received prior treatment including an anthracycline were eligible for PBS reimbursement.

"Now patients who have received prior treatment for their metastatic breast cancer, with or without an anthracycline, will be eligible."

ABRAXANE is the first solvent-free taxane available as a treatment option to cancer patients. Because it is solvent free, it eliminates the risk of solvent-related hypersensitivity reactions and potentially fatal anaphylaxis seen with solvent-based paclitaxel. [1-3]

It is approved for metastatic breast cancer in over 35 countries including the U.S., Canada, European Union and China. 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.

Ends.

About ABRAXANE

In Australia as of 1 July 2010, ABRAXANE will be approved and reimbursed by the Pharmaceutical Benefits Scheme (PBS) for the treatment of metastatic breast cancer after failure of prior therapy.

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.

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. [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 [1,2]. Anthracycline pre-treated patients lived significantly longer .[4]

The tolerability with ABRAXANE and solvent-based paclitaxel was comparable, despite the 49% greater dose of paclitaxel administered as ABRAXANE[1-2]. 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.[1-2]

For further information, physicians should consult the Abraxane Product 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.

References:

1. Abraxane Product Information
2. Gradishar WJ et al. J Clinical Oncology 2005;23:7794-7803
3. Irizarry LD et al. Community Oncology 2009;6(3): 132-134
4. Vukelja SJ et al. ASCO 2008, Abstract 1082