World Leading Breast Cancer Drug Now Available in New Zealand

Melbourne, Australia and Auckland, New Zealand – 21 February 2011 – New Zealand women now have access to a leading breast cancer drug ABRAXANE® (nanoparticle albumin-bound paclitaxel) for the treatment of metastatic breast cancer after failure of anthracycline therapy.

The drug, ABRAXANE, uses novel nanoparticle technology to deliver the chemotherapeutic agent to the tumour site and has been shown to prolong patient survival times with overall fewer side effects compared with traditional solvent-based chemotherapy treatments. [1-3]

Some of the side effects of traditional solvent-based chemotherapy treatments include serious solvent-related anaphylactic events, which can be fatal in some patients[4].

ABRAXANE is now available to patients in New Zealand via Specialised Therapeutics and will be distributed by Healthcare Logistics, based in Auckland.

Currently ABRAXANE is not subsidised in New Zealand, however a reimbursement application has been submitted to Pharmac, the Pharmaceutical Management Agency of New Zealand, for review. A decision is expected later this year.

ABRAXANE is fully reimbursed for Metastatic breast cancer after failure of prior therapy in Australia under the Pharmaceutical Benefits Scheme (PBS).

Specialised Therapeutics CEO Mr Carlo Montagner said ABRAXANE had rapidly become a standard of care in Australia and the US for the treatment of metastatic breast cancer.

“We are pleased to provide this new treatment option for women in New Zealand with metastatic breast cancer,” he said.

“We are hopeful that reimbursement approval will provide all women in New Zealand with metastatic breast cancer the option of a safer and more efficacious

taxane therapy". [2,3]

International Phase III registration trials of Abraxane for metastatic pancreatic and melanoma cancers are currently enrolling patients, with results expected in the next two to three years.

With the approval in New Zealand, ABRAXANE is now approved in 41 countries.

About Specialised Therapeutics
Specialised Therapeutics is a bio-pharmaceutical company primarily established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Australasian market. Currently Specialised Therapeutics markets two world leading cancer and cancer supportive care therapies, ABRAXANE and ALOXI® (palonosetron) respectively. 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

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option for metastatic breast cancer.[1]

In Australia, ABRAXANE is currently listed on the PBS for the treatment of metastatic breast cancer after failure of prior therapy.

Developed using Celgene's proprietary nanoparticle albumin-bound (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, eliminating 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]

About nab-Driven Chemotherapy

nab technology leverages albumin nanoparticles for the active and targeted delivery of chemotherapeutics to the tumour. This nab-driven chemotherapy provides a new paradigm for penetrating the blood-stroma barrier to reach the tumour cell. The proposed mechanism of delivery of this nab-driven chemotherapy is thought to be by targeting a previously unrecognised tumour-activated, albumin-specific biologic pathway with a nanoshell of the human blood protein albumin. This nano-shuttle system is believed to activate an albumin-specific (Gp60) receptor-mediated transcytosis path through the cell wall of proliferating tumor cells, using caveolin-1 activated caveolar transport. Once in the stromal micro-environment, the albumin-bound drug may be preferentially localised by a second albumin-specific binding protein, SPARC, a protein secreted into the stroma by tumour cells. The resulting collapse of stroma surrounding the tumour cell may thus enhance the delivery of the nab-chemotherapeutic to the intracellular core of the tumour cell itself.

ABRAXANE is approved for metastatic breast cancer in 41 countries including the U.S., Canada, European Union, Japan and China, and more than 100,000 cancer patients have received ABRAXANE therapy in the past five years.

In a randomised Phase III study of metastatic breast cancer patients, ABRAXANE demonstrated a significant improvement in response rate and progression free survival compared to solvent-based paclitaxel,[1-2] while anthracycline pre-treated patients lived significantly longer.[5]

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

In Australia, ABRAXANE has also been granted orphan drug designation by the Therapeutic Goods Administration (TGA) 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. Additionally, ABRAXANE is currently under Phase III investigation for the treatment of the following cancers: non-small cell lung, malignant melanoma, and metastatic pancreatic.

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 x 109 /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.

For further information please refer to www.specialisedtherapeutics.com.au for the New Zealand ABRAXANE Product Information.

References:
1. Abraxane Product Information
2. Gradishar WJ et al. J Clinical Oncology 2005;23:7794-7803
3. Gradishar WJ et al. J Clinical Oncology 2009; 27(22): 3611-19
4. Irizarry LD et al. Community Oncology 2009;6(3):132-134
5. Vukelja SJ et al. ASCO 2008 Abstract 1082