STA Announces Breakthrough Cancer Drug ABRAXANE® to be PBS Listed for Metastatic Pancreatic Cancer

Melbourne, Australia, 31 October 2014: Australian biopharmaceutical company Specialised Therapeutics Australia (STA) is pleased to announce ABRAXANE®(nanoparticle albumin-bound paclitaxel) in combination with gemcitabine, will be reimbursed via the Pharmaceutical Benefits Scheme (PBS) for patients with metastatic pancreatic cancer from the 1st of November.

In Australia, pancreatic cancer is the 5th most common cause of cancer mortality. Pancreatic cancer accounts for 6% of all cancer deaths, with the lowest 5-year survival of all common cancers at 5.2%.[1]

ABRAXANE was approved by the Therapeutic Goods Administration (TGA) in March 2014 with the following indication:
ABRAXANE, in combination with gemcitabine, is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas.[2]

Both the TGA approval and PBS listing were based on the pivotal randomised phase III trial, MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial), published in the New England Journal of Medicine (NEJM) in October 2013 which showed ABRAXANE plus gemcitabine significantly improved overall survival, progression free survival, and response rates compared to gemcitabine alone.[3]

Australian oncologist Associate Professor Nick Pavlakis from Sydney's North Shore Hospital described ABRAXANE as the most significant breakthrough in pancreatic cancer in 15 years.

"I believe it is the most effective therapy (for pancreatic cancer) available on the PBS," Associate Professor Pavlakis commented. "This PBS listing is a major step and it is a new platform upon which we can move forward."

STA Chief Executive Officer Mr Carlo Montagner said, “The inclusion of ABRAXANE on the PBS for patients with metastatic pancreatic cancer is a “landmark achievement” and provides an important new treatment option for patients with this aggressive disease”.

“Until now, ABRAXANE has been widely available and PBS reimbursed for patients with metastatic breast cancer, but not for those with metastatic pancreatic cancer, who have been shown to also gain substantial clinical benefit.

“ABRAXANE will now be reimbursed and broadly accessible for Australian patients with metastatic pancreatic cancer and offers a new standard of care for treatment of this disease.

While ABRAXANE has been available via the PBS for metastatic breast cancer since 2009, over 1,000 Australian patients with other cancers have received ABRAXANE therapy via STA’s ABRAXANE Access Program (AAP). Since 2009, STA has provided $13.76M of ABRAXANE free of charge via the AAP to Australians who otherwise would not have been able to receive this treatment.

About MPACT[3]

MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial), was a Celgene-sponsored, open-label, randomised, international study of 861 patients with metastatic pancreatic cancer. Patients were randomised to receive either ABRAXANE plus gemcitabine (125 mg/m^2 followed by 1000 mg/m^2 gemcitabine for 3 weeks followed by a week of rest) or gemcitabine alone (1000 mg/m2 administered weekly for 7 weeks followed by a week of rest then weekly administration for 3 weeks followed by one week of rest).

The primary endpoint of the study was overall survival (OS). Secondary endpoints were progression-free survival and overall response rate determined by independent radiological review. Other endpoints included the safety and tolerability of this combination in patients with metastatic pancreatic cancer.

The study reported that patients treated with ABRAXANE plus gemcitabine had a statistically significant improvement in OS compared to patients receiving the

current standard of care, gemcitabine monotherapy (OS; median 8.5 months vs. 6.7 months; HR 0.72, P<0.001).[3] An updated analysis of OS presented at the American Society of Clinical Oncology Gastrointestinal Conference (ASCO GI) in January 2014 showed that the survival benefit was further extended in the ABRAXANE plus gemcitabine arm, with a 2.1 month median OS improvement compared to gemcitabine alone (OS; median 8.7 months vs 6.6 months; HR=0.72; p<0.0001).[4]

Australia contributed 120 patients to MPACT. In the Australian cohort, patients in the ABRAXANE plus gemcitabine arm showed a significant median OS benefit, with a 2.7 month improvement in median OS compared to patients in the gemcitabine alone arm (OS; median 9.4 months vs 6.7 months; HR=0.59; p=0.01).[4]

MPACT is the first phase III trial in metastatic pancreatic cancer to report greater than 3-year survival rates, with 4% of patients in the ABRAXANE plus gemcitabine arm alive after three years, and 3% of patients alive at 42 months, compared to 0% in the gemcitabine alone arm at both time points.[4]

The most common grade ≥3 treatment-related adverse events in MPACT for ABRAXANE plus gemcitabine vs. gemcitabine alone were neutropenia (38% vs. 27%), fatigue (17% vs. 7%), and peripheral neuropathy (17% vs. 1%), respectively. The median time to neuropathy improvement by one grade from grade ≥3 was 21 days in the ABRAXANE plus gemcitabine arm compared to 29 days in the gemcitabine alone arm. Neuropathy improved to grade 1 or lower in a median of 29 days for the ABRAXANE plus gemcitabine arm and was not reached for the gemcitabine alone arm. There was no difference in serious life threatening toxicity (4% in each arm).[3]

About ABRAXANE

Developed using the proprietary *nab*™ technology platform, ABRAXANE is a nanoparticle protein-bound chemotherapy agent. ABRAXANE combines paclitaxel with albumin, a naturally-occurring human protein, to deliver paclitaxel to the

tumour and therefore eliminates the need for solvents in the administration process.[2] ABRAXANE is approved for the treatment of metastatic breast cancer, advanced non-small cell lung cancer (NSCLC) and metastatic pancreatic cancer.[2] In Australia, ABRAXANE is currently listed on the PBS for the treatment of metastatic breast cancer and HER2 positive breast cancer in combination with trastuzumab, and metastatic pancreatic cancer. ABRAXANE is not PBS listed for the indication of NSCLC.

ABRAXANE is currently in various stages of investigation for the treatment of the following cancers: adjuvant pancreatic cancer, bladder cancer, colorectal cancer, NSCLC and expanded applications for breast cancer.

BEFORE PRESCRIBING PLEASE CONSULT THE ABRAXANE PRODUCT INFORMATION AVAILABLE HERE.

About Specialised Therapeutics Australia

Specialised Therapeutics Australia (STA) is dedicated to working with leading biotechnology and pharmaceutical companies worldwide. Our primary objective is to enable unrestricted access to breakthrough acute care therapies and genomic diagnostics to people with high unmet medical needs living in Australia and New Zealand.

The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, gene expression assays, ophthalmology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS).

References

1. Cancer in Australia. An Overview 2012. Australian Institute of Health and Welfare (AIHW).
2. ABRAXANE Product Information

3. Von Hoff DD et al. Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine. N Engl J Med 2013; 369(18):1691-703.
4. Goldstein D et al. Oral Abstract # 178. Updated survival from a randomized phase III trial (MPACT) of nab-Paclitaxel plus gemcitabine versus gemcitabine alone for patients (pts) with metastatic adenocarcinoma of the pancreas. ASCO GI 2014.