

# **Abraxis Bioscience and Specialised Therapeutics Announce Approval to Market ABRAXANE® for Metastatic Breast Cancer in New Zealand**

**Los Angeles, Calif. and Melbourne Australia - July, 2010** - Abraxis BioScience, Inc. (NASDAQ:ABII), a fully integrated, global biotechnology company, and Specialised Therapeutics Ltd. today announced that MEDSAFE, the New Zealand Medicines and Medical Devices Safety Authority, has approved for marketing ABRAXANE® (nanoparticle albumin-bound paclitaxel) for the treatment of metastatic breast cancer after failure of anthracycline therapy.

Abraxis BioScience granted exclusive marketing rights to Specialised Therapeutics for ABRAXANE in New Zealand. Specialised Therapeutics will commence distribution when reimbursement of Abraxane is approved through the New Zealand pharmaceutical reimbursement authority, Pharmac. ABRAXANE is currently fully reimbursed for “Metastatic breast cancer after failure of prior therapy” in Australia under the Pharmaceutical Benefits Scheme.

“In the U.S. and Australia ABRAXANE has rapidly become the taxane treatment of choice in its approved indication,” said Patrick Soon-Shiong, M.D., Executive Chairman of Abraxis BioScience. “We are pleased to provide this new treatment option for women in New Zealand with metastatic breast cancer.”

“Abraxane offers a safer and more efficacious taxane therapy for New Zealand women with metastatic breast cancer. Discussions with Pharmac will commence shortly and we hope to make Abraxane available as soon as an agreement with Pharmac is reached” said Carlo Montagner, CEO of Specialised Therapeutics.

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

-END-

## **About ABRAXANE**

ABRAXANE is a solvent-free chemotherapy treatment option for metastatic breast cancer which was developed using Abraxis BioScience's proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin, a naturally-occurring human protein. By wrapping the albumin around the active drug, ABRAXANE can be administered to patients at higher doses, delivering higher concentrations of paclitaxel to the tumor site than solvent-based paclitaxel. ABRAXANE is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast, non-small cell lung, malignant melanoma, pancreatic and gastric.

The U.S. Food and Drug Administration approved ABRAXANE for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) in January 2005 for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. For the full prescribing information for ABRAXANE please visit <http://www.abraxane.com>.

## **About nab-Driven Chemotherapy**

Abraxis BioScience has developed a proprietary nanoparticle albumin-bound (nab) technology which leverages albumin nanoparticles for the active and targeted delivery of chemotherapeutics to the tumor. This nab-driven chemotherapy provides a new paradigm for penetrating the blood-stroma barrier to reach the tumor cell. The proposed mechanism of delivery of this nab-driven chemotherapy is thought to be by targeting a previously unrecognized tumor-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 localized by a second albumin-specific binding protein, SPARC, a protein secreted into the stroma by tumor cells. The resulting collapse of stroma surrounding the tumor cell may thus enhance the delivery of the nab-chemotherapeutic to the intracellular core of the tumor cell itself.

## **IMPORTANT SAFETY INFORMATION**

The use of ABRAXANE has not been studied in patients with hepatic or renal dysfunction. In the randomized controlled trial, patients were excluded for baseline serum bilirubin >1.5 mg/dL or baseline serum creatinine >2 mg/dL.

ABRAXANE can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with ABRAXANE.

Men should be advised to not father a child while receiving treatment with ABRAXANE. It is recommended that nursing be discontinued when receiving ABRAXANE therapy. ABRAXANE contains albumin (human), a derivative of human blood.

Caution should be exercised when administering ABRAXANE concomitantly with known substrates or inhibitors of CYP2C8 and CYP3A4.

ABRAXANE therapy should not be administered to patients with metastatic breast cancer who have baseline neutrophil counts of less than 1,500 cells/mm<sup>3</sup>. It is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE. Patients should not be retreated with subsequent cycles of ABRAXANE until neutrophils recover to a level >1,500 cells/mm<sup>3</sup> and platelets recover to a level >100,000 cells/mm<sup>3</sup>. In the case of severe neutropenia (<500 cells/mm<sup>3</sup> for 7 days or more) during a course of ABRAXANE therapy, a dose reduction for subsequent courses is recommended.

Sensory neuropathy occurs frequently with ABRAXANE.

If grade 3 sensory neuropathy develops, treatment should be withheld until resolution to grade 1 or 2 followed by a dose reduction for all subsequent courses of ABRAXANE. Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients in the randomized trial. These events included chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary embolism, and hypertension.

In the randomized metastatic breast cancer study, the most important adverse events included alopecia (90%), neutropenia (all cases 80%; severe 9%), sensory

neuropathy (any symptoms 71%; severe 10%), asthenia (any 47%; severe 8%), myalgia/arthralgia (any 44%; severe 8%), anemia (all 33%; severe 1%), infections (24%), nausea (any 30%; severe 3%), vomiting (any 18%; severe 4%), diarrhea (any 27%; severe <1%), and mucositis (any 7%; severe <1%).

Other adverse reactions have included ocular/visual disturbances (any 13%; severe 1%), fluid retention (any 10%; severe 0%), hepatic dysfunction (elevations in bilirubin 7%, alkaline phosphatase 36%, AST [SGOT] 39%), renal dysfunction (any 11%; severe 1%), thrombocytopenia (any 2%; severe <1%), hypersensitivity reactions (any 4%; severe 0%), cardiovascular reactions (severe 3%), and injection site reactions (<1%). During postmarketing surveillance, rare occurrences of severe hypersensitivity reactions have been reported with ABRAXANE.

### **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. Currently STA markets two world leading cancer therapies, ABRAXANE and ALOXI (palonosetron). Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.

### **About Abraxis BioScience, Inc.**

Abraxis BioScience is a fully integrated global biotechnology company dedicated to the discovery, development and delivery of next-generation therapeutics and core technologies that offer patients safer and more effective treatments for cancer and other critical illnesses. The company's portfolio includes chemotherapeutic compound (ABRAXANE®), which is based on the company's proprietary tumor targeting technology known as the nab® platform. The first FDA approved product to use this nab® platform, ABRAXANE, was launched in 2005 for the treatment of metastatic breast cancer and is now approved in 41 countries. The company continues to expand the nab® platform through a robust clinical program and deep product pipeline. Abraxis trades on the NASDAQ Global Market under the symbol ABII. For more information about the company

and its products, please visit <http://www.abraxisbio.com>.

## **FORWARD-LOOKING STATEMENTS**

The statements contained in this press release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the clinical development plan, and the timing and scope of clinical studies and trials, for ABRAXANE and the global commercialization of ABRAXANE. Because these forward-looking statements involve risks and uncertainties, there are important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, the fact that results from pre-clinical studies may not be predictive of results to be obtained in other pre-clinical studies or future clinical trials; delays in commencement and completion of clinical studies or trials, including slower than anticipated patient enrollment and adverse events occurring during the clinical trials; decisions by regulatory authorities regarding whether and when to approve ABRAXANE for various indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of; unexpected safety, efficacy or manufacturing issues with respect to ABRAXANE; the need for additional data or clinical studies for ABRAXANE; regulatory developments (domestic or foreign) involving the company's manufacturing facilities; the market adoption and demand of ABRAXANE, the costs associated with the ongoing launch of ABRAXANE; research and development associated with the nab® technology platform; the impact of pharmaceutical industry regulation; the impact of competitive products and pricing; the availability and pricing of ingredients used in the manufacture of pharmaceutical products; the ability to successfully manufacture products in a time-sensitive and cost effective manner; the acceptance and demand of new pharmaceutical products; and the impact of patents and other proprietary rights held by competitors and other third parties. Additional relevant information concerning risks can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2009 and in other documents it has filed with the Securities and Exchange Commission.

The information contained in this press release is as of the date of this release. Abraxis assumes no obligations to update any forward-looking statements contained in this press release as the result of new information or future events or developments.

**Contacts:**

Investor and Media Inquiries

Pondel Wilkinson Inc.

Rob Whetstone

310.279.5963

Specialised Therapeutics Australia, Pty Ltd

Carlo Montagner

Chief Executive Officer

03 9854 6207

Monsoon Communications

Level 1 350 Collins Street

Melbourne VIC 3000

Ph: 03 9620 3333

[www.monsoon.com.au](http://www.monsoon.com.au)