

# **ARIAD Announces Commercial Agreement for ICLUSIG® (ponatinib) in Australia**

**Melbourne, Australia January 28, 2014:** ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) and Specialised Therapeutics Australia Pty Ltd (STA), a specialty pharmaceutical company, today announced that ARIAD has granted STA exclusive rights to commercialize Iclusig® (ponatinib) in Australia in patients with Philadelphia-positive (Ph+) leukemias.

Under the terms of the agreement, STA will be responsible for obtaining marketing authorization and pricing and reimbursement approval of Iclusig and assisting ARIAD in regulatory filings for Iclusig in Australia. STA will book sales of Iclusig to pharmacies and other distributors, while ARIAD will supply packaged drug to STA. The term of the agreement is seven years from the first commercial sale of Iclusig following reimbursement approval. At the conclusion of the term, ARIAD will have the option to take over commercialization of Iclusig in Australia or to extend the agreement with STA.

“This agreement illustrates how we plan to make Iclusig available to patients in geographies where we do not anticipate setting up our own commercial activities near term,” said Marty J. Duvall, executive vice president and chief commercial officer of ARIAD. “STA has a proven track-record in oncology marketing and market access in Australia and is successfully distributing several important oncology brands in this region.”

ARIAD submitted a marketing application for Iclusig in the third quarter of 2013 to the Therapeutic Goods Administration (TGA) in Australia. Marketing approval and commercial launch of Iclusig are expected in the fourth quarter of 2014. Prior to launch, ARIAD and STA will collaborate to make Iclusig available to patients with refractory chronic myeloid leukemia (CML) and Ph+ acute lymphoblastic leukemia (ALL) under a Special Access Program.

“Iclusig is as an important cancer medicine for patients with difficult-to-treat CML or Ph+ ALL who have few options available to them,” said Carlo Montagner, chief

executive officer at STA. “We look forward to a successful collaboration with ARIAD providing refractory CML patients in Australia with a new highly effective treatment option.”

According to the Australian Institute of Health and Welfare, there are more than 1,500 patients in Australia being treated for CML and approximately 290 patients are newly diagnosed with the disease each year.

“Some patients with this disease build resistance to current therapies and eventually run low on treatment options,” said Professor Timothy Hughes, Consulting Haematologist at the Royal Adelaide Hospital and one of the PACE trial investigators. “I anticipate that Iclusig will be a valuable new therapy for adult patients with refractory CML.”

## **About Iclusig® (ponatinib)**

Iclusig is a kinase inhibitor. The primary target for Iclusig is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig was designed using ARIAD’s computational and structure-based drug design platform specifically to inhibit the activity of BCR-ABL. Iclusig targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

## **About Specialised Therapeutics Australia**

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical companies worldwide to provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology, hematology, ophthalmology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be

found at [www.specialisedtherapeutics.com.au](http://www.specialisedtherapeutics.com.au)

## About ARIAD

ARIAD Pharmaceuticals, Inc., headquartered in Cambridge, Massachusetts and Lausanne, Switzerland, is an integrated global oncology company focused on transforming the lives of cancer patients with breakthrough medicines. ARIAD is working on new medicines to advance the treatment of various forms of chronic and acute leukemia, lung cancer and other difficult-to-treat cancers. ARIAD utilizes computational and structural approaches to design small-molecule drugs that overcome resistance to existing cancer medicines. For additional information, visit <http://www.ariad.com> or follow ARIAD on Twitter (@ARIADPharm).

This press release contains “forward-looking statements” which are based on management’s good-faith expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to the Company’s ability to manufacture, and supply STA with Iclusig; the ability of STA to perform the contracted services, such as obtaining marketing authorization and pricing and reimbursement approval for Iclusig in Australia; STA’s ability to distribute, promote, market and sell Iclusig in Australia; the timing and scope of the marketing authorizations, as well as the level of pricing obtained in Australia; the availability of Iclusig to patients under a Special Access Program in Australia; third-party reimbursement; and the timing and success of sales of Iclusig in Australia. These factors, risks and uncertainties also include, but are not limited to: the costs associated with ARIAD’s development and manufacturing, commercial and other activities; the adequacy of capital resources and the availability of additional funding; and other factors detailed in the Company’s public filings with the U.S. Securities and Exchange Commission. The information contained in this press release is believed to be current as of the date of original issue. After the date of this document, the Company does not intend to update any of the forward-looking statements to conform to actual results or to changes in the Company’s expectations, except as required by law.

# Contacts

Carlo Montagner  
Chief Executive Officer  
Specialised Therapeutics Australia  
(03) 9859 1493

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## **Specialised Therapeutics Australia Partners with Genomic Health Inc. to Deliver Novel Genomic Test to Breast Cancer Patients**

**Melbourne, Australia January 7, 2014:** Australian women will potentially have greater access to the only genomic test validated to predict whether patients with early-stage invasive breast cancer would benefit from chemotherapy, following an agreement between Specialised Therapeutics Australia (STA) and Genomic Health, Inc. (NASDAQ: GHDX).

STA has struck an agreement to represent the important diagnostic technology known as the *Oncotype DX* Breast Cancer Assay from Genomic Health, the world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of early stage cancer.

The *Oncotype DX* test is a 21 gene assay that predicts a patient's likely benefit from chemotherapy and the overall risk of breast cancer recurrence. This technology has been shown to guide treatment decisions, sparing patients the impact of unnecessary chemotherapy while identifying those patients who may

benefit from this additional treatment.

Under the terms of the agreement, STA will undertake all commercial operations including sales and marketing of the product within Australia as well as providing product support and practitioner education.

As part of this agreement, STA has partnered with Healthscope Pathology who will continue to oversee logistics in Australia, including tissue sample management.

Announcing the distribution agreement with Genomic Health, STA Chief Executive Officer Carlo Montagner said the *Oncotype DX* assay was a high calibre tool for women diagnosed with early stage breast cancer who sought to avoid chemotherapy where possible, because it provided information about the likelihood of a cancer recurrence.

“This ground breaking test, which has been universally adopted in the US, helps women make informed decisions,” he said.

“Many Australian women with early stage breast cancer have endured debilitating chemotherapy regimens as a precautionary measure. This test will arm women and their physicians with more information about the likelihood of the patient benefitting from chemotherapy, as well as recurrence, helping them make a well-informed treatment decision.”

Developed by US based Genomic Health, *Oncotype DX* has been evaluated in 15 clinical studies in more than 6,000 patients. These studies include a large validation study published in the *New England Journal of Medicine*<sup>1</sup> and a study published in the *Journal of Clinical Oncology* that examined whether *Oncotype DX* could predict the benefit of chemotherapy.<sup>2</sup> Since becoming available in 2004, more than 400,000 *Oncotype DX* tests have been requested by more than 19,000 physicians in over 70 countries.

The *Oncotype DX* Breast Cancer Test is appropriate for recently diagnosed women with Stage I or II node-negative, oestrogen-receptor-positive, HER2 negative, invasive breast cancer; and postmenopausal women with node-positive, hormone-receptor-positive, HER2 negative, invasive breast cancer. The *Oncotype DX* results are provided in the form of a Recurrence Score®, a number between 0 and 100, which correlates to a specific likelihood of breast cancer

recurrence within 10 years of initial diagnosis and the likely benefit of chemotherapy.

The *Oncotype DX* DCIS Breast Cancer Test is also appropriate for women with newly diagnosed pre-invasive or Ductal Carcinoma in Situ of the Breast (DCIS) who are treated with local excision, with or without adjuvant tamoxifen therapy. The DCIS Score™ result predicts local recurrence of DCIS or invasive carcinoma and helps inform decisions regarding the need for additional treatments, like radiation, following surgical removal of the tumour.

The National Comprehensive Cancer Network (NCCN)<sup>3</sup>, the American Society of Clinical Oncology (ASCO)<sup>4</sup>, St Gallen<sup>5</sup>, and the European Society for Medical Oncology (ESMO)<sup>6</sup> have all incorporated the *Oncotype DX* test into their guidelines. In the UK, the National Institute for Health and Care Excellence (NICE) has recommended *Oncotype DX* as the only multi-gene breast cancer test for use in clinical practice to guide chemotherapy treatment decisions for patients with early-stage, hormone-receptor-positive, invasive breast cancer.<sup>7</sup>

“The *Oncotype DX* technology has played a critical role in predicting benefit of chemotherapy for more than 400,000 oestrogen-receptor-positive breast cancer patients globally in the past 10 years,” said Peter Zuendorf, Vice President, International, Genomic Health. “As adoption of *Oncotype DX* continues to grow, we are delighted to enter this partnership to broaden patient access to this unique test and the important information it provides to enable more individualised breast cancer treatment.”

This commercial arrangement between STA and Genomic Health commenced on 1st January 2014.

*Oncotype DX*, Recurrence Score and DCIS Score are trademarks of Genomic Health, Inc.

## **About Specialised Therapeutics Australia**

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provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at [www.specialisedtherapeutics.com.au](http://www.specialisedtherapeutics.com.au)

- Agreement to Distribute *Oncotype DX*® in Australia and New Zealand
- *Oncotype DX* now regarded as standard-of-care for early stage breast cancer treatment planning in the US since becoming available there in 2004

## References:

1. Paik et al. NEJM 2004; 351: 2817-2826
2. Paik et al. J Clin Oncol 2006; 24: 3726-3734
3. National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer. Version 3, 2013. Available at: [www.nccn.org](http://www.nccn.org)
4. Harris L et al. J Clin Oncol 2007; 25: 5287-5312
5. Goldhirsch A et al. Ann Oncol 2011; 22: 1736
6. Aebi S et al. Ann Oncol 2012; 22 (Supp 6): vi12-vi24
7. National Institute for Health and Care Excellence NICE diagnostic guidance 10. Issued September 2013. Available at: <http://guidance.nice.org.uk/DG10>

## Contacts

Carlo Montagner  
Chief Executive Officer  
Specialised Therapeutics Australia  
(03) 9859 1493

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# **Specialised Therapeutics to License Brain Tumour Visualisation Drug GLIOLAN® in Australia & NZ**

**Melbourne, Australia and Hamburg, Germany, 17 June 2011:** A new drug which aids neurosurgeons to better visualise and operate on high grade glioma, a type of brain tumour which has a poor prognosis, has been in-licensed by Melbourne bio-pharmaceutical company Specialised Therapeutics Australia Pty Ltd (STA).

STA has signed a binding term sheet with German company photonamic GmbH and Co. KG to in-license the drug Gliolan. The drug is used in brain surgery to selectively induce fluorescence in brain tumour cells to assist surgeons in defining and resecting gliomas.

An article published in The Lancet Oncology medical journal indicated complete resection of the malignant brain tumour tissue was achieved in 65% of patients receiving Gliolan, compared to 36% of patients in the control arm. Additionally, 6-month progression-free survival was achieved in 41% of patients receiving Gliolan compared to 21.1% of patients who received surgery without the use of the drug.<sup>1</sup>

The drug is already approved for use in 27 countries, including the United Kingdom, France and Germany. STA plan to lodge an application later this year with the Therapeutic Goods Administration to have the drug formally approved for widespread use in Australia.



Announcing the plan, STA chief executive officer Mr Carlo Montagner said STA would be responsible for marketing and clinical/regulatory development of the product in Australia and NZ. Photonamic would receive a confidential upfront payment, as well as milestone and royalty payments.

“The widespread adoption of Gliolan in Europe as a result of the Phase III randomised study published in The Lancet clearly demonstrates that patients significantly benefit from its use during surgery,” Mr Montagner said.

“Australian neurosurgeons will welcome the opportunity to access Gliolan.

“For our part, we have made clear our strategy of building Specialised Therapeutics Australia through the acquisition and growth of specialist medicines that offer unique clinical benefits to patients.

“Gliolan is an excellent fit in our growing portfolio and we look forward to driving its growth.”

Photonamic managing director, Mr Ulrich Kosciessa, said Gliolan which has recently been approved in Korea was now widely available and phase III trials of the drug had demonstrated “extremely positive” data.

“We anticipate similar results when the drug is used on patients with malignant gliomas in Australia and New Zealand,” he said. “We are delighted this drug is now being made available in Australia.”

Gliolan is used in adult patients with malignant glioma. Gliolan helps surgeons to visualise brain tumours more clearly during surgery which enables improved complete resection of the malignant tissue in the brain.

The active substance in Gliolan is 5-aminolevulinic acid, a natural biochemical precursor of heme, which is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). <sup>2</sup>

Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue which enables the surgeon to literally see the tumour more clearly during

brain surgery and to remove it more accurately, sparing healthy brain tissue.<sup>2</sup>

Gliolan was first approved in Europe in 2007 and is marketed by medac in Europe, Africa, South America and Asia (excepting Japan and Korea).

## **References:**

1. Stummer W, Pichlmeier U, Meinel T, et al., Fluorescence-guided surgery with 5-aminovulinec acid for resection of malignant glioma: a randomised controlled multicentre phase III trial, *Lancet Oncol*, 2006;7:392-401
2. European Public Assessment Report Gliolan; [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Summary\\_for\\_the\\_public/human/000744/WC500021786.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000744/WC500021786.pdf)

## **About Gliolan®**

The active substance in Gliolan is 5-aminolevulinic acid. It is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue. This enables the surgeon to see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.<sup>2</sup>

## **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. Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nanoparticle albumin-bound paclitaxel) and ALOXI® (palonosetron) respectively. Based in Melbourne, Australia, the privately held company is currently developing several more

important therapeutic agents for release in Australasia and other regional markets.

### **About photonamic GmbH and Co KG**

photonamic GmbH and Co KG was established in 2003 to develop photosensitizers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed 5-ALA for the fluorescence guided resection of glioblastoma (Gliolan) and for the photodynamic therapy of skin lesions (Alacare). Both products are approved in Europe and will further be developed for the global market. photonamic is based in Hamburg, Germany.

- Phase III study shows 6-month progression-free survival is doubled in patients receiving Gliolan® (5-aminolevulinic acid, 5-ALA) <sup>1</sup>
- Drug improves visualisation and resection of brain tumour cells

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# **Specialised Therapeutics and Helsinn Group Announce a PBS Listing for ALOXI® (Palonosetron) in Australia**

**Melbourne, Australia and Lugano, Switzerland 1st November 2010:** A world leading anti-nausea/anti-vomiting drug for cancer patients undergoing chemotherapy will be available in Australia on the Pharmaceutical Benefits Scheme (PBS) from November 1st 2010.

Aloxi® (palonosetron hydrochloride) is a new therapy to prevent acute and delayed

nausea and vomiting which can occur in cancer patients undergoing chemotherapy<sup>1</sup>.

The drug is licensed in Australia by Specialised Therapeutics Australia Pty Ltd (STA) following an agreement with Swiss Pharmaceutical Company, The Helsinn Group.

This agreement grants STA the exclusive license and distribution rights for Aloxi® in Australia and New Zealand.

Specialised Therapeutics Australia chief executive officer Mr Carlo Montagner said thousands of Australian cancer patients would now benefit from Aloxi® and its listing on the PBS.

“Aloxi® is a leading antiemetic. Many of the international medical community regards this as the first choice anti-nausea drug for cancer patients following treatment,” he said.

“This PBS listing ensures Australian cancer patients affordable access to this leading treatment.”

“It enables a better quality of life for cancer patients and adds to our portfolio of leading oncology medications.”

Mr Montagner said Aloxi® was highly regarded by the world’s cancer organisations. It is the only drug of its class specifically recommended by the European Society of Medical Oncology (ESMO), and the Multinational Association of Supportive Care in Cancer (MASCC), for moderately emetogenic chemotherapy<sup>3</sup>.

Aloxi® is a second generation 5-HT<sub>3</sub> receptor antagonist, which is differentiated to older 5-HT<sub>3</sub> antagonists by its higher receptor binding affinity and longer duration of its activity<sup>1,2</sup>.

A single intravenous dose of Aloxi® is given on the day of chemotherapy, and has been shown to be effective for up to five days<sup>1</sup>.

Aloxi® has been available in the USA since 2003, and is indicated in Australia for the management of nausea and vomiting associated with cytotoxic chemotherapy.

Today the product is approved in 63 countries, with annual sales last year of over 400 million US dollars.

Mr Montagner added: "The Helsinn Group has done a first class job of developing Aloxi®.

Helsinn Group chief executive officer Dr Riccardo Braglia said he looked forward to co-operating with STA on the Australian launch.

"We are delighted to sign this new agreement with STA and look forward to initiating a successful co-operation for Aloxi® in Australia," he said.

"STA has demonstrated a commitment to grow products in the specialist oncology market, while the patients and the medical community in Australia will enjoy the benefits of an innovative antiemetic like Aloxi®."

Aloxi® is PBS approved for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

For further information please contact:

Emma Power at Monsoon Communications on 03 9620 3333 or 0419 149 525.

## **About ALOXI®**

Palonosetron (palonosetron hydrochloride) is a second generation 5-HT<sub>3</sub> Receptor Antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. Palonosetron demonstrates, in clinical trials and clinical practice, a unique long-lasting action in the prevention of CINV. The product has shown to be effective in preventing both acute and delayed CINV in patients receiving moderately emetogenic chemotherapy (MEC). A single intravenous dose of palonosetron provides better protection from CINV than first-generation 5-HT<sub>3</sub> receptor antagonists throughout a 5-day post-chemotherapy period. Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions in

CINV trials with palonosetron were headache (9 percent) and constipation (5 percent), and they were similar to the comparators. Palonosetron has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi®, Onicit®, and Paloxi® in more than 60 countries world-wide. Palonosetron, marketed as Aloxi®, is the leading brand in the USA within the CINV Day of Chemo segment, and it is steadily growing in the European markets. In Australia, Aloxi® is PBS listed for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. For more information about palonosetron, please visit the website: [www.aloxi.com](http://www.aloxi.com)

## **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. Currently STA 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.

<http://www.specialisedtherapeutics.com.au>.

## **About Helsinn Group**

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and subsidiaries in Ireland and USA. Helsinn's business model is focused on the licensing of pharmaceuticals and medical devices in therapeutic niche areas. The Group in-licenses early to late stage new chemical entities, completes their development from the performance of pre-clinical/clinical studies and Chemistry, Manufacturing and Control (CMC), development to the filing for and attainment of their market approval worldwide. Helsinn's products are sold directly through the Group's subsidiaries or out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how, and assisted and supported with a full range of product and

scientific management services, including commercial, regulatory, financial, legal and medical marketing advice. The active pharmaceutical ingredients and the finished dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers. Helsinn is the worldwide licensor of palonosetron, a second generation 5-HT<sub>3</sub> receptor antagonist, for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer and of post-operative nausea and vomiting (PONV), and of the original nimesulide, a non-steroidal anti-inflammatory drug (NSAID) distributed in more than 50 countries worldwide.

Helsinn, with a workforce of around 450 employees in Switzerland, Ireland and USA, reported a 2009 turnover of over CHF 305.6 million, covering 85 countries worldwide, with over 20% of this turnover invested in R&D.

For more information about Helsinn Group, please visit the website: [www.helsinn.com](http://www.helsinn.com)

- Leading anti-nausea/anti-vomiting drug available November 1st
- PBS listed for Australian cancer patients

#### **References:**

1. Aloxi product Information
2. Wong E, et al Br J Pharmacol 1995; 114: 851-859.
3. [www.mascc.org](http://www.mascc.org)

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# **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.  
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## 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**

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### **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)