STA Receives TGA Approval for ABRAXANE® in Combination with Gemcitabine for First-Line Treatment of Metastatic Pancreatic Cancer

Melbourne, Australia – March, 2014: Australian biopharmaceutical company Specialised Therapeutics Australia (STA) is pleased to announce that ABRAXANE® (nanoparticle albumin-bound paclitaxel) in combination with gemcitabine in now approved by the Therapeutic Goods Administration (TGA) for the first-line treatment of metastatic pancreatic cancer.

The TGA approved indication is:

ABRAXANE, in combination with gemcitabine, is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas.[1]

TGA approval was 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.[2] The study reported that patients treated with ABRAXANE plus gemcitabine had a statistically significant improvement in overall survival (OS) compared to patients receiving the current standard of care, gemcitabine monotherapy (OS; median 8.5 months vs. 6.7 months; HR 0.72, $P<0.001$).[2] An updated analysis of OS presented at a recent international cancer conference in January 2014 (ASCO GI) showed 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; $p<0.0001$).[3]

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.[3]

STA Chief Executive Officer Mr Carlo Montagner said TGA approval paves the way for Australian patients with metastatic pancreatic cancer to access this more effective treatment option.

He commented: “In Australia, pancreatic cancer is the fifth most common cause of death from cancer for both men and women, and very few treatment options exist for this group of patients. No new drugs have been approved by the TGA for this disease since 2006. We are extremely pleased to receive TGA approval in recognition that ABRAXANE is capable of prolonging survival for patients with metastatic pancreatic cancer, and look forward to a Pharmaceutical Benefits Scheme (PBS) listing for this difficult to treat cancer.”

ABRAXANE is now TGA approved for three indications; metastatic breast cancer, first-line Non-Small Cell Lung Cancer (NSCLC) and first-line metastatic pancreatic cancer.[1]

STA is currently seeking a PBS listing for ABRAXANE in first line metastatic pancreatic cancer.

About MPACT[2]

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/m^2 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. 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 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).[2]

About Advanced Pancreatic Cancer[4]

Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is approximately 5% and is less than 2% for those with advanced disease. There are two main types of pancreatic cancer – adenocarcinomas, which accounts for approximately 90% of all pancreatic cancer, and neuroendocrine tumours. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers. However, pancreatic cancer is the fifth most common cause of cancer death for men and women in the United States and Australia, and the ninth most commonly diagnosed cancer in Australia.[4]

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 the drug and therefore eliminates 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.[1,5]

ABRAXANE is approved for the treatment of metastatic breast cancer, NSCLC and metastatic pancreatic cancer.[1] 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. Abraxane is not PBS listed for the indications of NSCLC or metastatic pancreatic cancer.

For the first-line treatment of metastatic pancreatic cancer, the recommended dosing regimen for ABRAXANE is 125 mg/m^2 administered as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of each 28-day cycle. Gemcitabine 1000 mg/m^2 is administered as an intravenous infusion beginning immediately after the completion of ABRAXANE administration on Days 1, 8 and 15 of each 28-day cycle.[1]

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

BEFORE PRESCRIBING PLEASE CONSULT THE ABRAXANE PRODUCT INFORMATION AVAILABLE AT www.specialisedtherapeutics.com.au

ABRAXANE® Minimum Product Information

ABRAXANE: Nanoparticle albumin-bound paclitaxel 100 mg powder for injection (suspension)

Indications:
Metastatic carcinoma of the breast after failure of anthracycline therapy.
First-line treatment of non-small cell lung cancer (NSCLC) in combination with carboplatin, in patients who are not candidates for potentially curative surgery and/or radiation.
First-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

Contraindications: Baseline neutrophil count < 1.5 x 10^9/L, hypersensitivity to ABRAXANE or albumin, pregnancy, lactation.

Precautions: Administer under the supervision of a physician experienced in the use of chemotherapeutic agents. ABRAXANE is not clinically interchangeable with other paclitaxel formulations. Dose dependent and dose limiting bone marrow suppression (frequent peripheral blood cell counts recommended for all patients). Peripheral neuropathy, sepsis, severe hypersensitivity, pneumonitis, patients with hepatic impairment, cardiotoxicity, affects fertility, pregnancy (category D), lactation, paediatric use. In elderly – more frequent myelosuppression, peripheral neuropathy, arthralgia, diarrhoea, decreased appetite, dehydration and epistaxis. Refer to full PI for more information.

Interactions: Inhibitors or inducers of either CYP2C8 or CYP3A4 (e.g. inhibitors: erythromycin, ketoconazole, fluoxetine, imidazole antifungals, gemfibrozil, cimetidine, ritonavir, saquinavir, indinavir, and nelfinavir; inducers: rifampicin, carbamazepine, phenytoin, efavirenz, nevirapine). CYP2C8 and CYP3A4 substrates, quinidine, PEG-35 castor oil, quercetin, clozapine, morin, and resveratrol. Refer to full PI for details.

Adverse Effects: Very common effects in ABRAXANE monotherapy: Neutropenia, anaemia, leukopenia, thrombocytopenia, lymphopenia, bone marrow suppression, peripheral neuropathy, neuropathy, hypoaesthesia, paraesthesia, myalgia, arthralgia, asthenia, nausea, vomiting, diarrhoea, constipation, stomatitis, anorexia, pyrexia, alopecia, rash, fatigue, mucositis. Additional very common effects in combination with carboplatin: Peripheral oedema, dyspnoea, decreased appetite. Additional very common effects in combination with gemcitabine: chills, abdominal pain, dysgeusia, headache, dizziness, dehydration, hypokalemia, cough, epistaxis, weight decreased, ALA increased, pain in extremity, insomnia, depression, anxiety. This is not a full list of adverse effects – refer to full PI for more information.

Dose:

Metastatic Breast Cancer: ABRAXANE 260 mg/m^2 every 3 weeks.

NSCLC: ABRAXANE 100 mg/m^2 on days 1, 8, and 15 of each 21-day cycle. Recommended carboplatin dose is AUC = 6 mg•min/mL on day 1 only of each 21-

day cycle, beginning immediately after the end of ABRAXANE administration.

Metastatic Pancreatic Cancer: ABRAXANE 125 mg/m^2 on Days 1, 8 and 15 of each 28-day cycle. Recommended gemcitabine dose is 1000 mg/m^2 beginning immediately after the end of ABRAXANE administration on Days 1, 8 and 15 of each 28-day cycle.

Dose adjustments: Required for severe neutropenia, severe peripheral neuropathy and certain non-haematological toxicities (see full PI for details). Hepatic Impairment: Patients with severe hepatic impairment should not be treated with ABRAXANE. Consider dose reduction in patients with bilirubin >2 ULN. Refer to full PI for details.

Administration: Administered intravenously over 30 minutes. No premedication to prevent hypersensitivity reactions is required for ABRAXANE. Do not mix any other drugs with the ABRAXANE infusion.

Preparation for Intravenous Administration: Reconstitute with 20 mL of 0.9% Sodium Chloride. Inject appropriate amount of reconstituted ABRAXANE into an empty, sterile, polyvinyl chloride (PVC) or non-PVC type IV bag for IV infusion. Protect from light. For more details, refer to full PI.

Patients should consult their oncologist or the ABRAXANE Consumer Medicine Information available on www.specialisedtherapeutics.com.au

ABRAXANE® is a registered trademark of Celgene Corporation.

ABRAXANE® is distributed by STA under license from Celgene Corporation, in Australia and New Zealand.

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, infectious diseases, and haematology. STA also has interests in the therapeutic areas of ophthalmology, respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

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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

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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

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 Onco*type* 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 Onco*type* 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 Onco*type* 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, Onco*type* 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[1] and a study published in the Journal of Clinical Oncology that examined whether Onco*type* DX could predict the benefit of chemotherapy.[2] Since becoming available in 2004, more than 400,000 Onco*type* DX tests have been requested by more than 19,000 physicians in over 70 countries.

The Onco*type* 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 Onco*type* 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 Onco*type* 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)[3], the American Society of

Clinical Oncology (ASCO)[4], St Gallen[5], and the European Society for Medical Oncology (ESMO)[6] 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.[7]

”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.

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

About Specialised Therapeutics Australia

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- Agreement to Distribute Onco*type* DX® in Australia and New Zealand
- Onco*type* DX now regarded as standard-of-care for early stage breast

cancer treatment planning in the US since becoming available there in 2004

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Contacts

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

Specialised Therapeutics Australia Receives Therapeutic Goods Administration Approval for Brain Tumour Visualisation Drug – GLIOLAN®

Melbourne, Australia and Hamburg, Germany, November 2013: A novel drug which assists neurosurgeons to better visualise and remove malignant brain tumours has been approved by the Therapeutic Goods Administration (TGA).

Until now, GLIOLAN (aminolevulinic acid HCl) has only been available via the Federal Government's Special Access Scheme (SAS). It will now be made widely available for use by neurosurgeons to treat patients with high grade glioma, specifically glioblastoma multiforme (GBM), which are tumours that typically have a very poor prognosis.

GLIOLAN is indicated in adult patients for **visualisation of malignant tissue during surgery for malignant gliomas that are glioblastoma multiforme (GBM) on preoperative imaging, and who are intended for resection of the tumour**.

GLIOLAN causes brain tumours (gliomas) to become fluorescent and glow during surgery. This enables neurosurgeons to better visualise these tumours and more completely remove them. GLIOLAN is given to the patient as a drink three hours before surgery. During surgery, a modified neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue to glow fluorescent red whilst normal brain tissue appears blue.

Melbourne bio-pharmaceutical company Specialised Therapeutics Australia Pty Ltd (STA) in-licenses the drug from German partner photonamic GmbH and Co. KG.

Announcing the TGA approval, STA chief executive officer Mr Carlo Montagner said GLIOLAN had already been used to treat over 100 Australian patients via the

SAS and a number of hospitals have been quick to upgrade neurosurgical microscopes with fluorescence capability.

“We are pleased with the positive response from neurosurgeons since GLIOLAN was made available via the SAS and this approval from the TGA is an extremely positive outcome,” he said.

“It has always been our intention to make this high class compound available to all patients who may benefit. Brain tumour surgery using GLIOLAN has been widely adopted throughout Europe and we expect a similar uptake in Australia to improve outcomes for all GBM patients.”

The chief executive officer of photonamic Mr Ulrich Kosciessa said: “The approval in Australia is another milestone in our global development of GLIOLAN, which is now registered in more than 30 countries world wide.

“GLIOLAN was developed to provide neurosurgeons with an effective tool to increase radicality of brain tumour resection without compromising safety for the patients. We are pleased that our partner STA has successfully been able to achieve an approval from the TGA.”

International studies have shown that use of GLIOLAN during brain tumour surgery has nearly doubled the rate of achieving a complete resection, which in turn has resulted in a doubling of the number of patients without progression of their brain cancer six months post surgery.[1]

The pivotal Phase III registration study published in The Lancet Oncology medical journal reported 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. This resulted in 6-month progression-free survival being achieved in 41% of patients receiving GLIOLAN compared to 21.1% of patients who received surgery without the use of the drug.[1]

Brisbane neurosurgeon, Lindy Jeffree, has used GLIOLAN in 36 patients since the drug was first made available via the SAS. She regards fluorescence guided surgery as an important tool in helping surgeons distinguish parts of a tumour which would otherwise be invisible to the naked eye.

She commented: “It makes it much easier to distinguish tumour from normal

brain tissue, which has undoubtedly assisted during some complex surgical procedures. Our aim is to provide optimal patient benefit. Using GLIOLAN to see tumour tissue more clearly enables better and more thorough resection which can make a big difference to a patient's response to subsequent treatment and ultimately to survival."

"I am extremely pleased to see this drug being made more widely available to improve surgical outcomes for patients with GBM around the country."

The approval by the TGA approval brings the number of countries where GLIOLAN is registered to 31, including 27 in the EU as well as Japan, Korea and Taiwan. GLIOLAN was first approved in Europe in 2009 and is marketed by medac in Europe, Africa, South America and Asia (except Japan and Korea).

- Novel drug which improves visualisation and resection of malignant brain tumours now widely available
- Twice as many patients are without progression of brain cancer six months after surgery with GLIOLAN
- To date over 100 Australian patients have been treated with GLIOLAN via the Federal Government's Special Access Scheme

The following Australian hospitals currently perform fluorescence-guided resection of brain tumours using GLIOLAN:

1. Royal Brisbane and Woman's Hospital, Queensland
2. The Wesley Hospital, Queensland
3. The Mater Private Hospital, Queensland
4. Princess Alexandra Hospital, Queensland
5. Prince of Wales Hospital, New South Wales
6. Newcastle Private Hospital, New South Wales
7. Calvary Hospital, Tasmania
8. The Royal Melbourne Hospital, Victoria
9. St Vincent's Private Hospital, Victoria

About GLIOLAN®

The active substance in GLIOLAN, aminolevulinic acid (ALA), is a photoreceptive compound which 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.[2]

Like all medications GLIOLAN may cause side effects. GLIOLAN should not be used in patients with hypersensitivity to ALA or porphyrins, or in cases of acute or chronic porphyria, or in pregnancy. Cardiac disorders, gastrointestinal disorders and skin and subcutaneous disorders are all reported as being uncommon.

About Specialised Therapeutics Australia

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About photonamic GmbH and Co KG

photonamic GmbH and Co KG was established in 2003 to develop photosensitisers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed 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.

References:

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Contacts

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

New ‘Superbug’ Antibiotic Approved for Use in Australia

MELBOURNE, Australia – April 26, 2013 – An effective new antibiotic designed to specifically treat the common superbug* infection *Clostridium difficile*-associated diarrhoea will be available to patients in Australia from 14th May 2013.

Melbourne biopharmaceutical company Specialised Therapeutics Australia Pty

Ltd (STA) has received Therapeutic Goods Administration (TGA) approval to market the drug DIFICID (fidaxomicin) in Australia. Until now, it has only been available in Australia under the Special Access Scheme.

DIFICID is indicated for the treatment of confirmed *Clostridium difficile* (CDI) infections in adults.[1]

The macrocyclic antibiotic therapy, taken in tablet form, is regarded as a breakthrough treatment to help fight serious CDI, which typically develops in patients following broad-spectrum antibiotic use. CDI targets the large intestine, causing diarrhoea which can range from moderate & debilitating to severe & life-threatening. It is extremely common in hospitals and aged care facilities as older patients are particularly vulnerable, and can be fatal.[2]

A recent media report indicated 14 Victorians died from the infection during a 15-month period in 2010 and 2011.[3] According to data generated by the Quebec provincial hospitalisation database, there were 7004 cases of *C. difficile* across Quebec from April 1st 2003 to March 31st 2004, and 1270 people died after contracting CDI.[4]

Medical experts say Australian infection rates have at least doubled in recent years in major public hospitals, but concede the incidence of CDI is under reported.

STA Chief Executive Officer Mr Carlo Montagner is excited about the valuable treatment alternative DIFICID offers Australian patients who contract CDI.

“DIFICID is a potentially life saving drug for this extremely serious infection plaguing public hospitals and the wider community,” he said. “Unfortunately, it is estimated that almost 30% of patients can have a recurring infection. DIFICID is the only approved drug on the market which studies have shown will lower the risk of that infection returning.”

DIFICID is the first in a new class of antibiotics which are minimally absorbed by the bloodstream and have been shown to fight CDI while leaving healthy gut flora untouched.[5]

Hypervirulent strains of *C. difficile*, including the PCR ribotype 027 strain

recently identified in Australia, have been associated with epidemic spread and high rates of severe disease and death.[6]

Risk factors for CDI include exposure to antimicrobial drugs, gastric acid-suppressive therapy, advanced age, prolonged hospitalisation, cancer chemotherapy, co-morbidity and immuno- suppression. Although most cases have been in hospital inpatients, increasing numbers of community-associated cases are now being reported.[2]

Leading Australian CDI expert Professor Thomas Riley from The University of Western Australia, acknowledged that studies had demonstrated patients treated with DIFICID were significantly less likely to develop recurrent infections.[7,8]

He regarded DIFICID as an important new treatment alternative, with infection rates of *C. difficile* climbing substantially in public hospitals around the country.

“Introducing DIFICID to Australia basically means we have another drug in the arsenal to treat this infection. Until now, we have had only two drugs available.

“Fewer recurrences will help contain the spread of the illness. Most importantly, DIFICID will benefit individual patients, who become weaker and more vulnerable with each recurrent infection, enormously.”

STA licenses DIFICID for the Australian market from US-based Optimer Pharmaceuticals. Optimer Chief Executive Officer & Chairman of the Board, Dr Henry McKinnell, said he was confident DIFICID would provide a valuable new treatment option for an unmet medical need in Australia. “With the recent approval in Australia, fidaxomicin is now approved by four regulatory agencies, broadening access to patients in need across the globe,” said Dr. Henry McKinnell. “CDI infections represent a global healthcare challenge, and we believe an innovative drug like DIFICID that can deliver a substantial clinical improvement over existing therapies is an important new option that should be widely available to patients.”

About DIFICID®

Fidaxomicin is a novel antibiotic agent and the first of a new class of antibacterials called macrocycles. Fidaxomicin is bactericidal against *C difficile* in vitro, inhibiting RNA synthesis by RNA polymerases.[1]

DIFICID was studied for the treatment of CDI in two randomised Phase III studies and was found to have equivalent efficacy to vancomycin. Notably, DIFICID was associated with significantly greater improvements in the rate of sustained clinical response and significantly lower rates of CDI recurrence (than vancomycin).[1,7,8]

Contraindications and side effects:[1]

Like all medications, DIFICID may cause side effects. DIFICID should not be used in patients who are hypersensitive to any ingredient in the formulation or component of the container. As there is minimal systemic absorption of DIFICID, it should not be used for the treatment of systemic infections. Most common side effects (≥1/10) caused by DIFICID include nausea, constipation and vomiting.

For further information regarding DIFICID and potential side effects, physicians should review the DIFICID Approved Product Information available from www.specialisedtherapeutics.com.au/index.php?q=clinician-resources.html and patients should consult their prescribing physician or the DIFICID Consumer Medicine Information available in the pack or via www.specialisedtherapeutics.com.au/index.php?q=dificid.html

About CDI

CDI has become a significant medical problem in hospitals, long-term care facilities and the community. CDI is a serious illness resulting from infection of the inner lining of the colon by *C. difficile*, which produces toxins that cause inflammation of the colon, severe diarrhoea and, in the most serious cases, death.

Patients typically develop CDI following the use of broad-spectrum antibiotics which disrupt normal gastrointestinal (gut) flora, possibly allowing *C. difficile* to enter the gut and flourish. Older patients in particular are at risk for CDI, potentially because of a weakened immune system or the presence of underlying disease. Approximately two-thirds of CDI patients are 65 years of age or older. Historically, approximately 20 – 30% of CDI patients who initially respond to treatment experience a clinical recurrence.[7]

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 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

About Optimer Pharmaceuticals

Optimer Pharmaceuticals, Inc. is a global biopharmaceutical company focused on developing and commercialising innovative hospital specialty products that have a positive impact on society. Optimer developed DIFICID (fidaxomicin) tablets, an FDA-approved macrolide antibacterial drug for the treatment of *Clostridium difficile*-associated diarrhoea (CDAD) in adults 18 years of age and older and is commercializing DIFICID in the US and Canada. Optimer also received marketing authorisation for fidaxomicin tablets in the European Union, where its partner, Astellas Pharma Europe, is commercialising fidaxomicin under the trade name DIFICLIR™. The company is exploring marketing authorisation in other parts of the world where *C. difficile* has emerged as a serious health problem. Additional information can be found at www.optimerpharma.com.

OPTIMER and DIFICID are trademarks of Optimer Pharmaceuticals, Inc. All other trademarks are the property of their respective owners.

* Superbug is a common term to describe a bacterium that is resistant to multiple antibiotics.

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Contacts

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

Emma Power
Monsoon Communications
(03) 9620 3333

ABRAXANE® Plus Gemcitabine Improves Survival in Phase III Study of Patients with Advanced Pancreatic Cancer

MELBOURNE, Australia – January 23, 2013 – Australian biopharmaceutical company Specialised Therapeutics Australia announces that a phase III clinical trial of world leading breast cancer drug ABRAXANE® (nanoparticle albumin-bound paclitaxel) in combination with current standard of care gemcitabine in patients with advanced pancreatic cancer has demonstrated substantially improved survival times, with double the number of patients surviving two years.[1]

The MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial) investigation involved 861 treatment naïve patients internationally.

Researchers found those patients treated with ABRAXANE plus gemcitabine had a statistically significant improvement in overall survival compared to patients receiving gemcitabine alone .[1]

Moreover, ABRAXANE plus gemcitabine demonstrated a 59% increase in one-year survival (35% vs. 22%, p=0.0002) and demonstrated double the rate of survival at two years (9% vs. 4%, p=0.02) as compared to gemcitabine alone.[1]

ABRAXANE plus gemcitabine also demonstrated statistically significant improvements in key secondary endpoints compared to gemcitabine alone, including a 31% reduction in the risk of progression or death with a median progression-free survival (PFS) of 5.5 vs. 3.7 months (HR 0.69, P=0.000024) and an overall response rate (ORR) of 23% compared to 7% (response rate ratio of

3.19, p=1.1 x 10^{-10}). Another endpoint assessed included time to treatment failure, which was significantly improved with the ABRAXANE combination compared to gemcitabine alone .[1]

“The past few decades have brought us very few treatment advances for patients with advanced pancreatic cancer, which is both deadly and incredibly difficult to treat with success,” said Daniel D. Von Hoff, M.D., F.A.C.P., Lead Principal Investigator of the MPACT study and Chief Scientific Officer for Scottsdale Healthcare’s Virginia G. Piper Cancer Centre Clinical Trials and Physician-In-Chief for TGen. “The fact that ABRAXANE plus gemcitabine demonstrated an overall survival benefit, and also did so at one and two years, is a significant step forward in offering potential new hope for our patients.”

Professor John Zalcberg, Chief Medical Officer and Executive Director of Cancer Medicine at the Peter MacCallum Cancer Centre in Melbourne, said the evidence strongly supported using ABRAXANE in combination with gemcitabine as a new standard of care to treat appropriate patients, many of whom were not diagnosed until the disease was metastatic.

While acknowledging that this advance could not be seen as a cure for pancreatic cancer, Professor Zalcberg said the 59% increase in the number of patients who lived beyond 12 months was very encouraging.

“We are extremely encouraged by the results of this study involving ABRAXANE and regard this outcome as a significant breakthrough in terms of the future management of this disease,” he said.
“In addition to treating women with metastatic breast cancer with ABRAXANE in the appropriate setting, we look forward to its approval in Australia for treating patients with advanced pancreatic cancer.”

Specialised Therapeutics Australia (STA) Chief Executive Officer Mr Carlo Montagner said the positive data paved the way for Australian patients with advanced pancreatic cancer to access more effective treatment options.

He commented: “In Australia, pancreatic cancer is the fourth most common cause of death from cancer for both men and women2 and very few treatment options exist for this group of patients. We are extremely pleased to demonstrate that ABRAXANE is capable of prolonging survival for patients with advanced

pancreatic cancer and we hope to have ABRAXANE approved by the Australian Therapeutic Goods Administration (TGA) in the latter half of 2014."

The most common grade ≥ 3 treatment-related adverse events in the study for ABRAXANE plus gemcitabine vs. gemcitabine alone were neutropenia (38% vs. 27%), fatigue (17% vs. 7%), and neuropathy (17% vs. 1%). In the ABRAXANE plus gemcitabine arm, the median time to neuropathy improvement was 29 days. There was no difference in serious life threatening toxicity (4% in each arm).[1]

Further details of the study will be highlighted in a late-breaking oral presentation by Dr. Daniel D. Von Hoff:

Abstract: LBA #148: Final results of a randomized phase III study of weekly nab-paclitaxel plus gemcitabine versus gemcitabine alone in patients with metastatic adenocarcinoma of the pancreas. Friday, January 25th between 2:00 to 3:30 pm PST at the American Society of Clinical Oncology's (ASCO) 2013 Gastrointestinal Cancers Symposium in San Francisco, CA.

These results are from an investigational study. ABRAXANE is not approved for the treatment of advanced pancreatic cancer. Following TGA review and approval, STA will seek to have ABRAXANE included on the Pharmaceutical Benefits Scheme (PBS) for the reimbursement of ABRAXANE for advanced pancreatic cancer.

About the MPACT Study[1]

In the MPACT (**M**etastatic **P**ancreatic **A**denocarcinoma **C**linical **T**rial) study, a Celgene-sponsored, open-label, randomised, international study of 861 patients with metastatic pancreatic cancer 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/m^2 administered weekly for 7 weeks followed by a week of rest followed by cycles of weekly administration for 3 weeks followed by one week of rest).

The primary endpoint for the study is improvement in overall survival. Secondary

endpoints were progression-free survival, and overall response rate determined by independent radiological review. Other endpoints included progression-free survival, overall response rate determined by investigator and the safety and tolerability of this combination in this patient population.

About Advanced Pancreatic Cancer

Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is 6% and is less than 2% for those with advanced disease. There are two main types of pancreatic cancer – adenocarcinomas, which accounts for approximately 90% of all pancreatic cancer, and neuroendocrine tumors. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers. However, pancreatic cancer is the fourth most common cause of cancer death for men and women in the United States and Australia, and the ninth most commonly diagnosed cancer in Australia.[2]

About ABRAXANE®

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option for metastatic breast cancer.[3] 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.

ABRAXANE is approved for metastatic breast cancer in over 40 countries including the U.S., Canada, European Union, Japan and China, and more than 500,000 cancer patients have received ABRAXANE therapy in the past five years.

In Australia, ABRAXANE has 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.

ABRAXANE is currently in various stages of investigation for the treatment of the following cancers: metastatic melanoma, bladder, ovarian, and expanded applications for breast cancer.

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 the drug and eliminates 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.[3-4]

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. [3-4]

Anthracycline pre-treated patients in the study lived significantly longer.[5] The tolerability with ABRAXANE and solvent-based paclitaxel was comparable, despite the 49% greater dose of paclitaxel administered as ABRAXANE.[3-4] 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.[3-4]

Contraindications and side effects[3]:

Like all medications, ABRAXANE may cause side effects.
ABRAXANE should not be used in patients who have baseline neutrophil counts of $<1.5 \times 10^9$ /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.

Most common side effects (≥1/10) caused by ABRAXANE include; neutropenia,

anemia, leucopenia, thrombocytopenia, lymphophenia, anorexia, peripheral neuropathy, hypoaesthesia, paraethesia, nausea, diarrhoea, vomiting, constipation, stomatitis, alopecia, rash, arthralgia, myalgia, fatigue, asthenia, pyrexia.

For further information regarding ABRAXANE and potential side effects, physicians should review the ABRAXANE Product Information and patients should consult their oncologist or the ABRAXANE Consumer Medicine Information available on www.specialisedtherapeutics.com.au.

ABRAXANE® is a registered trademark of Celgene Corporation.

ABRAXANE® is distributed by STA under license from Celgene Corporation in Australia and New Zealand.

About Specialised Therapeutics Australia, Pty Ltd

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.

Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nab-paclitaxel) and ALOXI® (palonosetron HCl) respectively, and has recently licensed two new agents from the Helsinn Group. Firstly Anamorelin, which is a novel ghrelin receptor agonist for the treatment of anorexia-cachexia in NSCLC, and a fixed-dose combination product (in both oral and intravenous forms) containing netupitant, a neurokinin-1 (NK1) receptor antagonist, combined with Aloxi, a serotonin-3 (5-HT_3) receptor antagonist. STA also has interests in the therapeutic areas of anti-infectives with the rights to commercialise DIFICID® (fidaxomicin) for the treatment of Clostridium difficile infections, respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

- ABRAXANE plus gemcitabine demonstrated highly statistically significant and clinically meaningful results across primary and key secondary endpoints and patient subgroups
- ABRAXANE plus gemcitabine patients showed 59% higher chance of

survival at one year; survival rates doubled at two years
- A new standard of care for patients with advanced pancreatic cancer
- Oral Presentation Scheduled for Friday, January 25th at ASCO's Gastrointestinal Cancers Symposium Annual Meeting

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ABRAXANE® Demonstrates Significant Improvement in Progression-Free Survival Compared to Standard Chemotherapy in Advanced

Melanoma Patients

MELBOURNE, Australia – October 25, 2012 – Specialised Therapeutics Australia Pty Ltd today announced that abstracts for the upcoming Society for Melanoma Research meeting have been published online in the organization's official journal. The publication includes an abstract reviewing results from a phase III metastatic melanoma study with ABRAXANE® (nanoparticle albumin-bound paclitaxel).

Helsinn Grants Specialised Therapeutics Australia (STA) Rights to Anamorelin, a First-in-Class Compound to Treat Cachexia-Anorexia Related to Non-Small Cell Lung Cancer (NSCLC)

Lugano, Switzerland and Melbourne, Australia, October 15th, 2012 – Melbourne biopharmaceutical company Specialised Therapeutics Australia (STA) has been granted exclusive commercialisation rights to a new drug for the treatment of NSCLC cachexia-anorexia. This condition is a serious multifactorial disorder which involves muscle wasting and metabolic impairment and commonly affects patients with advanced cancer. STA has reached agreement with Swiss pharmaceutical company Helsinn Healthcare to in-license the novel ghrelin receptor agonist anamorelin for both Australia and New Zealand.

GLIOLAN® Granted Orphan Drug Status by the Therapeutic Goods Administration

Melbourne, Australia April 2012: A drug which aids neurosurgeons to better visualise and more completely remove malignant brain tumours has been granted orphan drug status by the Therapeutic Goods Administration (TGA).

The drug, Gliolan, is currently in-licensed by Melbourne biopharmaceutical company, Specialised Therapeutics Australia (STA) and is currently only available to neurosurgeons via the federal government's Special Access Scheme (SAS).

Gliolan has been granted orphan drug designation for photodynamic diagnosis of gliomas that are glioblastoma multiforme (GBM) (malignant) on preoperative imaging, and intended for gross macroscopic resection of all visible tumour. STA will lodge an application for TGA approval later this year. Orphan drug designation also means TGA application fees are waived.

STA chief executive officer, Mr Carlo Montagner, said orphan drug status is an important milestone as the company progressed plans to register the drug with the TGA.

"After we submit our documentation for registration by the TGA, approval for Gliolan could take 12 to18 months. We look forward to making this product broadly available to patients as it has been shown to significantly improve outcomes in glioma patients."

Gliolan is administered to patients three hours prior to surgery and causes cancerous tissue to glow fluorescent red during brain surgery. This enables improved visualisation of the boundary between healthy and diseased brain tissue, and aids the surgeon to more thoroughly remove the tumour. International studies have shown the use of Gliolan during surgery has nearly doubled the rate of achieving a complete resection, which has resulted in a

doubling of the number of patients without progression of their brain cancer six months after their surgery.[1]

The pivotal Phase III registration study published in The Lancet Oncology medical journal reported 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. This resulted in 6-month progression-free survival being achieved in 41% of patients receiving Gliolan compared to 21.1% of patients who received surgery without the use of the drug.[1]

Gliolan has been accessed via the SAS and used in five brain tumour (high grade glioma) operations to date in Australia, at the Royal Melbourne Hospital and the Wesley Hospital in Brisbane.

The drug has been approved for use in 29 countries since 2007, including the United Kingdom, France, Germany, and Korea. Gliolan is used in adult patients with malignant glioma. The active substance in Gliolan, 5-aminolevulinic acid, is a photoreceptive compound which is predominantly absorbed by highly proliferative cells in the body and converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX).[2]

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 visualise the tumour more clearly during brain surgery and to remove it more completely and accurately, sparing healthy brain tissue.[2]

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2. European Public Assessment Report

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.[2]

Like all medications Gliolan may cause side effects. Gliolan should not be used in patients with hypersensitivity to 5-ALA or porphyrins, in cases of acute or chronic porphyria, or in pregnancy. Cardiac disorders, gastrointestinal disorders and skin and subcutaneous disorders are all reported as being uncommon.

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 negotiating the rights to several more important therapeutic agents for release in Australasia and other regional markets.

Specialised Therapeutics Australia Extends Collaboration with Swiss Helsinn Group

Melbourne, Australia and Lugano, Switzerland, 10 August 2011: Melbourne bio-pharmaceutical company Specialised Therapeutics Australia plans to further expand its oncology portfolio, to include a new product for the prevention of chemotherapy-induced nausea and vomiting (CINV).

The Australian company has signed a letter of intent with its Swiss partner, Helsinn Group, to in-license Helsinn's new compound for the prevention of chemotherapy induced nausea and vomiting. The arrangement covers the development of a fixed-dose combination product (in both oral and intravenous forms) containing netupitant, a neurokinin-1 (NK_1) receptor antagonist, and Aloxi® (palonosetron), a serotonin-3 (5-HT_3) receptor antagonist.

This further collaboration follows the successful Australian launch in November last year of the second generation 5-HT_3 antagonist, Aloxi®, which is listed on the Pharmaceutical Benefits Scheme (PBS).

Aloxi® has been available internationally after being registered by Helsinn Group in the USA in 2003 and Europe in 2005, and is indicated for the prevention of nausea and vomiting induced by cytotoxic chemotherapy. It is successfully marketed in over 50 countries, with annual sales in 2010 in excess of $500M worldwide.

Under the terms of the agreement, Helsinn will manufacture the new product in the group's plant located in Ireland and will also be responsible for the supply of the product for clinical and commercial use in Australia.

STA will be responsible for regulatory/clinical development and commercial activities within Australia and New Zealand. It is anticipated approval submissions will be lodged with the Therapeutic Goods Administration in 2014 following the successful completion of the Phase III registration program.

STA chief executive officer Mr Carlo Montagner said his company would pay an

upfront payment to Helsinn, as well as milestone and royalty payments.

Given the promising data from the phase I and II studies, he said he was optimistic this new product would further establish both STA and Helsinn as market leaders in oncology patient supportive care.

Riccardo Braglia, CEO of Helsinn Group said the company is very proud that the existing successful collaboration with STA for Aloxi® is now extending to netupitant-palonosetron fixed dose combination. He added that the strength of the two companies will enable Australian patients to have additional treatments for CINV now and in the future.

Ends.

For further information please contact Emma Power at Monsoon Communications on (03) 9620 3333 or 0419 149 525.

About Netupitant

Netupitant is a highly selective NK_1 receptor antagonist, an antiemetic that works by blocking the action of Substance P, an endogenous neurotransmitter contained in high concentrations in the vomiting centre of the brainstem that can stimulate the vomiting reflex. The fixed-dose combination of netupitant and palonosetron has entered Phase III for the prevention of acute and delayed nausea and vomiting following both highly and moderately emetogenic chemotherapy.

About Palonosetron (Aloxi®, Onicit®, Paloxi®)

Aloxi® (palonosetron hydrochloride) is a second generation 5-HT_3 receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting in cancer patients. Aloxi® has a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. In clinical trials and clinical practice, Aloxi® demonstrates unique long-lasting action in the prevention of CINV. A single intravenous dose of Aloxi® provides better protection from CINV than first-generation 5-HT_3 receptor antagonists.

Aloxi® is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions

(incidence ≥ 2 percent) in trials with Aloxi® 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 50 countries world-wide. Aloxi® is the leading brand in the USA and in Japan within the CINV Day of Chemo segment, and it is steadily growing in the European markets. For more information about palonosetron, please visit the website: www.aloxi.com

About Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating 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 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. For more information about Helsinn Group, please visit the website: www.helsinn.com

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