Ariad and STA Announce Approval of ICLUSIG™ (ponatinib) in Australia

Cambridge, MA, and Melbourne, Australia, November 24, 2014: ARIAD Pharmaceuticals, Inc. (NASDAQ: ARIA) and Specialised Therapeutics Australia Pty Ltd (STA), today announced the marketing approval of ICLUSIG™ (ponatinib) in Australia by the Therapeutic Goods Administration (TGA).

The Australian Product Information for ICLUSIG states that it is indicated for the treatment of adult patients with:

- Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) whose disease is resistant to, or who are intolerant of at least two prior tyrosine kinase inhibitors; or where there is a T315I mutation.
- Philadelphia-chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) whose disease is resistant to, or who are intolerant of dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or where there is a T3151 mutation.

Therapy should be initiated and monitored by a haematologist with expertise in managing adult leukaemias.

“Up to thirty percent of patients with CML become resistant to current therapies, and patients with resistant disease eventually run low on treatment options,” said Professor Timothy Hughes, Consulting Haematologist at the Royal Adelaide Hospital and one of the PACE trial investigators. “ICLUSIG will be a valuable new therapy for refractory leukaemia patients and treating clinicians in Australia.”

ARIAD submitted its marketing application for Iclusig in the third quarter of 2013 to the Therapeutics Goods Administration (TGA), in Australia. Commercial launch of ICLUSIG is expected to occur early in 2015.

“We are very pleased with the approval of ICLUSIG in Australia and will work

closely with STA to make Iclusig available to appropriate Philadelphia-positive leukaemia patients as quickly as possible," stated Harvey J. Berger, M.D., chairman and chief executive officer of ARIAD. "We look forward to continuing our strong collaboration with STA to provide this important treatment option to refractory CML patients in Australia."

"ICLUSIG provides a new treatment option for patients with difficult-to-treat CML or Ph+ ALL who previously had limited therapies available to them," said Carlo Montagner, chief executive officer at STA. "We look forward to the Pharmaceutical Benefit Advisory Committee's decision on ICLUSIG's reimbursement for Australian patients under the Pharmaceutical Benefits Scheme."

The TGA decision was based on results from the pivotal Phase 2 PACE (Ponatinib Ph+ ALL and CML Evaluation) trial in patients with CML or Ph+ ALL who were resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy, or who had the T315I mutation of BCR-ABL. ICLUSIG demonstrated anti-leukemic activity achieving a major cytogenetic response (MCyR) in 54 percent of chronic-phase CML patients and in 70 percent of patients with the T315I mutation.[1,2] MCyR within the first 12 months was the primary endpoint of the PACE trial for chronic-phase patients.[1,2]

In patients with advanced disease, 57 percent of accelerated-phase CML patients and 34 percent of blast-phase CML patients achieved a major hematologic response (MaHR) with Iclusig. MaHR within the first 6 months was the primary endpoint in the trial for patients with advanced disease.[1,2]

The most common (>1%) serious adverse reactions for Iclusig were pancreatitis, abdominal pain, decrease in platelet count, lipase increased, anaemia, cardiac failure, coronary artery disease, diarrhoea, decreased neutrophil count, febrile neutropenia, pancytopenia, and pyrexia.[2] The most common (≥20%) adverse reactions of any severity were decrease in platelet count, rash, dry skin, and abdominal pain.[2]

CML is a cancer of the white blood cells that is diagnosed in approximately 330 patients each year in Australia.[3] CML and Ph+ ALL patients treated with TKIs can

develop resistance or intolerance over time to these therapies. ICLUSIG is a targeted cancer medicine discovered and developed at ARIAD. It was designed by ARIAD scientists using ARIAD's platform of computational chemistry and structure-based drug design to inhibit BCR-ABL, including drug-resistant mutants that arise during treatment. ICLUSIG is the only TKI that has received an approval in Australia for an indication that includes CML and Ph+ ALL patients with the T315I mutation.

For further information, please consult the full ICLUSIG Product Information.

About CML and Ph+ ALL

CML is characterised by an excessive and unregulated production of white blood cells by the bone marrow due to a genetic abnormality that produces the BCR-ABL protein. After a chronic phase of production of too many white blood cells, CML typically evolves to the more aggressive phases referred to as accelerated phase and blast crisis. Ph+ ALL is a subtype of acute lymphoblastic leukaemia that carries the Ph+ chromosome that produces BCR-ABL. It has a more aggressive course than CML and is often treated with a combination of chemotherapy and tyrosine kinase inhibitors. The BCR-ABL protein is expressed in both of these diseases.

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.

Minimum Product Information ICLUSIG™ (ponatinib HCl)

Indications: Adult patients with: Chronic phase, accelerated phase, or blast phase chronic myeloid Ieukaemia (CML) whose disease is resistant to, or who are intolerant of at least two prior tyrosine kinase inhibitors; or where there is a T3151mutation. Philadelphia chromosome positive acute lymphoblastic Ieukaemia (Ph+ ALL) whose disease is resistant to, or who are intolerant of dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or where there is a T3151 mutation. Therapy should be initiated and monitored by a haematologist with expertise in managing adult leukaemias. **Contraindications:** Hypersensitivity to ponatinib or excipients.

WARNING: VASCULAR OCCLUSION AND HEART FAILURE. Vascular Occlusion: Arterial and venous thrombosis and occlusions have occurred in at least 23% of ICLUSIG treated patients, including fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularisation procedures. Patients with and without cardiovascular risk factors, including patients less than 50 years old, experienced these events. Monitor for evidence of thromboembolism and vascular occlusion. Interrupt or stop ICLUSIG immediately for vascular occlusion (see Precautions). Heart Failure, including fatalities, occurred in 8% of ICLUSIG-treated patients. Monitor cardiac function. Interrupt or stop ICLUSIG for new or worsening heart failure (see Precautions).

Precautions: Actively monitor and manage patients for vascular occlusions, cardiac failure, hypertension, haemorrhage, myelosuppression, hepatotoxicity, pancreatitis and QT prolongation before and during treatment. Interrupt, reduce or discontinue ICLUSIG as clinically indicated (see full PI). ***Vascular occlusion:*** Do not use if history of myocardial infarction, prior revascularisation or stroke, unless the benefit outweighs the risk. Monitor cardiovascular status and optimise therapy throughout. ***Cardiac failure:*** Monitor for heart failure and treat as clinically indicated. ***Hypertension:*** Monitor and treat hypertension to normalise blood pressure. ***Haemorrhage:*** including fatalities occurred. Mostly in patients with grade 4 thrombocytopaenia. ***Myelosuppression:*** Severe thrombocytopenia, neutropenia or anaemia. Perform complete blood counts every

2 weeks initially. ***Hepatotoxicity:*** Including severe drug induced liver injury and fatal hepatic failure. Monitor Liver Function Tests (LFT's) at baseline and at least monthly. ***Pancreatitis and serum lipase:*** Monitor serum lipase every 2 weeks initially. ***QT prolongation:*** QT prolongation seen with other BCR-ABL inhibitors. ***Lactose:*** contains lactose. ***Special populations:*** Caution or avoid in patients with moderate to severe hepatic impairment, pregnancy (category D), breastfeeding, the elderly, paediatric patients, driving or operating machinery (see full PI). ***Interactions with Other Medicines:*** Caution with concurrent strong CYP3A inhibitors, strong CYP3A inducers, substrates of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) (see full PI). ***Adverse Effects:*** *Most common (≥ 20%) adverse drug reactions (ADRs)*: Platelet count decreased, rash, dry skin, and abdominal pain. *Most common (> 1%) serious ADRs*: Pancreatitis (5.1%), abdominal pain (1.8%), platelet count decreased (1.8%), lipase increased (1.3%), anaemia (1.3%), cardiac failure (1.3%), coronary artery disease (1.1%), diarrhoea (1.1%), neutrophil count decreased (1.1%), febrile neutropenia (1.1%), pancytopenia (1.1%), and pyrexia (1.1%). *Other very common (>10%) ADRs*: Upper respiratory tract infection, anaemia, neutrophil count decreased, decreased appetite, insomnia, headache, dizziness, hypertension, dyspnoea, cough, diarrhoea, vomiting, constipation, nausea, lipase increased, ALA increased, AST increased, bone pain, arthralgia, myalgia, pain in extremity, back pain, muscle spasms, fatigue, asthenia, oedema peripheral, pyrexia, pain. This is not a full list of adverse effects – refer to full PI for more information on common (>1%) and uncommon (>0.1%) ADRs. **Dosage and administration:** Monitor and manage cardiovascular risk factors before and throughout treatment. Dose: Starting dose, 45 mg once daily, with or without food. *Dose adjustments based on disease response*: Consider reducing the dose of ICLUSIG to 30 mg or 15 mg for chronic phase (CP) CML patients who have achieved a major cytogenetic response, especially in subjects at risk of vascular adverse events. Consider discontinuing ponatinib if a haematologic response has not occurred by 3 months (90 days) especially in subjects at risk of vascular adverse event. *Dose adjustments for toxicity*: Consider dose modification or treatment cessation to manage myelosuppression, vascular occlusion, uncontrolled hypertension, pancreatitis or elevated serum lipase and other severe adverse reactions. Provide haematologic support (platelet transfusion or haematopoietic growth factors) if clinically indicated.

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, haematology, ophthalmology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS).

About ARIAD

ARIAD Pharmaceuticals, Inc., headquartered in Cambridge, Massachusetts and Lausanne, Switzerland, is an integrated global oncology company focused on transforming the li

ves 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 utilises 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 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 authorisations, as well as the level of pricing obtained 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.

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STA to License New Drug – ILUVIEN® – to Improve Vision in Patients with Diabetes-Induced Vision Loss

Melbourne, Australia and Atlanta, Georgia, 28 April 2014: Australian and New Zealand patients suffering from vision impairment due to a type of diabetes-induced eye disease will have access to a new treatment, following a license deal between Australian biopharmaceutical company Specialised Therapeutics

Australia (STA) and Alimera Sciences. (NASDAQ: ALIM).

The exclusive agreement enables STA to distribute ILUVIEN® (190 micrograms fluocinolone acetonide intravitreal implant in applicator) – a sustained release intravitreal implant used to treat vision impairment associated with chronic diabetic macular oedema (DMO), when the condition is deemed insufficiently responsive to current available therapies.

Under the terms of the license arrangement, STA will be responsible for all regulatory and commercial activities for ILUVIEN in Australia and New Zealand. The agreement includes a milestone payment to Alimera Sciences on achievement of a Pharmaceutical Benefits Scheme (PBS) listing, as well as an increasing royalty payment based upon a specific sales target.

Australian Ophthalmologist Professor Mark Gillies from the Department of Clinical Ophthalmology and Eye Health, University of Sydney, said ILUVIEN was a welcome treatment option for patients with DMO who no longer respond to conventional therapies and who face progression to loss of vision.

“ILUVIEN provides a new treatment option for those patients for whom other current therapies are unsuitable,” Professor Gillies commented. “All people with diabetes, even those with well-managed conditions, face an increased risk of loss of vision from retinal disease.

“While there may be some side effects of ILUVIEN, these are treatable and a large clinical trial has demonstrated that many patients with advanced retinal disease will experience sustained improvement in their vision after receiving the implant in their eye which may last for up to three years. Some drugs that are currently injected into the eye may only last four weeks.”

Each ILUVIEN implant provides a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of the corticosteroid, fluocinolone acetonide (FAc).[1-3] ILUVIEN is injected into the back of the patient’s eye to take advantage of the eye’s natural fluid dynamics. The applicator employs a 25-gauge needle, which allows for a self-sealing wound.[1]

DMO is a primary cause of vision loss associated with diabetic retinopathy. The disease affects the macula, the part of the retina responsible for central vision.

When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition has progressed to DMO. Onset of the condition is painless and may go undetected until it manifests as blurred central vision, or vision loss.

STA Chief Executive Officer, Mr Carlo Montagner, said as the population of people with diabetes increases, it is anticipated the annual incidence of diagnosed DMO will also rise.

He said ILUVIEN was not yet approved for sale in Australia and New Zealand but would be made available to patients via the Special Access Scheme until it is approved by the Therapeutic Goods Administration (TGA) and Medsafe.

“We look forward to ILUVIEN providing benefit to thousands of diabetic patients who suffer vision impairment as a result of type 1 or type 2 diabetes,” Mr Montagner said.

“We will seek regulatory approval from the TGA and Medsafe as well as reimbursement through the PBS to enable wider availability of this important ophthalmic treatment.”

The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) has issued final guidance recommending ILUVIEN as an option for patients with chronic DMO.

President and Chief Executive Officer of Alimera Sciences, Mr Dan Myers, commented: “Not only does STA have a proven track record of successful product launches, STA has also consistently topped the IMS physicians surveys for having the most highly qualified and experienced sales force. We look forward to ILUVIEN making a difference to patients 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 and biotechnology 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, haematology, 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

About Alimera Sciences, Inc.

Alimera Sciences, Inc., based in Atlanta, Georgia, is a biopharmaceutical company that specialises in the research, development and commercialisation of prescription ophthalmic pharmaceuticals. Presently Alimera is focused on diseases affecting the back of the eye, or retina. Its primary product, ILUVIEN, is an intravitreal implant containing fluocinolone acetonide (FAc), a non-proprietary corticosteroid with demonstrated efficacy in the treatment of ocular disease.

About DMO

Diabetic macular oedema (DMO), the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition has progressed to DMO. The onset of DMO is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. As the population of people with diabetes increases, it is anticipated the annual incidence of diagnosed DMO will increase.

About ILUVIEN®

ILUVIEN (190 micrograms of fluocinolone acetonide intravitreal implant in applicator) is a sustained release intravitreal implant used to treat vision impairment associated with chronic DMO considered insufficiently responsive to available therapies. Each ILUVIEN implant provides a therapeutic effect of up to

36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FAc).[1-3] ILUVIEN is injected into the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. The applicator employs a 25-gauge needle, which allows for a self-sealing wound.[1]

In July 2010, Alimera submitted a Marketing Authorization Application (MAA) to seven European countries via the Decentralised Procedure (DCP) with the Medicines and Healthcare products Regulatory Agency of the UK (MHRA) serving as the Reference Member State (RMS). The MAA included data from two Phase 3 pivotal clinical trials (collectively known as the FAME™ Study) for ILUVIEN conducted by Alimera.[4-5] The trials involved 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of ILUVIEN for the treatment of DMO.[4-5] At the end of the DCP, a consensus was reached by the RMS and the other six countries that the MAA for ILUVIEN was approvable. To date, six of the seven countries, Austria, the UK, Portugal, France, Spain and Germany have granted national licenses for ILUVIEN. The national phase in Italy is ongoing. ILUVIEN has not been approved by the United States Food and Drug Administration.

Clinical trial data from the FAME Study showed that in patients with chronic DMO at month 30, after receiving the ILUVIEN implant, 38 percent experienced an improvement from baseline in their best corrected visual acuity on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart of 15 letters or more. At the completion of the 36-month study, 34 percent of patients had achieved the same result. This effect was highly statistically significant ($p < 0.001$) as compared to the sham control group, which received laser and other intravitreally administered therapies.[5]

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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

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

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