ICLUSIG™ to be PBS Listed November 1, 2015

ICLUSIG will be listed for the treatment of the following patients:

- Chronic Myeloid Leukaemia (CML) patients who are resistant or intolerant to both nilotinib and dasatinib
- CML patients who are expressing the T315I mutation after prior TKI therapy
- Philadelphia positive Acute Lymphoblastic Leukaemia (Ph+ ALL) patients who are expressing the T315I mutation after prior therapy with chemotherapy (with or without a TKI)

The Authority Required listing will commence from 1st November. For more information regarding the PBS listing please refer to the PBS website http://www.pbs.gov.au/pbs/home

As a result of the PBS listing the current ICLUSIG Access Program (IAP) will close prior to the effective listing date. Existing PBS eligible patients on the program will transition to PBS reimbursed drug at the listing date. The final date for supply of ICLUSIG to current registered IAP patients will be on Friday 16th October.

A revised IAP will be offered to Australian patients with Ph+ ALL who are not expressing the T315I mutation. Access under this program will be on the basis of a co-payment for the initial four bottles of supply.

For more information regarding the PBS listing or for information on the Access

Program please contact Elwyn Rayson of STA vi email: erayson@specialisedtherapeutics.com.au or call the STA Customer Service Team on 1300 798 820.

TAILORx Trial Finds 99 Percent of Women with Low Oncotype DX Recurrence Score® Results are Free of Breast Cancer Recurrence After Five Years of Hormone Therapy Alone

MELBOURNE, Australia, REDWOOD CITY, Calif, USA and GENEVA, Switzerland, 29 September 2015: Specialised Therapeutics Australia and Genomic Health announce the presentation of the first results[1] from the **T**rial **A**ssigning **I**ndividua**L**ised **O**ptions for Treatment (**Rx**), or **TAILORx**, a large, prospectively conducted trial, designed and conducted by the ECOG-ACRIN Cancer Research Group under the sponsorship of the U.S. National Cancer Institute (NCI).

The study, published online in the *New England Journal of Medicine*, demonstrated that the group of trial participants with early-stage breast cancer and with low Oncotype DX Recurrence Score results of 10 or less, who received

hormonal therapy alone without chemotherapy, had less than a 1% chance of distant recurrence at five years.

The results from 1,626 eligible patients with node-negative, oestrogen receptor-positive (or progesterone receptor-positive, or both), HER2-negative breast cancer who had a Recurrence Score result between 0 and 10 were presented at the 2015 European Cancer Congress (ECC2015). 99.3% of these patients had no distant recurrence at five years after treatment with hormonal therapy alone. These outcomes were consistent irrespective of patient age, tumour size, and tumour grade.

'This is the first prospectively conducted clinical trial evaluating this multi-gene test – or any breast cancer multi-gene test for that matter – in which patients with early stage breast cancer were uniformly treated based on their test results,' said Joseph Sparano, MD, Montefiore Medical Center, Bronx, NY, and ECOG-ACRIN study chair. 'The compelling results seen in this global study provide unequivocal evidence supporting the clinical utility of Oncotype DX to risk-stratify patients with early stage breast cancer.'

The TAILORx trial enrolled 10,273 patients across 1,182 centres in the United States, Canada, Peru, Ireland, Australia and New Zealand. TAILORx used the Oncotype DX test on every patient to quantify individual risk of recurrence in order to assign them to the appropriate treatment. These results are from the patient group with Recurrence Score results from 0-10, who were assigned to receive hormone treatment alone. The data safety monitoring board of the TAILORx trial, as mandated by the study protocol, will continue to monitor outcomes in the primary study group of patients with a Recurrence Score result of 11 to 25 who were randomised to chemo-endocrine therapy or endocrine therapy alone. Previous Oncotype DX studies have already confirmed the benefit of adjuvant chemotherapy for those in the high Recurrence Score range.

Oncotype DX Recurrence Score used to select treatment and optimise outcomes

Complementing the data from TAILORx, Genomic Health announced the presentation of real-world clinical outcomes from a large cohort of patients in the

Clalit registry.[2] Patients were followed up for a median of 5.9 years. Over half of the 930 patients in the analysis had a low Recurrence Score result (0-18) and were treated with hormonal therapy alone, showing very high 5 year breast cancer specific survival rates (99.8%) and low distant recurrence rates (0.5%).

Patients with high Recurrence Score results (greater than 31), most of whom (85%) received chemotherapy, showed 5 year breast cancer specific survival rates of 96% and distant recurrence rates of 4% while for patients in the intermediate Recurrence Score results (18-31) showed a 5 year breast cancer specific survival rate of 98.8% and distant recurrence rate of 2.3%.

'Results from our registry suggest that adding molecular information provided by the Oncotype DX test is essential in order to spare low-risk patients the toxicity and side effects of chemotherapy,' said Prof Salomon Stemmer, Lead investigator of the study, Department of Oncology, Davidoff Center, Rabin Medical Center affiliated to Tel Aviv University, Israel. 'Knowing that Oncotype DX is predictive of chemotherapy benefit gave us confidence to move forward with appropriate, individualised treatment for each patient.'

This study, presented at the 2015 European Cancer Congress (ECC2015), is an analysis of medical records of patients receiving the Oncotype DX breast cancer test in four medical centres within Clalit Health Services, the largest health services organisation in Israel. Researchers will continue to follow patients and will report results and outcomes.

The Oncotype DX breast cancer test is the only genomic test validated for its ability to predict the likelihood of chemotherapy benefit as well as risk of recurrence in early-stage breast cancer.

Healthcare systems across Europe are recognising the value of the test, which is incorporated in all major international clinical guidelines. Most recently, the National Health Service (NHS) in England agreed to an access programme for the Oncotype DX breast cancer test which allows NHS hospitals to implement the National Institute for Health and Care Excellence's (NICE) guidance. NICE recommended the Oncotype DX breast cancer test as the only genomic test validated for its ability to predict the likelihood of chemotherapy benefit as well as risk of recurrence in early stage breast cancer. Other countries that reimburse the test include the USA, Canada, Switzerland, Ireland, Greece and Spain.

Specialised Therapeutics Australia submitted to the Medical Services Advisory Committee (MSAC) of the Department of Health for the Oncotype DX Breast Cancer Assay to be funded in Australia. This will enable equitable access to this important genomic test to Australians with early breast cancer. These new compelling data will be sent to the MSAC to support the submission which is currently under consideration.

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions. The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, supportive care and genomics. 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

About Genomic Health

Genomic Health, Inc. is a world-leading provider of genomic-based diagnostic tests that inform treatment decisions and help to ensure each patient receives appropriate treatment for early stage cancer. The company applies its state-of-the-art scientific and commercial expertise and infrastructure to translate significant amounts of genomic data into clinically actionable results for treatment planning throughout the cancer patient's journey; from screening and surveillance, through diagnosis and treatment selection. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com.

To learn more about Oncotype DX, visit: www.OncotypeDX.com or www.specialisedtherapeutics.com.au/oncotypedx

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the benefits of the test to physicians, patients and payors. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the ability of test results to change treatment decisions; the risks and uncertainties associated with the regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes; the risk that the company may not obtain or maintain sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks of competition; unanticipated costs or delays in research and development efforts; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's quarterly report on Form 10-Q for the year ended June 30, 2015. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

- Study results published today in the New England Journal of Medicine
- Additional clinical outcomes from large patient registry confirm accuracy of Oncotype DX test in guiding treatment decisions

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2. Stemmer S, et al. "First prospective outcome data in 930 patients with more than 5-year median follow up in whom treatment decisions in clinical practice have been made incorporating the 21-Gene Recurrence

Score" (Abstract #1963. The European Cancer Congress 2015. Vienna, Austria)

Specialised Therapeutics' Breakthrough Brain Tumour Visualisation Drug GLIOLAN® Approved for Use in New Zealand

Melbourne, Australia, 17 September 2015: A NOVEL drug which helps neurosurgeons to better visualise and remove malignant brain tumours has been approved for marketing and distribution in New Zealand by Medsafe.

The drug, GLIOLAN (aminolevulinic acid HCl), assists neurosurgeons to better visualise and more completely remove malignant brain tumours (gliomas) by causing them to become fluorescent and glow during surgery.

GLIOLAN is given to the patient as a drink three hours before surgery. During surgery, a neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue to glow fluorescent pink whilst normal brain tissue appears blue. This enables neurosurgeons to better visualise these tumours and more completely remove them, without damaging the neighbouring healthy brain tissue.

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**.[2]

The drug will be made available in New Zealand by Australian based bio-pharmaceutical company Specialised Therapeutics (ST). ST in-licenses the drug from German partner photonamic GmbH and Co. KG. According to New Zealand Ministry of Health 2012 figures, around 260 people in New Zealand are diagnosed with brain cancer each year, with nearly half of these being GBM.[3]

Specialised Therapeutics' Chief Executive Officer Mr Carlo Montagner said regulatory approval by Medsafe is the first step in having GLIOLAN broadly available for New Zealand patients with GBM.

"Our next step is to have this important drug reimbursed and listed on the Pharmaceutical Schedule in New Zealand as soon as possible, to make this high class compound available to all patients with GBM. GLIOLAN is already under consideration for reimbursement as a high priority by PHARMAC, the New Zealand reimbursement authority" he said.

"Using GLIOLAN for complicated brain tumour surgery can lead to substantially improved outcomes for patients, as it improves the chances of the tumour being more completely removed. In Australia, more than 230 patients have had their surgery done using GLIOLAN, where it has been approved since November 2013.

Leading New Zealand neurosurgeon Dr Kelvin Woon described glioblastoma as a very aggressive brain tumour and said it had been proven that maximum (complete macroscopic) resection of the tumour increased the chances of overall survival. "Achieving this in surgery is often difficult, as the brain and tumour look similar," he said. "Trying to find tumour margins is challenging, which can limit maximum resection.

"GLIOLAN has enabled neurosurgeons to find the ill-defined tumour margin, and gives us the confidence to go further to achieve maximum resection. Having Medsafe approval provides New Zealand patients and neurosurgeons with another weapon to treat these very aggressive tumours."

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

The pivotal Phase III study published in The Lancet Oncology Medical Journal reported complete resection of malignant brain tumour tissue in 65% of patients receiving GLIOLAN compared to 36% of patients in the study's control arm (difference between groups 29% [95% CI 17–40], p<0•0001). Six-month progression-free survival was achieved in 41% of patients receiving GLIOLAN compared to 21% of patients who were operated on without the use of the drug (difference between groups 20% [95% CI 9•1–30•7], p=0•0003).[1]

The Chief Executive Officer of photonamic, Mr Ulrich Kosciessa, said that GLIOLAN is already approved for use in 33 countries, including Germany, United Kingdom, Japan, South Korea, and Australia, and the approval in New Zealand is another milestone in the global development of the drug.

"We are delighted that ST has been able to successfully achieve an approval from Medsafe and that GLIOLAN will be available also for GBM patients in New Zealand," he said. "Approximately 60,000 patients globally have already benefited from the use of GLIOLAN in brain tumour resection."

GLIOLAN was first approved in Europe in 2007 and is marketed by medac GmbH in Europe, Africa, South America and Asia (excepting Japan and Korea). The following hospitals in New Zealand have fluorescence-guided surgery capabilities:

1. Wellington Hospital, Wellington
2. Dunedin Hospital, Dunedin
3. Christchurch Hospital, Christchurch
4. Waikato Hospital, Hamilton

The following Australian hospitals currently perform fluorescence-guided surgery using GLIOLAN:

1. Royal Brisbane and Woman's Hospital, Queensland
2. Princess Alexandra Hospital, Queensland
3. Prince of Wales Hospital, New South Wales
4. John Hunter Hospital, New South Wales
5. Wollongong Hospital, New South Wales
6. Calvary Hospital, Tasmania
7. The Royal Melbourne Hospital, Victoria
8. Flinders Medical Centre, South Australia

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.

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

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions. The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, supportive care and genomics. 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

About photonamic GmbH and Co KG

photonamic GmbH and Co KG, a privately held company, was established in 2002

to develop photosensitisers in the field of fluorescence guided diagnostics and photodynamic therapy. photonamic has developed ALA (GLIOLAN) for the fluorescence guided resection of glioblastoma and for the photodynamic therapy of non melanoma skin cancer (NMSC) with a transdermal patch formulation (ALACARE). Both products are approved in Europe and will further be developed for the global market. photonamic is based in Wedel/Hamburg, Germany.

- Medsafe has approved GLIOLAN® for marketing and distribution in New Zealand
- GLIOLAN is under consideration for reimbursement as a “high priority” for use in all New Zealand public hospitals
- Phase III study shows complete resection rates and 6-month progression-free survival is doubled in patients receiving GLIOLAN[1]

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Cutting Edge Breast Cancer Test

‘Should Be Reimbursed’ – Medical Experts

Melbourne, Australia, 3 September 2015: A BREAKTHROUGH genetic test that could spare thousands of Australian women with early stage breast cancer from chemotherapy and its toxic side effects will be considered for reimbursement later this year.

The multi-gene test, known as the Onco*type* DX® Breast Cancer Assay, predicts a patient’s likely benefit from chemotherapy and the overall risk of breast cancer recurrence.

Internationally endorsed and reimbursed in many other countries, the test helps a patient and her doctor make more informed, personalised treatment decisions about whether or not to proceed with chemotherapy.

The test is currently available in Australia but costs patients $4,500. Medical experts are now joining calls for reimbursement so it is accessible to all Australian breast cancer patients.

Leading Australian breast cancer surgeon, Associate Professor Michael Hughes, said that for many patients, chemotherapy did not reduce the chances of cancer recurrence.

“Patients are often placed in the situation where they need to balance the side effects of chemotherapy against any potential benefit,” he said.

“Chemotherapy comes at a cost physically, psychologically, socially and financially. Very occasionally the health side effects can be catastrophic. The usual immediate physical effects of chemotherapy are fatigue, nausea, hair loss, nerve changes and low immunity leading to infections and hospital admissions. In the long term chemotherapy can result in infertility and premature menopause as well as permanent changes in the blood cells. Chemotherapy also means time away from work for the patient and often for their carers as well. There is a significant disruption to family life.

“Genomic DNA profiling of breast cancers in appropriately selected patients

predicts the likely benefit of chemotherapy in reducing the risk of relapse. We have found that many ladies that would normally have had chemotherapy, do not need to have it. If genomic DNA profiling demonstrates that chemotherapy is likely to improve outcomes, then we would advise this course of action.

“Tests like this are likely to be increasingly useful in the future, allowing improved tailoring of treatment based on the biology of the individual’s tumour.”

Recent studies have demonstrated that Onco*type* DX has changed treatment decisions in approximately 50% of women with early-stage ER-positive, HER2-negative breast cancers.

The Onco*type* DX test was developed in the USA by Genomic Health, Inc. Women diagnosed with hormone receptor-positive, HER2-negative breast cancer are advised to have the test soon after surgery and before commencing follow-up treatment. The test is performed on tumour tissue that was already removed during the original surgery.

Results are available within 3 weeks and are reported as a Recurrence Score®, with each patient given a number between 0 and 100 based on their own tumour biology. Women with a low Recurrence Score result have a low risk of their cancer returning and derive little to no benefit from chemotherapy. Women with higher Recurrence Score results have a greater risk of their breast cancer returning and are more likely to benefit from chemotherapy.

Women in many countries including the United States, Canada, England, Ireland, Switzerland, Spain, Israel and Greece can have the test free of charge as it is reimbursed by governments in these regions. In Australia, where the test is not yet reimbursed by the Federal Government, the test costs $4,500.

In countries where the test is funded, studies have demonstrated it is cost effective. In some instances, it has been cost-saving due to reduced use of chemotherapy.

Fewer than 400 Australian women take this test every year, with some doctors reluctant to discuss the technology with patients because of the high cost involved.

The Onco*type* DX Breast Cancer Assay is the only such test recommended for use

in clinical practice by the United Kingdom's National Institute of Health and Care Excellence (NICE) and is recommended in the 5 major international oncology treatment guidelines.

Specialised Therapeutics Australia, a biopharmaceutical company which has been distributing the test in Australia since 2014, made a reimbursement submission to the Medical Services Advisory Committee (MSAC) in June 2015.

A final decision on whether Onco*type* DX will be reimbursed for Australian women will be made at the Medical Services Advisory Committee meeting in Canberra on November 26-27.

STA Chief Executive Officer Mr Carlo Montagner said he looked forward to a positive outcome.

"We would like to see a level playing field," he said. "Women in other parts of the world have affordable access to this important technology that in many cases, changes treatment decisions.

"We want Australian women to have the same affordable, government reimbursed access and avoid unnecessary chemotherapy treatment where possible."

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions. The STA therapeutic portfolio and pipeline at present encompasses oncology, haematology, supportive care and genomics. 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

STA: License Agreement with PharmaMar to Market, Distribute Oncology Drug APLIDIN® (plitidepsin) in AU and NZ

Melbourne, Australia, 20 August 2015: Australian biopharmaceutical company Specialised Therapeutics Australia has struck an exclusive license and commercialisation agreement with European pharmaceutical partner company PharmaMar to market and distribute the novel oncology drug APLIDIN® (plitidepsin) in Australia and New Zealand.

Under the terms of the agreement, PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory and sales milestones achieved by APLIDIN® (plitidepsin).

PharmaMar will retain production rights and will supply the finished product to STA for exclusive commercial use in Australia and New Zealand.

APLIDIN® (plitidepsin) is PharmaMar´s second anticancer drug candidate obtained from a marine organism. This first in class drug is currently in development for the treatment of multiple myeloma and a type of T cell lymphoma. The company announced in June that patient recruitment of the international pivotal Phase III trial (ADMYRE) for APLIDIN® (plitidepsin) in refractory/relapsed multiple myeloma was successfully completed.[1]

Specialised Therapeutics Australia Chief Executive Officer Mr. Carlo Montagner said: “Multiple myeloma remains relatively rare, but it is an insidious disease with one of the lowest survival rates in oncology.

“There is a desperate need for new therapies and all data to date suggests APLIDIN® could become a first in class, novel drug to potentially improve therapeutic tools for multiple myeloma patients.

“This drug is a welcome addition to STA’s expanding oncology portfolio and we look forward to making this treatment option available to patients in Australia and New Zealand, pending the release of pivotal Phase 3 data confirming its efficacy.

“We applaud PharmaMar’s commitment in developing this important therapy and are delighted to collaborate with a partner of this calibre.”

José María Fdez. Sousa-Faro,Chairman of PharmaMar said: “Our commitment to bringing innovative therapies to all patients continues, and this collaboration with a strong pharmaceutical group in Australia and New Zealand is crucial for the role of the anticancer drug plitidepsin in these two important territories.”

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading international pharmaceutical and diagnostic companies to provide patient access to innovative healthcare solutions.

With the highest professional and ethical standards, we commercialise therapies and technologies that uniquely fulfil the unmet medical needs of our community. The STA therapeutic portfolio and pipeline at present encompass oncology, haematology, urology and ophthalmology.

Additional information can be found at www.specialisedtherapeutics.com.au

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of

drug candidates and a robust R&D oncology program. YONDELIS® is the first anticancer drug of marine origin and is commercially available in 81 countries for the treatment of advanced soft tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL®/CAELYX®. PharmaMar develops and commercializes YONDELIS® in Europe and has three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. To learn more about PharmaMar, please visit us at www.pharmamar.com.

About APLIDIN® (plitidepsin)

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including a Phase III study in relapsed or refractory multiple myeloma, a Phase Ib trial in relapsed or refractory multiple myeloma as a triple combination of plitidepsin, bortezomib and dexamethasone, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma. Plitidepsin has received orphan drug designation by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood cancer that accounts for 10% of all hematological malignancies and that is caused by malignant plasma cells that very rapidly multiply.[2] Normal plasma cells are white blood cells found in the bone marrow that form part of the immune system and produce the antibodies necessary to fight infections.[3] Abnormal cells produce a type of

antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly. Almost all patients with multiple myeloma progress from an initial, asymptomatic pre-malignant stage to established disease. In 2015, 26,850 new cases will be diagnosed in the US, and about 11,200 people will die of this disease.[4] In Europe, there will be 4.5–6.0 out of 100,000 people diagnosed per year.[5] In Australia, approximately 1,200 Australians are diagnosed each year.[6]

- APLIDIN® currently in Phase 3 trial for multiple myeloma
- Novel, first in class drug may prolong survival times

Disclaimer

This document is a press release, not a prospectus. This document does not constitute or form part of an offering or invitation to sell or a solicitation to purchase, offer or subscribe shares of the company. Moreover, no reliance should be placed upon this document for any investment decision or contract and it does not constitute a recommendation of any type with regard to the shares of the company.

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TGA Approves AKYNZEO® (netupitant/palonosetron) for the Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV)

Melbourne, Australia, and Lugano, Switzerland, 8 May 2015: Australian biopharmaceutical company Specialised Therapeutics Australia (STA) and Helsinn, a Swiss group focused on building quality cancer care, announce that the Therapeutic Goods Administration (TGA) has approved AKYNZEO® for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy.

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.

Reference:

1. Cortes JE, et al. N Engl J Med. 2013; 369:1783-96.
2. ICLUSIG (ponatinib) Approved Product Information.
3. Leukaemia Foundation, http://www.leukaemia.org.au/blood-cancers/leukaemias/chronic-myeloid-leukaemia-cml.

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

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

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

ABRAXANE was approved by the Therapeutic Goods Administration (TGA) in

March 2014 with the following indication:
ABRAXANE, in combination with gemcitabine, is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas.[2]

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

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

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

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

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

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

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

About MPACT[3]

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

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

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

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

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

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

About ABRAXANE

Developed using the proprietary *nab*™ technology platform, ABRAXANE is a nanoparticle protein-bound chemotherapy agent. ABRAXANE combines paclitaxel with albumin, a naturally-occurring human protein, to deliver paclitaxel to the tumour and therefore eliminates the need for solvents in the administration process.[2] ABRAXANE is approved for the treatment of metastatic breast cancer, advanced non-small cell lung cancer (NSCLC) and metastatic pancreatic cancer.[2] In Australia, ABRAXANE is currently listed on the PBS for the treatment of metastatic breast cancer and HER2 positive breast cancer in combination with trastuzumab, and metastatic pancreatic cancer. ABRAXANE is not PBS listed for the indication of NSCLC.

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

BEFORE PRESCRIBING PLEASE CONSULT THE ABRAXANE PRODUCT INFORMATION AVAILABLE HERE.

About Specialised Therapeutics Australia

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

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

References

1. Cancer in Australia. An Overview 2012. Australian Institute of Health and Welfare (AIHW).
2. ABRAXANE Product Information
3. Von Hoff DD et al. Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine. N Engl J Med 2013; 369(18):1691-703.
4. Goldstein D et al. Oral Abstract # 178. Updated survival from a randomized phase III trial (MPACT) of nab-Paclitaxel plus gemcitabine versus gemcitabine alone for patients (pts) with metastatic adenocarcinoma of the pancreas. ASCO GI 2014.

Channel 7 Adelaide: November

2014

The following story appeared on Channel 7 Adelaide November 2014. Click to view.

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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3. Campochiaro PA et al; FAMOUS Study Group. Aqueous levels of fluocinolone acetonide after administration of fluocinolone acetonide inserts or fluocinolone acetonide implants. Ophthalmology. 2013;120:583-587.
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sustained-delivery fluocinolone acetonide vitreous inserts for diabetic macular edema. Ophthalmology 2011; 118: 626–635.
5. Campochiaro PA et al; FAME Study Group. Sustained delivery fluocinolone acetonide vitreous inserts provide benefit for at least 3 years in patients with diabetic macular edema. Ophthalmology 2012. 119: 2125-32.