Study Finds ABRAXANE Combination Chemotherapy is Superior to Other Chemotherapy Combinations in Women with Metastatic Triple Negative Breast Cancer

Melbourne, Australia and Singapore, 23 December 2016: An international study has found that women with metastatic triple-negative breast cancer (mTNBC) demonstrated improved progression-free survival when treated with a combination of ABRAXANE (nanoparticle albumin-bound paclitaxel) and carboplatin, compared to other chemotherapy combinations.

Aeterna Zentaris and Specialised Therapeutics Asia Sign Exclusive License Agreement for the Potential Marketing of Zoptrex™ in Australia and New Zealand

Charleston, South Carolina and Singapore, October 12, 2016: Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the "Company") and Specialised Therapeutics Asia ("STA") today announced the signing of an exclusive license

agreement for the Company's lead investigational anti-cancer compound, Zoptrex™ (zoptarelin doxorubicin), for the territories of Australia and New Zealand (the "Territory"). Zoptrex™, a novel synthetic peptide carrier linked to doxorubicin, is currently undergoing a fully-enrolled Phase 3 clinical trial to evaluate the compound in endometrial cancer. The Company expects to complete the Phase 3 clinical trial in 2016 and, if the results of the trial warrant doing so, to submit a new drug application for Zoptrex™ to the United States Food and Drug Administration (FDA) in the first half of 2017. Zoptrex™ is the Company's proposed tradename for zoptarelin doxorubicin. The proposed tradename is subject to approval by the FDA.

Under the terms of the License Agreement, Aeterna Zentaris will be entitled to receive a non refundable upfront payment in consideration for the license to STA of the Company's intellectual property related to Zoptrex™ and the grant to STA of the right to commercialize Zoptrex™ in the Territory. STA has also agreed to make additional payments to the Company upon achieving certain pre-established regulatory and commercial milestones, as well as double-digit royalties on future net sales of Zoptrex™ in the Territory. STA will be responsible for the development, registration, reimbursement and commercialization of the product in the Territory. The Company and STA have also entered into a supply agreement, pursuant to which the Company will supply Zoptrex™ to STA for the duration of the license agreement.

David Dodd, President and CEO of the Company, stated, "I am very pleased that we have now concluded four agreements for the commercial rights to Zoptrex™, if approved, outside the United States. We believe that the interest in Zoptrex expressed by our licensees supports our view that Zoptrex™, if it is approved by the FDA for its initial indication, could be an important treatment option for women with the most severe form of endometrial cancer. We are particularly pleased to have a company of the caliber of STA as a licensee. STA enjoys the highest reputation in its markets and, with its existing portfolio of oncology products, it has the capability to position Zoptrex™ very well in the market."

STA Chief Executive Officer Mr. Carlo Montagner said Zoptrex™ had demonstrated great potential and was poised to add further value to the company's expanding oncology portfolio. "All results to date suggest Zoptrex™ is a potent new compound and we look forward to collaborating closely with Aeterna Zentaris to maximise its full potential in our key markets," he said.

About Zoptrex™

Zoptrex™ (zoptarelin doxorubicin) is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is (D)-Lys6-LHRH, a modified natural hormone believed to have a strong affinity for the LHRH receptor. The design of the compound allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors. Potential benefits of this targeted approach include enhanced efficacy and a more favorable safety profile with lower incidence and severity of side effects as compared to doxorubicin.

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd ("STA") is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand. The company is a close affiliate of Specialised Therapeutics Australia, which also collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases. STA is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.specialisedtherapeutics.com.au.

About Aeterna Zentaris Inc.

Aeterna Zentaris is a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in oncology, endocrinology and women's health. We are engaged in drug development activities and in the promotion of products for others. We are now conducting Phase 3 studies of two internally developed compounds. The focus of our business development efforts is the

acquisition or license of products that are relevant to our therapeutic areas of focus. We also intend to license out certain commercial rights of internally developed products to licensees in territories where such out-licensing would enable us to ensure development, registration and launch of our product candidates. Our goal is to become a growth-oriented specialty biopharmaceutical company by pursuing successful development and commercialization of our product portfolio, achieving successful commercial presence and growth, while consistently delivering value to our shareholders, employees and the medical providers and patients who will benefit from our products. For more information, visit www.aezsinc.com.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the US Securities Litigation Reform Act of 1995. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words “expects,” “believes,” “intends,” “anticipates,” and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known and unknown risks and uncertainties that could cause the Company’s actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue R&D projects and clinical trials, the successful and timely completion of clinical studies, the risk that safety and efficacy data from any of our Phase 3 trials may not coincide with the data analyses from previously reported Phase 1 and/or Phase 2 clinical trials, the rejection or non-acceptance of any new drug application by one or more regulatory authorities and, more generally, uncertainties related to the regulatory process, the ability of the Company to efficiently commercialize one or more of its products or product candidates, the degree of market acceptance once our products are approved for commercialization, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, the ability to protect our intellectual property, the potential of liability arising from shareholder lawsuits and general changes in economic conditions. Investors should consult the Company’s quarterly and annual filings with the Canadian and US securities commissions for

additional information on risks and uncertainties relating to forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake to update these forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except if required to do so.

Specialised Therapeutics Strikes Deal with World Courier Australia to Manage Logistics for Specialty Pharma Products

Melbourne, Australia 16 June 2016: International biopharmaceutical company Specialised Therapeutics Australia has struck an important agreement with global logistics partner World Courier Australia (WCA) to manage and handle its growing portfolio of specialist healthcare products around the country.

Novel Multiple Myeloma Drug APLIDIN® Shows Positive Results

in Pivotal Phase 3 Study

Singapore, Madrid and Melbourne, Australia, 31 March 2016: International biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST Asia) will seek regulatory approvals for novel multiple myeloma drug Aplidin® (plitidepsin) following the release of positive results in a pivotal Phase 3 study.

Specialized Therapeutics Grants Sublicense for Anti-Emetic Products to Mundipharma for Australia and New Zealand Anti-emetic Products Covered Under the Sublicense Agreement Include ALOXI® (palonosetron hydrochloride) and AKYNZEO® (netupitant/palonosetron).

Melbourne, Australia, 7 March 2016: Specialized Therapeutics Pty Ltd and Mundipharma Pty Limited today announce a sublicense agreement enabling Mundipharma to assume all commercialisation responsibilities for the anti-emetic products ALOXI® (palonosetron hydrochloride) and AKYNZEO® (netupitant/palonesetron).

Under the terms of the arrangement, Specialized Therapeutics grants

Mundipharma exclusive marketing, promotion, distribution and sales rights for the anti-nausea and vomiting pharmaceutical products ALOXI® and AKYNZEO® in Australia and New Zealand markets.

ALOXI® is indicated for the prevention of acute nausea and vomiting associated with chemotherapy[1] and has been commercially available in Australia since 2010 under license from Helsinn Healthcare SA, a Swiss pharmaceutical company which has consented to the sublicense agreement.

AKYNZEO® is the first fixed combination oral agent targeting two critical signalling pathways associated with chemotherapy induced nausea and vomiting (CINV) by combining netupitant, an NK1 receptor antagonist, and palonosetron, a 5-HT_3 receptor antagonist, in a single capsule.[2]

AKYNZEO® is also supplied by Helsinn, and was approved by Australia's Therapeutic Goods Administration in May 2015. A submission for reimbursement on the Pharmaceutical Benefits Scheme (PBS) was submitted in 2015 and is nearing completion.

About ALOXI® (palonosetron hydrochloride)

ALOXI® (palonosetron hydrochloride) is a second generation 5-HT_3 receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours. ALOXI® has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi®, Onicit® and Paloxi® in more than 50 countries worldwide. In Australia, Aloxi® is PBS listed for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.[3]

For more information about ALOXI®, please visit the website: www.aloxi.com

About AKYNZEO® (netupitant/palonosetron)

AKYNZEO® is an oral, fixed combination of an NK1 receptor antagonist, netupitant, and a 5-HT_3 receptor antagonist, palonosetron, in a single capsule, that targets two critical signalling pathways associated with chemotherapy-induced nausea and vomiting (CINV).[2]

AKYNZEO® was approved by the US Food and Drug Administration (FDA) in October 2014 and by the European Commission in May 2015. In Australia, AKYNZEO® was approved by the Therapeutic Goods Administration in May 2015. It is indicated in adult patients for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy and for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.[2] An application to New Zealand's regulatory authority MEDSAFE has been submitted and is under review. Additional regulatory submissions for netupitant/palonosetron fixed combination are underway worldwide.

About Specialized Therapeutics Pty Ltd

Specialized Therapeutics Pty Ltd, a wholly owned subsidiary of Specialised Therapeutics Australia Pty Ltd, is a biopharmaceutical company dedicated to working with leading international pharmaceutical companies to provide patient access to innovative healthcare solutions.

For more information, please visit www.specialisedtherapeutics.com.au.

About the Helsinn Group

Helsinn is a privately owned cancer supportive care pharmaceutical group with an extensive portfolio of marketed products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by

core family values of respect, integrity and quality, through a unique integrated licensing business model working with long standing partners in pharmaceuticals, medical devices and nutritional supplement products. Helsinn is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US (Helsinn Therapeutics), a representative office in China, as well as a product presence in about 90 countries globally.

For more information, please visit www.helsinn.com.

About Mundipharma

Mundipharma's global network of companies are privately owned entities covering the world's pharmaceutical markets. Mundipharma provides patients across 6 continents with a growing portfolio of 19 products in 5 therapeutic areas, which include moderate-to-severe pain, consumer healthcare, oncology, respiratory disease, rheumatoid arthritis, antiseptics and laxatives. Mundipharma is a prime example of a company that consistently delivers high quality products while standing by the values that represent the company. Our mission is to alleviate the suffering of patients and to substantially improve their quality of life.

For more information, please visit: www.mundipharma.com.au

References

1. ALOXI® Approved Product Information available at: http://www.specialisedtherapeutics.com.au/assets/files/d-aloxi_pi.pdf
2. AKYNZEO® Approved Product Information available at: http://www.specialisedtherapeutics.com.au/assets/files/d-akynzeo_pi.pdf
3. The Pharmaceutical Benefits Scheme available at:http://www.pbs.gov.au/pbs/home, Accessed March 2016.

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

References

1. Sparano JA, et al. "Prospective Validation of a 21-Gene Expression Assay in Breast Cancer" New Engl J Med 2015. This article was published on September 28, 2015, at NEJM.org
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]

References

1. Stummer W, Pichlmeier U, Meinel T, et al., Fluorescence-guided surgery with 5-aminovulinec acid for resection of malignant glioma: a randomised controlled multicentre phase III trial, Lancet Oncol, 2006;7:392-401
2. GLIOLAN Product Information
3. New Zealand Ministry of Health 2012. Cancer: New registrations and deaths 2009.

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

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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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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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