

New Early-Breast Cancer Drug to be Made Available in Australia, New Zealand and South East Asia following License Deal

Singapore, 23 November 2017:

A NEW breast cancer drug shown to reduce the risk of cancer recurrence will soon be made available in Australia, New Zealand and throughout South-East Asia, following a key license deal between Specialised Therapeutics Asia (ST Asia) and US biopharmaceutical company Puma Biotechnology, Inc. (NASDAQ: PBYI).

Under the terms of the exclusive arrangement, Specialised Therapeutics will market the drug NERLYNX[®] (neratinib) throughout the Asia-Pacific, beginning with Australia, Singapore, Malaysia and Brunei. It will be available to women with early-stage, HER2+ breast cancer following standard of care adjuvant chemotherapy and 12 months of trastuzumab-based therapy.

Commercial terms of the agreement are not being disclosed, but Puma will receive an upfront payment as well as milestones and other payments on NERLYNX sales in all ST Asia regions.

NERLYNX is the first treatment to be FDA approved for extended adjuvant therapy in early-stage HER2+ breast cancer following adjuvant trastuzumab-based therapy.

Results from a double blind, placebo-controlled, randomised Phase 3 study showed that NERLYNX reduces the risk of invasive disease recurrence or death by 27% compared to placebo after a median follow up of 5.2 years. The 5-year invasive disease-free survival (iDFS) rate for the NERLYNX arm was 90.2% compared to 87.7% in the placebo arm ($p=0.008$).¹

For the pre-defined subgroup of patients with hormone receptor positive disease, approximately 57% of the overall study population, the results of the trial demonstrated that at 5 years, treatment with neratinib resulted in a 40%

reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.60, $p = 0.002$).³ In this sub-group, the 5-year iDFS rate for the neratinib arm was 91.2% compared to 86.8% in the placebo arm.¹

The safety results showed the most frequently observed adverse event for the NERLYNX-treated patients was diarrhoea, with approximately 40% of the NERLYNX-treated patients experiencing grade 3 or higher diarrhoea (1 patient (<1%) had grade 4 diarrhoea). Patients who received NERLYNX in this trial did not receive any prophylaxis with anti-diarrhoeal agents.^{1,2}

Principal trial investigator, Professor Arlene Chan, said the availability of NERLYNX in Australia and other regions was an important step forward in further reducing recurrence in HER2+ early breast cancer.

“This is a drug that provides a potential cure for some women who may otherwise have had a recurrence,” she said.

“Despite the clear proven benefit of standard of care chemotherapy and trastuzumab therapy, one in four women diagnosed with early-stage HER2+ breast cancer can still have a relapse within five years.

“This drug will now prevent some of those women from experiencing that recurrence.

“My hope and expectation is that with longer follow up, not only will recurrence rates be reduced, but they will show that the use of NERLYNX will improve overall survival.”

Specialised Therapeutics Chief Executive Officer Carlo Montagner said NERLYNX was a valuable inclusion to the company’s expanding oncology portfolio.

“We are thrilled to be able to provide this therapy to women in our regions, working in collaboration with our new international partner, Puma Biotechnology,” he said.

“We plan to expedite access to this important medicine, with a Special Access Program to open in Australia in Q1 2018. This will provide early subsidised access for appropriate patients. In tandem, we will file for TGA registration and seek regulatory approval to market in other regions, including Singapore, Brunei,

Malaysia and New Zealand.”

President and CEO of Puma Biotechnology Alan H. Auerbach said this license agreement demonstrates the commitment to bringing NERLYNX to patients around the world.

“We are confident this new partnership with ST Asia will ensure all appropriate patients in the region can access this new medicine at the earliest opportunity,” he said.

NERLYNX is an oral medication taken after chemotherapy and after 12 months of treatment with a trastuzumab-based therapy, which is the global standard of care.

About NERLYNX⁴

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4.

NERLYNX is the first HER2-targeted medication approved by the US Food and Drug Administration (FDA) as extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer, for patients who have previously been treated with the medicine trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).

Extended adjuvant therapy is the next step of treatment that follows adjuvant therapy (treatment after surgery) to further reduce the risk of breast cancer returning.

NERLYNX is an oral tablet and works by binding to multiple receptors inside the cancer cell, blocking signals that tell cancer cells to grow and multiply.

About HER2+ Breast Cancer

Approximately 20% to 25% of breast cancer tumours over-express the HER2 protein. HER2+ breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early-stage HER2-positive breast cancer returning after surgery, up to 24% of patients treated with trastuzumab experience recurrence.¹

About the ExteNET Study^{1, 2}

The ExteNET trial was a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in patients with early-stage HER2-positive breast cancer.

The ExteNET trial randomized 2,840 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomised to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of five years after randomisation in the trial.

The primary endpoint of the trial was invasive disease free survival (iDFS). The trial demonstrated that after a median follow up of 5.2 years, treatment with neratinib resulted in a 27% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.73, $p = 0.008$). The 5-year iDFS rate for the neratinib arm was 90.2% and the 5-year iDFS rate for the placebo arm was 87.7%.

A secondary endpoint of the trial was invasive disease free survival including ductal carcinoma in situ (iDFS-DCIS). The trial demonstrated that treatment with neratinib resulted in a 29% reduction of risk of disease recurrence including DCIS or death versus placebo (hazard ratio = 0.71, $p = 0.004$). The 5-year iDFS-DCIS rate for the neratinib arm was 89.7% and the 5-year iDFS-DCIS rate for the placebo arm was 86.8%.

For the pre-defined subgroup of patients with hormone receptor positive disease,

approximately 57% of the overall study population, the trial demonstrated that at 5 years, treatment with neratinib resulted in a 40% reduction of risk of invasive disease recurrence or death versus placebo. In this sub-group, the 5-year iDFS rate for the neratinib arm was 91.2% compared to 86.8% in the placebo arm (hazard ratio = 0.60, $p = 0.002$).³

The safety results showed the most frequently observed adverse event for the neratinib-treated patients was diarrhoea, with approximately 40% of the neratinib-treated patients experiencing grade 3 or higher diarrhoea (1 patient (<1%) had grade 4 diarrhoea).

Puma is conducting the Phase 2 CONTROL study investigating a structured prophylactic regimen of loperamide for the first 1-2 cycles of neratinib therapy. Emerging data suggest that loperamide prophylaxis reduces the incidence, severity and duration of neratinib-associated diarrhoea as compared with events observed in ExteNET.

About Puma Biotechnology, Inc.

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialisation of innovative products to enhance cancer care. The Company in-licenses the global development and commercialisation rights to three drug candidates — PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. NERLYNX is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX.

Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST Asia) 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.

ST Asia and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases. ST Asia is committed to making new and novel therapies available to patients around the world, targeting diseases where there remains an unmet medical need. STA's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stabiopharma.com

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New Early-Breast Cancer Drug to be Made Available in Australia, New Zealand and South East Asia following License Deal

- Specialised Therapeutics Asia to make NERLYNX[®] (neratinib) available in Australia, New Zealand and South-East Asia for women with early-stage, HER2+ breast cancer following exclusive license agreement
- Five-year follow up data shows NERLYNX reduces risk of invasive disease recurrence by 27% in women with early-stage, HER2+ breast cancer

- Special Access Program to open in Australia Q1 2018 followed by other countries in the territory

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3. Martin M. et. Al. ESMO 2017. Oral Presentation #1490.
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Specialised Therapeutics Asia to License a Promising Anti-Cancer Compound Lurbinectedin (PM1183) for South East Asia, Australia and New Zealand

SINGAPORE and MELBOURNE, Australia, May 17, 2017: International biopharmaceutical company Specialised Therapeutics Asia (ST Asia) is set to commercialise a promising new anti-cancer drug throughout South East Asia, after signing a second major licensing deal with European pharmaceutical company PharmaMar.

The latest agreement allows ST Asia marketing and distribution rights to new anti-cancer compound lurbinectedin (PM1183) in Australia, New Zealand and

throughout SE Asia.

This promising agent is currently in final stage (Phase 3) trials as a potential new therapy for various solid tumours, including platinum-resistant ovarian cancer and small cell lung cancer. In addition, it is in a Phase 2 trial for metastatic breast cancer with BRCA1 and BRCA2 mutations.

Commercial terms of the new license agreement are not being disclosed by ST Asia, but PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory and sales milestones achieved in these new markets.

An ST Asia affiliate company will also make an equity investment in PharmaMar.

PharmaMar will also retain development and production rights for lurbinectedin (PM1183), and pending completion of all regulatory processes, will supply the finished product to ST Asia for exclusive commercial use in all agreed regions.

ST Asia Chief Executive Officer Mr Carlo Montagner said this new licensing deal cemented the company's existing strong relationship with PharmaMar and demonstrated high confidence in the partner company's development pipeline.

"We have the highest regard for PharmaMar and are pleased to partner once again, pursuing development of this highly promising oncology compound," he said.

"We eagerly await data from these final stage studies and look forward to making new therapies like this available to patients throughout our regions who are affected by difficult to treat cancers."

Lurbinectedin (PM1183) is the third marine-derived organism in development by PharmaMar.

Data from the Phase 3 study of lurbinectedin (PM1183) in resistant ovarian cancer (CORAIL) is expected to be available later this year, following the completion of patient recruitment in October 2016.

A Phase 3 trial in small cell lung cancer (ATLANTIS) was initiated in August 2016.

PharmaMar Chairman José María Fernandez Sousa-Faro said: "We are proud to

enter into a new agreement with ST Asia, enabling us to reach new populations of cancer patients who may benefit from our novel therapies.

“We remain committed to advancing the development of innovative therapies that may benefit society.”

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd (ST Asia) 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 (STA), 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. ST Asia is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, haematology, urology and ophthalmology. Additional information can be found at www.STAbiopharma.com

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercialises YONDELIS® in Europe and has three other clinical stage programs under development for several types of solid and haematological cancers PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland United Kingdom, Belgium and the United States. PharmaMar fully owns three other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

About lurbinectedin (PM1183)

PM1183 is a compound under clinical investigation. It is an inhibitor of RNA polymerase II. This enzyme is essential for the transcription process that is over-activated in tumours with transcription addiction. The antitumour efficacy of lurbinectedin is being investigated in various types of solid tumours.

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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 Asia to Distribute Novel Multiple Myeloma Drug APLIDIN® in South East Asia, Australia and New Zealand

SINGAPORE and MELBOURNE, Australia, Feb. 2, 2016 /PRNewswire/ — International biopharmaceutical company Specialised Therapeutics Asia (ST Asia) will supply and

distribute a novel oncology drug candidate throughout South East Asia, following an exclusive licensing deal with European pharmaceutical company PharmaMar.

Under the terms of the latest agreement, ST Asia will be allowed marketing and distribution rights to new multiple myeloma compound APLIDIN® (plitidepsin) in key regions including Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Papua New Guinea, Philippines, Singapore, Timor-Leste, Thailand, and Vietnam, as well as in Australia and New Zealand.

APLIDIN is a first in class drug currently in development for the treatment of multiple myeloma and a type of T cell lymphoma.

Commercial terms of the agreement are not being disclosed, but PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory and sales milestones achieved by APLIDIN in these new markets.

PharmaMar will retain production rights and will supply the finished product to ST Asia for exclusive commercial use in all agreed regions.

APLIDIN is PharmaMar's second anti-cancer drug candidate obtained from a marine organism. The company announced in June 2015 that patient recruitment of the international pivotal Phase 3 trial (ADMYRE) for APLIDIN in refractory/relapsed multiple myeloma was successfully completed.¹ Data from this study is expected to be reported later this year.

Specialised Therapeutics Asia Chief Executive Officer Mr Carlo Montagner said the APLIDIN licensing deal was an important step forward as the company expanded operations to include key territories in South East Asia.

"We look forward to working with PharmaMar to ensure this valuable multiple myeloma therapy is available as soon as possible to patients in key South East Asia regions, as well as in Australia and New Zealand," he said.

"APLIDIN may be highly valuable as a new therapeutic for this difficult to treat cancer. While multiple myeloma remains relatively rare, it is an insidious disease with one of the lowest survival rates in oncology. ST Asia has been established to provide new therapeutics like this one to patients where there is a high unmet need."

“APLIDIN is the first step. We look forward to changing the lives of patients affected by a range of diseases – not only in oncology – in these new and important markets.”

PharmaMar Chairman José María Fernandez Sousa-Faro said: “We are proud to enter into agreements with laboratories such as STA that enable us to ensure that all patients who need plitidepsin can avail themselves of it. We are firmly committed to advancing in the development of innovative therapies that benefit society.”

The total population of South East Asian regions including Australia and New Zealand is put at 650 million, with an estimated 300,000 people living with multiple myeloma overall and between 30,000 and 40,000 new cases of the disease diagnosed annually.

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd (ST Asia) 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 (STA), 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. ST Asia 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 PharmaMar

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YONDELIS® in Europe and has three other 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. PharmaMar fully owns three other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova and Xylazel. 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

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.

- APLIDIN® is a novel drug to treat multiple myeloma, which has one of the lowest survival rates in oncology
- First major license deal for Specialised Therapeutics Asia – international biopharmaceutical company supplying novel oncology drug candidates to key SE Asia regions, as well as Australia and New Zealand
- Specialised Therapeutics Asia is new partner company of Specialised Therapeutics Australia

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myeloma

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SOURCE Specialised Therapeutics Asia

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

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

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

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

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

“Iclusig is as an important cancer medicine for patients with difficult-to-treat CML or Ph+ ALL who have few options available to them,” said Carlo Montagner, chief executive officer at STA. “We look forward to a successful collaboration with ARIAD providing refractory CML patients in Australia with a new highly effective treatment option.”

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

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

About Iclusig® (ponatinib)

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

About Specialised Therapeutics Australia

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

About ARIAD

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

This press release contains “forward-looking statements” which are based on management’s good-faith expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to the Company’s ability to manufacture, and supply STA with Iclusig; the ability of STA to perform the contracted services, such as obtaining marketing authorization and pricing and reimbursement approval for Iclusig in Australia; STA’s ability to distribute, promote, market and sell Iclusig in Australia; the timing and scope of the marketing authorizations, as well as the level of pricing obtained in Australia; the availability of Iclusig to patients under a Special Access Program in Australia; third-party reimbursement; and the timing and success of

sales of Iclusig in Australia. These factors, risks and uncertainties also include, but are not limited to: the costs associated with ARIAD's development and manufacturing, commercial and other activities; the adequacy of capital resources and the availability of additional funding; and other factors detailed in the Company's public filings with the U.S. Securities and Exchange Commission. The information contained in this press release is believed to be current as of the date of original issue. After the date of this document, the Company does not intend to update any of the forward-looking statements to conform to actual results or to changes in the Company's expectations, except as required by law.

Contacts

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

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

Health, Inc. (NASDAQ: GHDX).

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

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

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

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

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

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

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

Developed by US based Genomic Health, *Oncotype DX* has been evaluated in 15 clinical studies in more than 6,000 patients. These studies include a large validation study published in the *New England Journal of Medicine* and a study

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

The *Oncotype DX* Breast Cancer Test is appropriate for recently diagnosed women with Stage I or II node-negative, oestrogen-receptor-positive, HER2 negative, invasive breast cancer; and postmenopausal women with node-positive, hormone-receptor-positive, HER2 negative, invasive breast cancer. The *Oncotype DX* results are provided in the form of a Recurrence Score[®], a number between 0 and 100, which correlates to a specific likelihood of breast cancer recurrence within 10 years of initial diagnosis and the likely benefit of chemotherapy.

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

The National Comprehensive Cancer Network (NCCN)³, the American Society of Clinical Oncology (ASCO)⁴, St Gallen⁵, and the European Society for Medical Oncology (ESMO)⁶ have all incorporated the *Oncotype DX* test into their guidelines. In the UK, the National Institute for Health and Care Excellence (NICE) has recommended *Oncotype DX* as the only multi-gene breast cancer test for use in clinical practice to guide chemotherapy treatment decisions for patients with early-stage, hormone-receptor-positive, invasive breast cancer.⁷

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

This commercial arrangement between STA and Genomic Health commenced on

1st January 2014.

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

About Specialised Therapeutics Australia

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

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

References:

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

Contacts

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

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

pharmaceutical company Helsinn Healthcare to in-license the novel ghrelin receptor agonist anamorelin for both Australia and New Zealand.

Specialised Therapeutics Australia Extends Collaboration with Swiss Helsinn Group

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

The Australian company has signed a letter of intent with its Swiss partner, Helsinn Group, to in-license Helsinn's new compound for the prevention of chemotherapy induced nausea and vomiting. The arrangement covers the development of a fixed-dose combination product (in both oral and intravenous forms) containing netupitant, a neurokinin-1 (NK₁) receptor antagonist, and Aloxi® (palonosetron), a serotonin-3 (5-HT₃) receptor antagonist.

This further collaboration follows the successful Australian launch in November last year of the second generation 5-HT₃ antagonist, Aloxi®, which is listed on the Pharmaceutical Benefits Scheme (PBS).

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

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

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

STA chief executive officer Mr Carlo Montagner said his company would pay an upfront payment to Helsinn, as well as milestone and royalty payments.

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

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

Ends.

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

About Netupitant

Netupitant is a highly selective NK₁ receptor antagonist, an antiemetic that works by blocking the action of Substance P, an endogenous neurotransmitter contained in high concentrations in the vomiting centre of the brainstem that can stimulate the vomiting reflex. The fixed-dose combination of netupitant and palonosetron has entered Phase III for the prevention of acute and delayed nausea and vomiting following both highly and moderately emetogenic chemotherapy.

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

Aloxi® (palonosetron hydrochloride) is a second generation 5-HT₃ receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting in cancer patients. Aloxi® has a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. In

clinical trials and clinical practice, Aloxi® demonstrates unique long-lasting action in the prevention of CINV. A single intravenous dose of Aloxi® provides better protection from CINV than first-generation 5-HT₃ receptor antagonists.

Aloxi® is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions (incidence ≥ 2 percent) in trials with Aloxi® were headache (9 percent) and constipation (5 percent), and they were similar to the comparators. Palonosetron has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi®, Onicit®, and Paloxi® in more than 50 countries world-wide. Aloxi® is the leading brand in the USA and in Japan within the CINV Day of Chemo segment, and it is steadily growing in the European markets. For more information about palonosetron, please visit the website: www.aloxi.com

About Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and operating subsidiaries in Ireland and USA. Helsinn's business model is focused on the licensing of pharmaceuticals and medical devices in therapeutic niche areas. The Group in-licenses early to late stage new chemical entities, completes their development from the performance of pre-clinical/clinical studies and Chemistry, Manufacturing and Control (CMC), development to the filing for and attainment of their market approval worldwide. Helsinn's products are out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how, and assisted and supported with a full range of product and scientific management services, including commercial, regulatory, financial, legal and medical marketing advice. The active pharmaceutical ingredients and the finished dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers. For more information about Helsinn Group, please visit the website: www.helsinn.com

About Specialised Therapeutics Australia, Pty Ltd

Specialised Therapeutics Australia Pty Ltd (STA) was established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Australasian market. Currently STA markets two world leading cancer and cancer supportive care therapies, ABRAXANE® (nab paclitaxel) and ALOXI®

(palonosetron) respectively, and has recently licensed GLIOLAN®(5-aminolevulinic acid, 5-ALA) for intraoperative visulisation of malignant glioma. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.