New Drug for Diabetes-Induced Vision Loss TGA-Approved for Australian patients

Melbourne, Australia and Atlanta, Georgia, 5 August 2019: Australian patients with diabetes-induced eye disease can now access a new treatment option that provides consistent and continuous treatment with long-lasting effect.

The Therapeutic Goods Administration has now approved the drug ILUVIEN® (fluocinolone acetonide intravitreal implant), which delivers fluocinolone acetonide via a sustained release implant and provides therapeutic effect for up to 36 months.

It is available to people who have vision impairment associated with chronic diabetic macular oedema (DME), and who have been previously treated with a course of corticosteroids and who have not experienced a clinically significant rise in intra-ocular pressure (IOP).

ILUVIEN will be supplied throughout Australia by independent biopharmaceutical company Specialised Therapeutics (ST), under exclusive license from US-based Alimera Sciences, Inc (NASDAQ: ALIM).

ST Chief Executive Officer Mr Carlo Montagner said ILUVIEN was the company's first ophthalmology candidate in an expanding therapeutic portfolio.

"We are delighted to make this important new therapy available to Australian patients affected by DME, after successfully navigating what has been a complex regulatory process," he said. "Our commercial teams will now work to ensure that all appropriate patients can access this therapy at the earliest opportunity."

DME is a primary cause of vision loss associated with diabetic retinopathy. The disease affects the macula, which is the part of the retina responsible for central vision. Diabetic retinopathy causes swelling in the macula due to blood vessel leakage, which leads to DME. Onset of the condition is painless and may go undetected until it manifests as blurred central vision, or vision loss.

Alimera President and CEO Rick Eiswirth said ILUVIEN was the only treatment providing CONTINUOUS MICRODOSING™ technology, and has demonstrated the ability to reduce oedema in the retina for up to 36 months with one intra-ocular injection, thereby enabling patients to maintain vision longer with fewer injections.

“We are thrilled that ILUVIEN can now be accessed by Australian patients, following on from its approval in other key healthcare markets, including the United States, Europe and Canada,” he said.

STA will seek to have ILUVIEN reimbursed via the Pharmaceutical Benefits Scheme.

Ends.

About Specialised Therapeutics Asia

Specialised Therapeutics is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout Australia as well as in New Zealand and South East Asia.

ST 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. Its mission is to provide therapies where there is an unmet need. The company’s broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stbiopharma.com.

About ILUVIEN

ILUVIEN (fluocinolone acetonide intravitreal implant) delivers 0.19 mg fluocinolone acetonide via a sustained release intravitreal implant indicated to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Each ILUVIEN implant with its continuous

microdosing delivery is designed to release submicrogram levels of fluocinolone acetonide, a corticosteroid, for 36 months, enabling the physician to treat this persistent disease consistently every day. ILUVIEN is contraindicated in the presence of pre-existing glaucoma or active or suspected ocular or periocular infection. The most frequently reported adverse drug reactions included cataract operation, cataract and increased intraocular pressure. www.ILUVIEN.com

About Diabetic Macular Oedema (DME)

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. Diabetic retinopathy causes swelling in the macula due to blood vessel leakage, which leads to DME. The onset of DME is painless and may go unreported by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision.

About Alimera Sciences, Inc.

Alimera, founded in June 2003, is a pharmaceutical company that specializes in the commercialization and development of prescription ophthalmic pharmaceuticals. Alimera is presently focused on diseases affecting the back of the eye, or retina, because these diseases are not well treated with current therapies and will affect millions of people in our aging populations. For more information, please visit www.alimerasciences.com.

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Specialised Therapeutics Asia Unveils 'Track and Trace' Pharma Model to Boost Drug Security, Improve Patient Safety

Singapore, 17 May 2019: Independent pharmaceutical company Specialised Therapeutics Asia (STA) is launching an innovative tracking system that will enable real time monitoring of every unit of drug product provided through its supply chain – from packing to patient.

The company, which markets specialist medicines to patients in Australia, New Zealand and across South East Asia, has adopted a model called the Unique Product Identification (UPI) system, that will see a unique 2D barcode printed on every drug product packaged and distributed by the company.

Current batches of two new products supplied by STA – NERLYNX® (neratinib) for breast cancer and APLIDIN® (plitidepsin) for multiple myeloma – are the first to be coded using this sophisticated technology. The UPI system is expected to be rolled out across the company's entire portfolio by 2020.

STA is an early pharmaceutical adopter of this tracking model in this region, which is mandated in both the United States and Europe. It is designed to improve product integrity by minimising or eliminating dispensing errors, as well as eliminate the potential for counterfeit products to enter the legitimate pharmaceutical supply chain.

Chief Executive Officer Mr Carlo Montagner said the company's UPI technology was "predominantly about ensuring international best practice is employed in terms of drug security and patient safety".

"Track and trace technologies enable us and our partners to ensure safe drug

distribution chains, and to implement any product recalls as rapidly as possible," Mr Montagner said.

"In the event of an urgent product recall, we can now quickly and effectively track every unit of product to ensure patient safety remains paramount."

Mr Montagner said it was common practice for pharmacy compounders to package intravenous cancer drugs for individual patients from multiple supply batches in order to minimise wastage.

"Without tracking technology, there has been poor visibility on the final destination of all batches produced," he said.

"Our new UPI model will ensure that we know exactly which vial any single patient has received from which batch. If there is a recall or any other problem, we can track every unit of product to the patient."

Mr Montagner said it was inevitable a Federal Government-mandated tracing system would be implemented industry-wide given the practice is now mandated in the EU and US.

"I would call on the Federal Government and indeed, all pharmaceutical manufacturers to introduce similar measures to ensure the highest patient safety standards are adopted," he said.

"We are proud to be Australian innovators but believe these measures must be widely adopted by all pharma companies in this region to mitigate potential patient risks."

About Specialised Therapeutics Asia

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New Early Breast Cancer Drug to Reduce Risk of Recurrence or Death Approved for Australian Women

19 March 2019: A NEW drug shown to significantly reduce the risk of cancer recurrence or death in an aggressive form of breast cancer has today been approved for use in Australian patients.

The drug, NERLYNX (neratinib) is an oral medication taken for 12 months by women with early stage HER2-positive (HER2+) breast cancer. It is now TGA approved with the following indication:

"NERLYNX is indicated for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy."[2]

The greatest benefit is seen in women who are hormone-receptor positive (HR+) and who initiate NERLYNX therapy within 12 months of completing trastuzumab based therapy. Their five-year risk of recurrence or death is reduced by 42% after completing 12 months of NERLYNX therapy.[3]

Leading Australian oncologist Professor Arlene Chan AM, from the Breast Cancer Research Centre Western Australia, is an international breast cancer authority and was the global study chair of the pivotal international NERLYNX registration trial known as ExteNET.[1]

Professor Chan described the TGA approval of NERLYNX as "a huge step forward", noting that women diagnosed with HER2+ breast cancer have a one-in-four chance of cancer recurrence even after surgery, chemotherapy and trastuzumab-based therapy.[4]

She expects that the availability of this new therapy will provide some Australian women with an opportunity to avoid experiencing a breast cancer recurrence.

"I am absolutely delighted that NERLYNX has been approved for use in Australia," Professor Chan said.

"This is a huge benefit for women with this disease. The ability to improve the lives and reduce the risk of relapse will be enormously appreciated by many, many people in Australia.

"I would say that any proven treatment able to reduce the risk of cancer recurring has to be a win. Those women who are spared an invasive relapse will be eternally grateful that they have received this drug."

Professor Chan noted that diarrhoea was the commonest side effect of the medication, but a new study known as CONTROL had been initiated and was now providing evidence that anti-diarrhoeal medications can substantially reduce these side effects.[2]

"We know that with appropriate and careful management, you can reduce the severity and frequency of the diarrhoea, which primarily occurs in the first month or two. Importantly, these symptoms are completely reversible."

NERLYNX is being made available in Australia and across South-East Asia by independent pharmaceutical company, Specialised Therapeutics Asia (STA), in partnership with the drug's US developer, Puma Biotechnology, Inc.

STA Chief Executive Officer Carlo Montagner said NERLYNX represented a new stage of treatment for Australian women and was currently being made available in Australia at no cost via the NERLYNX access program.

Mr Montagner said a reimbursement application had been submitted to the Pharmaceutical Benefits Advisory Committee and was currently under evaluation.

"This drug currently costs more than SGD $200,000 for a full course of treatment over 12 months in North America," he said.

"Our company is currently making NERLYNX available to appropriate women in Australia free of charge prior to PBS approval. However, we are concerned many eligible women may not be aware of this access program and therefore may be missing out on a potentially life-saving treatment.

"Every woman who has been diagnosed with HER2+ early breast cancer and is either currently taking trastuzumab-based therapy or has completed a course of trastuzumab-based therapy in the past 12 months, needs to be aware of this program and discuss with their oncologist whether it is appropriate for their condition.

"With this TGA approval, this is the first time Australian women are being presented with an opportunity for *extended*-adjuvant therapy that will reduce the risk of disease recurrence in some women who would otherwise have had a relapse.

"We are pleased to be at the forefront of this new treatment paradigm and look forward to changing outcomes for these women and their families and friends."

Puma Biotechnology's CEO and President Alan H. Auerbach added: "Reducing the risk of disease recurrence remains a need for patients, despite advances in the treatment of early-stage HER2-positive breast cancer. We are pleased that our partner STA will be bringing this new medicine to patients throughout Australia and would like to express our appreciation to the patients, caregivers and physicians who contributed to the neratinib clinical development program and

more specifically, the ExteNET trial. We are committed to continuing to expand NERLYNX accessibility to patients around the world."

Ends.

About NERLYNX

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER[4,5,6]

NERLYNX is the first HER2-targeted medication approved by the FDA as extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer, for patients who have previously been treated with trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).[4] NERLYNX is also the first anti-HER2 treatment to be EC-approved as extended adjuvant therapy for early stage HR+ / HER2-positive breast cancer following adjuvant trastuzumab-based therapy.[5,6]

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.

Click on this link for AU Product Information:
https://www.stabiopharma.com/assets/files/d-nerlynx_pi.pdf

Click on this link for US prescribing information:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf

Click on this link for EU prescribing information:
https://www.ema.europa.eu/en/documents/product-information/nerlynx-epar-product-information_en.pdf

About HER2+ Breast Cancer

Approximately 15−20% 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 25% of patients treated with trastuzumab-based adjuvant therapy experience recurrence.[4]

About the ExteNET Study[1,6]

The ExteNET trial was a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab and chemotherapy 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 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.

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%.[7]

An additional five-year sub-group analysis demonstrated a 42% risk reduction in women who were HR+ and who had commenced neratinib therapy within 12 months of completing treatment with trastuzumab-based therapy.[3]

The most common adverse reactions (≥ 5%) were diarrhoea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.[2]

Puma is conducting a Phase II CONTROL study investigating various prophylactic anti-diarrhoeal regimens for the first 1-2 cycles of neratinib therapy. Emerging data suggest that prophylactic management reduces the incidence, severity and duration of neratinib-associated diarrhoea as compared with events observed in ExteNET.[2]

About Specialised Therapeutics Asia

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6. NERLYNX (neratinib) European Medicines Agency Summary of Product Characteristics
7. Martin M, et. al. Lancet Oncol. Dec 2017;18(12):1688-1700

New Early Breast Cancer Drug to Be Made Available in Singapore via Special Access Program

Singapore, 18 February 2019: A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence is being made available to women in Singapore from **today** via a Special Access Program.

The drug, NERLYNX (neratinib) is an oral medication taken by women with HER2+ breast cancer who have completed adjuvant trastuzumab-based therapy.

NERLYNX has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients.[1] The greatest benefit was observed in women who were also hormone-receptor positive (HR+) and treated within 12 months following completion of trastuzumab-based adjuvant therapy. Their five-year risk of recurrence or death was reduced by 42%. In these patients, invasive disease-free survival (iDFS) was 90.8% in the patients treated with neratinib,

compared with 85.7% in those receiving placebo (hazard ratio = 0.58; 95% CI: 0.41−0.82; p = 0.002).

ST Asia Chief Executive Officer Mr. Carlo Montagner said a formal registration decision was not expected by Singapore's HSA before 2020, although he noted that NERLYNX is approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

"Data from the pivotal clinical trial tells us that the greatest benefit is seen in women who commence therapy as soon as possible after their adjuvant trastuzumab-based treatment has been completed," he said.

"Therefore, it is critical that women in Singapore who have recently completed adjuvant trastuzumab-based therapy or are about to complete adjuvant trastuzumab-based therapy, are provided access now to NERLYNX while the registration process is underway.

International breast cancer authority Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase III trial of NERLYNX, ExteNET.[2]

Professor Chan said its availability in Singapore and other regions would be "a huge step forward" to further reduce the risk of cancer recurrence in local women diagnosed with HER2+ early breast cancer.

"Despite the clear proven benefit of standard of care chemotherapy and trastuzumab therapy, women diagnosed with early-stage HER2+ breast cancer are still at risk of disease recurrence," Professor Chan said.

"This drug provides women with an opportunity to remain disease-free who may otherwise have had a recurrence."

Singapore health data shows that breast cancer is the most common cancer in women in the country, accounting for almost 30% of all cancer cases. It is estimated that one in 15 women will be diagnosed with breast cancer before age 75.[3]

NERLYNX is made available in Singapore by Specialised Therapeutics Asia, under exclusive license from Puma Biotechnology, Inc.

About NERLYNX

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7. Martin M, et. al. Lancet Oncol. Dec 2017;18(12):1688-1700.

World-First Approval for Multiple Myeloma Drug Aplidin®

Singapore, 11 December 2018: Australian multiple myeloma patients will have world-first access to a new first-in-class drug developed to treat the disease, following approval by Australian regulatory authorities.

The drug, APLIDIN (plitidepsin) will be available to patients who have failed or are resistant to other therapies, after the Therapeutic Goods Administration (TGA) decision to approve APLIDIN before any other country.

Leading Australian myeloma clinicians are welcoming the decision, saying APLIDIN will provide another valuable treatment option for patients.

Alfred Hospital Head of the Malignant Haematology and Stem Cell Transplantation Service, Professor Andrew Spencer, said: "APLIDIN provides a chance for some myeloma patients to extend their lives.

"We now have another drug to offer patients who have relapsed after being treated with existing therapies.

"This is important, because once patients become resistant to standard therapies, there have been very limited treatment options."

And Peter MacCallum Cancer Centre and Royal Melbourne Hospital haematologist, Professor Jeff Szer, who was the Australian principal investigator on the pivotal APLIDIN registration study, said APLIDIN had been shown to be effective and well tolerated.

He commented: "More Australian myeloma patients were enrolled into the pivotal international trial of APLIDIN than anywhere else in the world.

"These patients in the Phase 3 study known as ADMYRE have now paved the way for others to have access to a new and novel therapy.

"This really means that some patients with advanced myeloma have the possibility of improved outcomes, when previous therapies have failed."

Specialised Therapeutics will continue providing APLIDIN to eligible Australian patients at no cost via a Compassionate Access Program, prior to national reimbursement.

Chief Executive Officer of Specialised Therapeutics Asia, Carlo Montagner, said Australian regulatory authorities should be commended for ensuring Australian myeloma patients have the first opportunity to access this cutting-edge therapy.

He commented: “It is not often that Australian patients are the first in the world to access new medicines. In this case, the TGA is at the forefront, with decision-makers recognising the great need that exists in multiple myeloma. This disease remains incurable and patients eventually run out of treatment options.

The company is pursuing opportunities to provide APLIDIN to myeloma patients across South East Asia.

Specialised Therapeutics Asia has exclusive rights to market and distribute APLIDIN in Australia, Singapore and 12 other South East Asian countries under the terms of an exclusive arrangement with European partner, PharmaMar.

APLIDIN was the first drug licensed by Specialised Therapeutics Asia for the broader SE Asian market.

PharmaMar President, José María Fernández Sousa-Faro, said: “This approval for an incurable disease, corroborates the work that the PharmaMar team has done over the years with APLIDIN®. Patients and the medical community will now have a new therapeutic alternative with a new mechanism of action, that is different from the products currently in use.”

Managing Director of PharmaMar´s Oncology Business Unit, Luis Mora, added: “The approval of Aplidin® is a very important step forward for the company. This increases PharmaMar’s presence with a second drug on the Australian market and, together with our partners, we are initiating procedures for other markets, such as South America, Mexico, Canada, Asia and Israel.”

Ends.

About APLIDIN® (plitidepsin)

Plitidepsin is an 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 combination studies in relapsed or refractory multiple myeloma, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma.

About Multiple Myeloma in Australia

It is estimated that around 1800 Australians are diagnosed with MM every year and 1000 people die.[1] Fewer than 50% of patients survive five-years post diagnosis.[1]

MM accounts for between 10 and 15% of all haematological malignancies and is predominately a disease of the elderly, with median age at diagnosis 65-70 years.[2] This disease typically causes increased bone osteolysis resulting in pathological fractures, renal failure, hypercalcaemia, immune suppression, increased infection risk and bone marrow failure.[2]

Despite significant developments in frontline, maintenance and supportive therapy options, MM remains incurable, with treatment refractory relapse eventually occurring in all patients.[3]

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide innovative specialist therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. ST Asia's existing product portfolio spans oncology, haematology, neurology, urology and ophthalmology. Additional

information can be found at www.stbiopharma.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 commercializes 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.

Further Inquiries

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1599-605

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Specialised Therapeutics to Collaborate with Pharmacy Phusion to Improve Patient Outcomes

Singapore, 2 November 2018: Independent pharmaceutical company Specialised Therapeutics (ST) has struck a new agreement with specialty

pharmacy services group Pharmacy Phusion to assist with the distribution and patient support for a new medicine that treats HER2 overexpressing early-stage breast cancer.

Under the terms of the agreement, patients prescribed this new breast cancer treatment by medical oncologists via the Therapeutic Goods Administration (TGA) Special Access Scheme will be contacted by a specialist pharmacist weekly for the first five weeks of treatment, and then followed up monthly for the duration of therapy.

ST Chief Executive Officer Mr Carlo Montagner said this new program was testament to the company's ongoing commitment to patient care.

"This is about reassurance," he said. "We want all patients who are being administered our products to feel supported, as well as to ensure treatment is properly initiated and managed so that the best therapeutic outcomes are achieved."

"This program is for a new medicine that ST is currently making available to medical oncologists in Australia at no cost under a strictly-controlled patient access program while undergoing regulatory evaluation by the TGA.

"We know many patients live in regional and remote communities and can encounter challenges when it comes to immediate support.

To this end, we have engaged a team of experienced pharmacists who will implement regular well-being calls to help our patients during therapy and address any other queries or concerns that may arise.

"These pharmacists will consult as required with a patient's own medical oncologist. This is not about replacing the role of the doctor or other healthcare professional – it is about ensuring all patients have access to the right support exactly when they need it."

In addition to the formal calls, patients will also be able to telephone a pharmacist for advice at any time during business hours, seven days a week.

Pharmacy Phusion's Group Professional Manager Mark Silcock said the group works across a range of complex therapy areas, but all expert pharmacists engaged in customer support programs are experienced and uniquely positioned

to support patients prescribed new and often complex medicines.

“Pharma companies not only in Australia, but around the world can benefit from having an expert pharmacist team supporting their medications,” he said.

“Our specialist pharmacists have a deep understanding of the medicines they are discussing and how they might interact with other medicines.

“We find the primary role of the pharmacist in these programs is to provide support and reassurance, which ultimately leads to improved adherence.

“Time and time again, that is what patients want – it’s not just about the medicine, but about dosage and side effects.

“Our pharmacists take the time with each individual patient to help them understand what to expect and if they do experience any side effects, to manage them appropriately and efficiently.”
The Pharmacy Phusion customer support program takes effect from today.

Ends.

Media Inquiries:
Emma Power
STA Senior Corporate Affairs and Communications Manager
Phone: +61 419 149 525

About Specialised Therapeutics Asia

Specialised Therapeutics is an international, independent pharmaceutical company established to provide pioneering healthcare to patients throughout South East Asia, as well as in Australia and New Zealand.

ST collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing therapies and technologies to patients affected by a range of diseases. ST remains committed to making new and novel therapies available to patients in its key regions of Australia, New Zealand and throughout South-East Asia, targeting diseases where there remains an unmet

medical need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com.

New PBS Listing for Leukaemia Drug ICLUSIG™ (ponatinib)

Singapore, September 1, 2018: A DRUG currently used to treat Chronic Myeloid Leukaemia (CML) will be available on the Pharmaceutical Benefits Scheme from today as a new treatment for another aggressive form of the disease.

The drug, ICLUSIG (ponatinib) will now be available to all Philadelphia-positive Acute Lymphoblastic Leukaemia (Ph+ ALL) patients, who are intolerant or resistant to other therapies.

Leading Australian leukaemia authority, Professor Timothy Hughes, welcomed the new listing as "a major step forward" for this group of Ph+ ALL patients.

"These patients really have no prospect of long-term survival with current therapies and this PBS listing presents a really exciting new opportunity," he said.

"While outcomes for Ph+ ALL patients have improved a lot, we still have a very high incidence of relapse and resistance to imatinib and dasatinib, which have been the tyrosine kinase inhibitors (TKIs) we have used until now. Ponatinib is a potent TKI and has broad coverage against the resistant forms of leukaemia." [1]

"Essentially, the availability of ponatinib for this group of patients really does add to our capacity to provide more people with a stable, long-term response and, in some cases, the prospect of long-term remission."

ICLUSIG is made available in Australia by independent pharmaceutical company

Specialised Therapeutics Australia.

Chief Executive Officer Carlo Montagner said Ph+ ALL was a highly aggressive form of leukaemia with limited treatment options.

“Unfortunately, patients who are diagnosed continue to have a poor prognosis,” he said.

“There has been an urgent need for new treatments for these patients. Despite an initial complete remission rate of up to 90% following induction chemotherapy, most adult patients will relapse and die of ALL.[2,3,4]

“We are thrilled to be making ICLUSIG available to patients for whom other treatments have failed, and providing them with a new opportunity.”

The new PBS listing follows the recent publication of five-year data from a pivotal study of ICLUSIG, known as the PACE trial.[5]

Data from this international study demonstrated that ICLUSIG is able to achieve a long lasting and “clinically meaningful” response, irrespective of dose reductions and the presence of mutations in heavily-pre-treated CML patients.[5]

ICLUSIG was first made available in Australia in 2014 for Chronic Myeloid Leukaemia patients.

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

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.

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About ICLUSIG™ (ponatinib)

ICLUSIG is a kinase inhibitor. Its primary target 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 Pharmaceuticals' (now Takeda) 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 CML, ALL and the Philadelphia Chromosome

Leukemia is a blood cancer that forms in a person's bone marrow. Chronic Myeloid Leukemia (CML) is one of four main types of leukemia; it is a result of a genetic mutation that takes place in early, immature versions of myeloid cells, which form red blood cells, platelets and most types of white blood cells. Subsequently, an abnormal gene called BCR-ABL1 forms, turning the damaged cell into a CML cell. CML typically progresses slowly, but it can also change into a fast-growing acute leukemia that is hard to treat. Chronic phase (CP) is the

earliest phase of CML. Patients in CP have unusually high levels of white blood cells. Symptoms are generally mild and may include fatigue, weakness, shortness of breath, fullness or early satiety and weight loss.
Acute Lymphoblastic Leukemia (ALL) starts from the early version of white blood cells, called lymphocytes, in the bone marrow (the soft inner part of the bones, where new blood cells are made). The term “acute” means that the leukemia can progress quickly, and if not treated, would probably be fatal within a few months.

The Philadelphia chromosome is an abnormal chromosome formed when pieces of chromosomes 9 and 22 switch with each other. This forms a longer chromosome 9 and a shorter chromosome 22, which leads to the development of BCR-ABL1 and is associated with CML and Ph+ ALL.

PBS Information. Authority Required. Refer to PBS schedule for full information.

Minimum Product Information ICLUSIG™ (ponatinib HCl)

Please review Product Information before prescribing.
The Product Information can be access at www.ebs.tga.gov.au/ebs/

Indications: Adult patients with: **CML** 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

T315I mutation. **Ph+ ALL** 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 T315I 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, HEART FAILURE AND HYPERTENSION

Vascular Occlusion:

Arterial and venous thrombosis and occlusions have occurred in at least 23% of ICLUSIG-treated patients, resulting in fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease (sometimes resulting in amputation), vision loss 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, Vascular Occlusion).

Heart Failure:

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, Heart Failure).

Hypertension:

Hypertension, including hypertensive crisis, has been observed in ICLUSIG-treated patients (26% overall, 2% serious) (see Precautions, Hypertension).

Precautions: Actively monitor and manage patients for vascular occlusions, cardiac failure, hypertension, haemorrhage, myelosuppression, hepatotoxicity, pancreatitis, QT prolongation, reversible posterior leukoencephalopathy and hepatitis B reactivation 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. Monitor patient for decreased or blurred vision. ***Cardiac failure:*** Monitor for heart failure and treat as clinically indicated. ***Hypertension:*** Hypertension may contribute to risk of arterial thrombotic and occlusive events including renal artery stenosis. Monitor at each clinic visit and treat hypertension to normalise blood pressure. Interrupt treatment if hypertension is not medically controlled and consider evaluating for renal artery stenosis. ***Haemorrhage***, including fatalities occurred, mostly in patients with grade 4 thrombocytopaenia. Use anti-coagulants and/or anti-platelet agents with caution in patients at risk of bleeding. ***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. ***Reversible posterior leukoencephalopathy syndrome (RPLS):*** Post-marketing cases of RPLS have been reported in ICLUSIG treated patients. If diagnosed interrupt treatment until event is resolved and benefit of treatment outweighs risk. ***Hepatitis B reactivation*** in patients who are chronic carriers has been observed when treated with BCR-ABL TKIs. Test patients for HBV infection prior to therapy start and consult with liver disease experts if positive. Closely monitor carriers throughout therapy. ***Lactose:*** contains lactose. ***Special populations:*** Recommended starting dose of 30 mg for patients with hepatic impairment (Child-Pugh Classes A,B & C). Caution or avoid in patients with moderate to severe or end stage renal disease, pregnancy (category D), breastfeeding, the elderly, paediatric patients, or when driving or operating machinery (see full PI). ***Interactions with Other Medicines:*** Caution with concurrent strong CYP3A inhibitors and consider a starting dose of 30 mg. Caution with CYP3A inducers, P-glycoprotein (P-gp) substrates 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: Pneumonia (6.5%), pancreatitis (5.6%), pyrexia (4.2%), abdominal pain (4.0%), myocardial infarction (3.6%), anaemia (3.3%), atrial fibrillation (3.3%), platelet count decreased (3.1%), febrile neutropenia (2.9%), cardiac failure (1.8%), lipase increased (1.8%), dyspnoea (1.6%), diarrhoea (1.6%), neutrophil count decreased (1.3%),

pancytopenia (1.3%), pericardial effusion (1.3%). 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. Starting Dose: 45 mg once daily, with or without food; 30 mg for patients with hepatic impairment; 30 mg with concurrent strong CYP3A inhibitors. 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.

- ICLUSIG to be made available to all refractory/relapsed Ph+ ALL patients from September 1, 2018
- Leukaemia expert: “Ponatinib will provide more people with a stable, long-term response…”

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2. Litzow MR. Haematology Am Soc Haematol Educ Program 2009: 362 – 70
3. Fielding AK et al. BLOOD 2007; 109 (3): 944 – 50
4. Kako S et al. Br J Haematol 2013; 161 (1): 95 – 103
5. Cortes JE et.al. Blood 2018; 132(4) 393-404I

Specialised Therapeutics Celebrates 10 Years and Unveils Expansion Plan

Melbourne, Australia 27 August 2018: Privately-held pharmaceutical company Specialised Therapeutics Australia will today mark its 10th anniversary, unveiling new Australian headquarters and a business plan to drive healthcare innovation over the next decade.

The company, which was founded ten years ago by pharmaceutical expats Carlo Montagner and Bozena Zembrzuski with a single chemotherapy product, has emerged as the largest privately-owned Australian specialty pharma company in the region, employing close to 50 employees, generating revenues of ~$30 million and with an expansive specialty drug portfolio spanning oncology, haematology, ophthalmology, supportive care and neurology.

Officially opening new Australian headquarters in Melbourne today, Chief Executive Officer Carlo Montagner attributed the company's success to a strategy of in-licensing mid-to late stage products for full commercialisation, but said the next 10-year plan included in-licensing earlier-stage drugs, steering them through full clinical development and globally commercialising these products. "This may require us to list a subsidiary company either on the ASX or on Singapore's SGX to co-fund compound development," he said.

"Our vision for the first 10 years was to build a profitable pharmaceutical company partnering with leading global biotech and pharmaceutical companies. While we continue to invest aggressively to further expand our global partnerships and product pipeline into new therapeutic areas, it is now time to build on these solid foundations and execute the next stage of our company's development."

Federal Treasurer, Deputy Liberal Party leader and Member for Kooyong Josh Frydenberg MP will officially unveil the company's new headquarters, noting STA's role in cementing Victoria as a major pharmaceutical and biotech hub.

"This company is an Australian start-up success story," he said. "We know that as many as 90 per cent of start-ups fail to flourish after five years. STA is a stand-out in the pharmaceutical sector and continues to grow, providing employment and generating strong revenues."

Member for Kew and Shadow Education Minister Tim Smith MP commented:

"I am delighted that Specialised Therapeutics has chosen to set up their new headquarters in the eastern suburbs of Melbourne, specifically in my electorate of Kew. Small to medium enterprises are vitally important for our local economy and community.""

Mr Montagner said: "Bozena and I are extremely proud of what we have achieved in the past decade, which has laid the foundations for our ultimate vision: to build a global pharmaceutical company delivering specialist medicines to patients where there is an unmet clinical need."

Ends.

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About Specialised Therapeutics Australia

Specialised Therapeutics Australia is an independent, international pharmaceutical company providing new specialist medicines to patients in Australia, New Zealand and across South-East Asia. Dually headquartered in Melbourne, Australia and Singapore, STA and its affiliate company Specialised Therapeutics Asia Pte Ltd collaborates with leading global pharmaceutical, biotech and diagnostic companies to bring innovative specialist therapies and technologies to patients in its key regions.It's current portfolio includes products in oncology, haematology, supportive care, neurology and ophthalmology, but it is not confined to these therapeutic areas.

Specialised Therapeutics Asia Initiates Early Access Program for Neratinib

Singapore, 5 April 2018: Specialised Therapeutics Asia today announces the initiation of an early access program for neratinib, an extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer.

Under this Special Access Program (SAP) select patients in Australia will be provided access to the medicine, where appropriate and when permitted by relevant regulatory authorities.

The SAP protocol allows for neratinib to be available to patients with HER2 overexpressing cancers.

In all cases, the patient must have a special clinical need that cannot be met by currently approved and available medicines.

Specialised Therapeutics' neratinib Special Access Program follows the signing of a key license agreement with Puma Biotechnology Inc. (NASDAQ:PBYI) in November 2017, providing exclusive rights to commercialise neratinib in Australia, New Zealand and in South East Asia.

Ends.

About Neratib[1]

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

Neratinib 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.

Neratinib 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 Special Access Programs

Special Access Programs enable pharmaceutical companies a means of providing ethical access to off-label or unapproved medicines to assist patients where there is an unmet medical need. Enrolment in any access program is only provided

following request from an appropriate medical professional. Special Access Programs are strictly overseen to ensure full compliance, and are opened when no alternative treatment options are available.

About Specialised Therapeutics Asia

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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

Further enquiries: ST Asia Communications Manager Emma Power is available on +61 419 149 525.

References:

1. NERLYNX® (neratinib) US Product Information (approved) https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf

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 NERLYNX[4]

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

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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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4. NERLYNX (neratinib) US Product Information (approved) https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf