New Drug for Gastrointestinal Stromal Tumours (GIST) to be Launched in Australia, New Zealand and South East Asia Following Distribution Agreement

Singapore, 06 November 2020: A NEW therapy to treat advanced gastrointestinal stromal tumours (GIST) will be available to patients in Australia, New Zealand and in some parts of South East Asia, following an exclusive distribution agreement.

Independent pharmaceutical company Specialised Therapeutics Asia (STA) has signed an agreement with US-based Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH) to commercialise the switch-control tyrosine kinase inhibitor QINLOCK (ripretinib) in key regions, including Australia, New Zealand, Singapore, Malaysia and Brunei.

The therapy was one of the first approved by Australia's Therapeutic Goods Administration (TGA) earlier this year under Project Orbis, which enables concurrent review of oncology products by international regulators, including the TGA, FDA and Health Canada.

It is indicated **"for the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib"**.

QINLOCK has also been approved by the US Food and Drug Administration (FDA) and Health Canada (HC) for the fourth-line treatment of GIST.

The TGA approval was based on efficacy results from the pivotal global Phase 3 INVICTUS study in patients with advanced GIST as well as combined safety results from INVICTUS and the Phase 1 study of QINLOCK. In INVICTUS, QINLOCK demonstrated a median progression-free survival of 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of

disease progression or death by 85% (hazard ratio of 0.15; 95% CI 0.09-0.25; p<0.0001). In addition, QINLOCK demonstrated a median overall survival of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36; 95% CI 0.21-0.62).[1]

One of the INVICTUS study authors, Professor John Zalcberg who holds the Tony Charlton Chair of Oncology and is Head of the Cancer Research Program in the School of Public Health at Monash University as well as a consultant medical oncologist at Alfred Health, described QINLOCK as an important new agent in the GIST treatment armamentarium, noting it was the first TGA approved fourth-line therapy to treat the disease.

“QINLOCK represents another step forward to improve outcomes for patients who are affected by this rare cancer,” Professor Zalcberg said.

“This is an area of high unmet need because of the poor prognosis of patients whose tumours continue to grow on prior treatment.

“We are further encouraged by data demonstrating that QINLOCK is well-tolerated, with patient-reported outcomes (PROs) suggesting that patients who received QINLOCK therapy in the INVICTUS study were able to maintain their quality of life in contrast to the fact that quality of life deteriorated in patients not receiving QINLOCK.”

STA Chief Executive Officer Carlo Montagner said QINLOCK would bolster the company’s already-robust oncology portfolio, and was synergistic with its mission to address areas of unmet clinical need.

“We are thrilled to introduce this valuable therapy to patients with GIST in our region, working in collaboration with our new international partner, Deciphera Pharmaceuticals,” Mr Montagner said.

“STA will expedite access to this important medicine, with a Patient Access Program to open in Q1 2021. This will provide subsidised access for appropriate patients at the earliest opportunity, as we file for additional regulatory approvals in other key markets, including New Zealand, Singapore and Malaysia.”

Deciphera President and Chief Executive Officer Mr Steve Hoerter commented: “We are committed to ensuring QINLOCK’s global commercial availability and are

proud to be executing on our plan to deliver this important medicine to patients with advanced GIST worldwide.

“We look forward to collaborating with STA as we bring a much-needed therapeutic option to patients living in locations where we do not anticipate setting up our own commercial activities near term.”

A submission to have QINLOCK reimbursed for eligible Australian patients has been lodged with the Pharmaceutical Benefits Advisory Committee in November for consideration at the March 2021 meeting. If successful, QINLOCK could be reimbursed for Australian patients in the latter half of 2021.

Ends.

Further inquiries: STA Senior Manager Communications and Corporate Affairs Emma Power +61 419 149 525.

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.

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 remain unmet medical needs. 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

About Deciphera Pharmaceuticals

Deciphera is a biopharmaceutical company focused on discovering, developing and commercializing important new medicines to improve the lives of people with cancer. Deciphera is leveraging its proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from the company's platform in clinical studies, QINLOCK is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada and Australia. For more information, visit www.deciphera.com and follow the company on LinkedIn and Twitter (@Deciphera).

About GIST

Gastrointestinal stromal tumor (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST is the most common sarcoma of the gastrointestinal tract, with approximately 4,000 to 6,000 new GIST cases each year in the United States and a similar incidence rate in European and other countries. Most cases of GIST are driven by a spectrum of mutations. The most common primary mutations are in KIT kinase, representing approximately 80% of cases, or in PDGFRα kinase, representing approximately 6% of cases. Current therapies are unable to inhibit the full spectrum of primary and secondary mutations, which drives resistance and disease progression. Estimates for 5-year survival range from 48% to 90%, depending on the stage of the disease at diagnosis.

About the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomized, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose

previous therapies have included imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median PFS in the study was 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, $p<0.0001$). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p=0.0504$). QINLOCK also demonstrated a median OS of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).

About QINLOCK (ripretinib)Specialised

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRα mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation involved in systemic mastocytosis, or SM. QINLOCK also inhibits primary PDGFRα mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

QINLOCK is approved by the U.S. FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. It is also approved by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib and by the Australian Therapeutic Goods Administration for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

Deciphera Pharmaceuticals is developing QINLOCK for the treatment of KIT

and/or PDGFRα-driven cancers, including GIST, and maintains global development and commercial rights except for select geographies. Deciphera Pharmaceuticals has an exclusive license agreement with Zai Lab (Shanghai) Co., Ltd. for the development and commercialization of QINLOCK in Greater China (Mainland China, Hong Kong, Macau, and Taiwan). Deciphera Pharmaceuticals has an exclusive distribution agreement with Specialised Therapeutics Asia (STA) for the commercialization of QINLOCK in Australia, New Zealand, Singapore, Malaysia and Brunei.

- • Specialised Therapeutics Asia (STA) to make QINLOCK® (ripretinib) available to appropriate patients in Australia, New Zealand, Singapore, Malaysia and Brunei following exclusive distribution agreement
- • QINLOCK is already approved by the Therapeutics Good Administration (TGA) and US Food and Drug Administration (FDA)
- • In the INVICTUS study, QINLOCK reduced the risk of disease progression by 85% in advanced GIST patients who have received three prior therapies[1]

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STA Named Employer of Choice in

2020 ABA Business Awards

Melbourne, Australia, 8 October 2020: Independent pharmaceutical company Specialised Therapeutics Australia (STA) has been recognised as an Employer of Choice in The Australian Business Awards 2020.

The prestigious awards recognize organisations demonstrating business innovation, product innovation, technological achievement and employee engagement via a set of comprehensive award categories.

The Employer of Choice (EOC) accolade in particular, recognises workplaces that help employees reach their full potential, via the introduction of policies and practices encouraging recruitment, engagement and retention.

STA Chief Executive Officer and co-founder Mr Carlo Montagner said STA had a long-standing commitment to recruiting and retaining outstanding employees, and further building and maintain a company culture consistent with its core values of Passion, Integrity, Teamwork, Courage and Humanity, or 'PITCH'.

"Since Bozena and I established STA 12 years ago, we have remained determined to embed these core values into all facets of our business," Mr Montagner said.

"We are an independent, family-owned pharmaceutical company that has grown from two employees in 2008 to more than 35 currently, commercialising our portfolio of specialist medicines in Australia, Singapore, Malaysia and New Zealand.

"Our independence sets us apart, not only in terms of our family values, but in how we nurture and build our workforce. We have introduced a range of initiatives to attract and retain a top-quality team who bring extensive experience in global pharma. STA is proud to be recognised by the ABA and will continue striving to remain an Employer of Choice in the Australian pharma industry."

Some of the workplace initiatives introduced by STA to encourage recruitment, engagement and retention of high calibre employees include flexible work arrangements, additional leave, Weekend Arvo Kick Start or 'WEAKS' leave, over-and-above the legally required employer superannuation contributions, outstanding health insurance benefits and ongoing training and development.

Mr Montagner added: “Workplace flexibility has been a pillar of our business to date, and will remain so moving forward. Currently, a majority of our employees are women. While we have not hired based on gender but on capability, we understand that female employees are frequently balancing work and life requirements. We have worked hard to achieve an inclusive and accommodating environment at STA that helps all team members fulfill their obligations outside work as well as enjoy career success.”

ABA Program Director Ms Tara Johnston said: “Fifty-four organisations have been selected in this year’s ABA Employer of Choice Awards. These organisations have demonstrated adaptability in the workplace by utilising flexible and new ways of working and learning.

“The landscape of the workplace environment has changed rapidly, as technology has gained momentum, coinciding with businesses navigating a broad range of interrelated issues from the impact of the current challenges facing the global economy. The ability to work from anywhere, combined with the advances in connectivity tools makes us geographically neutral.

“Leading organisations have begun to implement an entirely new working environment that break down communication barriers, positioning organisations to harness the talent within their organisation, transform the employee experience and position businesses to be more resilient.”

Entrant organisations are required to demonstrate achievements across the key areas of Organisational Culture; Leadership & Strategy; Employee Education, Training & Development; Employee Health, Safety & Satisfaction; Performance Management; Recognition & Remuneration.

Organisational participation includes private companies, public companies, multi-national subsidiaries, non-government organisations, educational institutions, government departments, government agencies, local government and statutory bodies operating in Australia.

For more information visit https://employerofchoiceawards.com.au/eoc-winners-2020/specialised-therapeutics-2020-eoc/

Further Enquiries

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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

ST wins Prime Healthcare Award

We are so proud, that in an exceptional field of finalists (including some or the world's biggest pharma companies) it was our breast cancer patient support program that took out top prize. Special thanks to our program collaborators Pharmacy Phusion for their support and assistance overseeing this tremendous effort.

STA to market sarcoma drug in Australia, New Zealand and SE Asia Following License Deal

Singapore and Melbourne, Australia, 14 October 2019: Independent pharmaceutical company Specialised Therapeutics Asia (STA) has signed a new license deal, enabling it to provide a global advanced sarcoma therapy to patients in Australia, New Zealand and throughout SE Asia.

Under the terms of the agreement, STA will provide the marine-derived compound YONDELIS (trabectedin) to patients throughout Australia, New Zealand and in South East Asia under exclusive license from Spanish company PharmaMar.

YONDELIS – which has been shown to improve progression-free survival when used as second-line therapy for patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) [1] – is already approved and has been available to patients in the United States since 2015,[2] and in Europe since 2007.[3]

Until now, it has not been available in Australia and New Zealand, although it is currently provided to patients in Singapore, Malaysia and Brunei via a previous pharmaceutical arrangement. Former product licensee Janssen will continue to distribute YONDELIS in Singapore, Malaysia and Brunei until marketing authorisation is formally transferred to STA.

Announcing the new deal, STA Chief Executive Officer Mr Carlo Montagner said some Australian patients and their doctors had previously sought to access YONDELIS from international sources, at great difficulty and expense.

“We are delighted to provide this important therapy to patients in Australia, New Zealand and in South-East Asia,” he said.

“We will be immediately seeking approval from the Therapeutic Goods

Administration (TGA) and in the interim, will ensure YONDELIS is available to appropriate patients via a Special Access Program."

Associate Professor Jayesh Desai, Medical Oncologist at the Peter MacCallum Cancer Centre in Melbourne, Australia, and Deputy-Chair of the Australia New Zealand Sarcoma Association (ANZSA) said the availability of YONDELIS in Australia would be greatly appreciated by the sarcoma community.

"Sarcoma is a relatively rare cancer and treatment options are limited for Australian patients with advanced disease," Associate Professor Desai said.

"YONDELIS has been shown to provide a 45% reduction in the risk of disease progression or death versus dacarbazine in patients who have failed prior therapies,[1] and has been a global standard of care. We welcome news that Australian patients will soon be provided access to this therapy that is already providing benefit to sarcoma patients around the world."

Specialised Therapeutics will now seek formal regulatory approval to market YONDELIS in Australia from the Therapeutic Goods Administration (TGA) and subsequent reimbursement via the Pharmaceutical Benefits Scheme (PBS).

In the interim, a Special Access Program will be opened on November 1 to ensure YONDELIS is available at the earliest opportunity to eligible patients.

PharmaMar President, José María Fernández Sousa-Faro, commented: "This new license arrangement is the third we have struck with STA, and is a strong endorsement of their capabilities in these key marketing regions of Australia, New Zealand and South-East Asia.

"Patients and the medical community will now be provided the opportunity to readily access YONDELIS, which is already recognised as a global standard of care. We look forward to seeing sarcoma patients benefit with improved outcomes."

Ends.

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. STA 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 PharmaMar

Headquartered in Madrid, PharmaMar is a biopharmaceutical company focused on oncology and committed to research and development, taking its inspiration from the sea to discover molecules with antitumor activity. It is a company seeking innovative products to provide health care professionals with new tools to treat cancer. Its commitment to patients and to research has made it a world leader in the discovery of antitumor drugs of marine origin.

PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes YONDELIS® in Europe and has other clinical stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14.

About YONDELIS® (trabectedin)

YONDELIS® (trabectedin) is a novel, multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The anti-cancer medicine works by preventing tumor cells from multiplying and is

approved in 76 countries in North America, Europe, South America and Asia for the treatment of advanced soft-tissue sarcomas as a single-agent, and in 69 countries for relapsed ovarian in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection).

The approval was based on the results of a pivotal phase 3, randomised, open-label controlled study which evaluated YONDELIS versus dacarbazine in over 500 patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) previously treated with an anthracycline and at least one additional chemotherapy regimen. LPS and LMS are subtypes of soft tissue sarcoma (STS) and represent more than 35% of all STS cases.[4] The median PFS among the YONDELIS treatment group was 4.2 months (n=345; 95% confidence interval (CI): 3.0 – 4.8 months), while the median PFS in the dacarbazine treatment group was 1.5 months (n=173; 95% CI: 1.5 – 2.6 months), representing a 45% reduction in the risk of disease progression or death with YONDELIS (HR=0.55; 95% CI: 0.44 – 0.70; $p<0.001$).[1]

Among the 340 patients who YONDELIS and were included in the safety analysis in the randomised trial, the most common (≥20%) adverse reactions were nausea (73%), fatigue (67%), vomiting (44%), constipation (36%), decreased appetite (34%), diarrhoea (34%), peripheral oedema (24%), dyspnoea (25%) and headache (23%). The most common (≥20%) laboratory abnormalities were neutropenia (49%), increased alanine transaminase (ALT) (45%), thrombocytopaenia (30%), anaemia (39%), increased aspartate aminotransferase (AST) (35%) and increased blood alkaline phosphatase (20%).[1]

About Soft Tissue Sarcoma

Soft tissue sarcoma is a rare type of cancer that forms as a painless lump (tumour) in any one of the soft tissues connecting all the organs and body structures – including fat, muscle, nerves, deep skin tissue, blood vessels and the tissue surrounding joints (synovial tissue). Soft tissue sarcomas commonly develop in the thigh, shoulder and pelvis and may sometimes develop in the abdomen or chest.[5]

It is estimated around 1500 new cases of STS will be diagnosed in Australia every year, with more men than women typically affected.[6] Median survival from diagnosis has increased from 5.80 years in 1985-1989 to 8.18 years in 2010 – 2014.[7]The outcome of patients with metastatic disease is poor with a median overall survival (OS) estimated to be between 12 and 18 months.[8,9]

Metastatic or locally advanced STS is generally considered incurable, with the mainstay of treatment being systemic chemotherapy. For some patients with limited disease burden however, long-term remission can be achieved through a multimodality approach involving medical, surgical and radiation therapy.[10]

- YONDELIS® (trabectedin) is a globally recognised treatment for patients with advanced soft tissue sarcoma as second-line therapy and beyond, but has been difficult for Australians to access
- YONDELIS demonstrates 45% reduction in risk of disease progression or death versus dacarbazine[1]
- Specialised Therapeutics now filing for TGA approval
- YONDELIS to be made available in Australia via Special Access Program to open **November 1**.

Further Inquiries

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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

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Additional information can be found at www.stabiopharma.com

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 Ieukaemia (Ph+ ALL) whose disease is resistant to, or who are intolerant of dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or where there is a 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…”

Reference:

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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
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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

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

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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.

Disclaimer

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

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From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

THE AUSTRALIAN

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From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

Bozena Zembrzuski and Carlo Montagner reflect on their decision to found Specialised Therapeutics and bring Abraxane to Australia. Picture: Aaron Francis

After years working for big pharma in the US, Carlo Montagner and Bozena Zembrzuski risked their life savings to bring a leading cancer drug to Australia.

The two, who met at university, sold everything almost eight years ago — share portfolios and investment properties — and lived in rented accommodation when they returned to Australia to start their own pharmaceutical company, Specialised Therapeutics.

Montagner, who became chief executive, says he and his wife — parents to three children — took a risk on the Melbourne start-up. The early days of the business were a stark reminder of these risks.

The first drug they wanted to bring into Australia, Abraxane, developed to treat breast cancer, was originally rejected by the Pharmaceutical Benefits Scheme — the system under which the government subsidises the cost of medicine.

“I called my wife after I was told the PBS had rejected it and her first words were ‘we’re — ruined’,” Montagner says.

“I said we weren’t because ‘it is too good a drug not to get through, so let’s play it through’.”

The couple, like most Australians, have watched friends and family battle cancer. Montagner’s father died last September from mesothelioma and the oncology expert says that, given his role, he is often approached by friends and family for advice on the deadly disease.

“When I receive a call from a friend for advice, it’s usually not for financial advice, so I generally tense up,” he says.

“For most patients given cancer diagnosis, and I went through this myself with my father last year, it’s just mind numbing, you don’t know where to turn and there’s a lot of information out there,” Montagner says.

The privately owned company — Montagner has no interest in attracting third-party investors — generated more than $35 million in revenue last year but he says it isn’t just about money.

“I’m very passionate about this. I really do believe that this (Abraxane) is the chemotherapy that all Australian women should receive.”

Bringing a drug to the Australian market is usually reserved for those with deep pockets and time on their side. Drugs have to be licensed, which involves significant testing to secure the right local approvals. The testing needs to be done regardless of a drug’s use or approval in other jurisdictions.

Montagner tells The Weekend Australian the original financial risk they took as a family was worth it because he had a strong belief in Abraxane, which he had launched in the US in his previous role as president of the drug’s developer, Abraxis Bioscience.

Prior to the introduction of that drug into Australia in 2009, Montagner said breast cancer patients were using older chemotherapies that had been around for 20 years.

He says that today, Abraxane is one of the leading therapies for metastatic breast cancer and pancreatic cancer. Since the drug became available in Australia, more than 10,000 cancer patients have been treated with Abraxane.

The drug, which is now owned by US pharma Celgene, has been approved for distribution in about 50 countries, including the US, Europe, Japan and India.

Montagner says the early take-up of the drug in Australia had exceeded their expectations “several fold”.

“We got caught in the first 18 months never really having enough stock,” he says.

“I couldn’t believe how quickly it was being adopted. We put the manufacturing plant in Phoenix under pressure … the plant once pulled out all stops, working 24-7 for a week to make a batch for Australia because we were selling so much of it.”

Zembrzuski says while the company was started with some trepidation, they took the view that if it didn’t work, they would simply get jobs again.

“We had a lot of faith in all the training and experience we’d built up in our previous roles in Australia and overseas,” she says.

The company co-founder, who previously worked for global drug giant Novartis, says it's a different dynamic to have a married couple as the bosses, which she said had the potential to go terribly wrong.

"We were very aware right from the start that being married should not cause any confusion or stress to people," she says.

"If this was going to be a credible and professional venture then that couldn't happen."

Zembrzuski jokes that she was worried if she could take direction from her husband given he had taken on the CEO role. She says she decided to treat him at work as she would any of her previous managers.

"We both have strong opinions, are both self-motivated and have always worked for other people, never together," she says. "But we bring different strengths to the table and we do complement each other."

The company was originally started because Montagner says it was difficult to get a role in Australia that matched the remuneration he was accustomed to in the US as the president of a Nasdaq-listed biotech. He and his wife are passionate about conveying that they don't take the success of the company for granted.

"We feel very lucky that we are able to provide for the kids and are our own bosses," Zembrzuski says.

Teaching their three children, aged 9, 12 and 14, about giving and not just taking is central to the values they want to pass on as parents.

Montagner says that before they went to the US, they were like most Australians and saw people who sprouted philanthropic endeavours as "show-offs".

"Then we went to the US and there it's in the DNA of all successful people. We saw that and we completely changed our view and bought into the concept that people who do well and have the opportunity to give back should give back," he says.

"Plus, we both grew up in working class families that didn't have the opportunities to do what we do now, so the last thing we want is our kids to grow up in a privileged household where they became too materialistic and focused on

themselves than others in greater need.”

The family started its philanthropic efforts with a $1m donation to the Olivia Newton-John cancer research centre based at Melbourne’s Austin Hospital. They have also donated $US250,000 ($328,000) to build a trade school in East Timor.

Zembrzuski adds they are a “proud” Australian-owned company and while they will always maintain their head office in Melbourne, part of being entrepreneurial was looking at new options.

They expanded into Southeast Asia last year with the distribution of a drug to treat myeloma, a type of blood cancer.
“We aim to bring drugs to Australia and South East Asia that fulfil unmet medical needs,” Montagner says.

“We say no to drugs that don’t provide a unique benefit because then it becomes a pure marketing exercise if it doesn’t and we’re not interested in that.”

The company was founded on oncology drugs but it is also targeting haematology, urology and supportive care.

The rapid growth of Specialised Therapeutics has put it on the radar of larger companies but Montagner says he has no plans to sell.

“I love the fact we’re in a position where we can help others with some of the wealth we are generating and I love coming to the office each day and doing what we do. I see Rupert Murdoch and Warren Buffett … what I take from them is they love what they do, it’s not a job, it’s what you do every day.”

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

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

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

About APLIDIN® (plitidepsin)

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

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood cancer that accounts for 10% of all hematological malignancies and that is caused by malignant plasma cells that very rapidly multiply.[2] Normal plasma cells are white blood cells found in the bone marrow that form part of the immune system and produce the antibodies necessary to fight infections.[3] Abnormal cells produce a type of antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly.

Almost all patients with multiple myeloma progress from an initial, asymptomatic pre-malignant stage to established disease. In 2015, 26,850 new cases will be diagnosed in the US, and about 11,200 people will die of this disease.[4] In Europe, there will be 4.5–6.0 out of 100,000 people diagnosed per year.[5] In Australia, approximately 1,200 Australians are diagnosed each year.[6]

- APLIDIN® 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

References

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

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