Breast Cancer Patients Can Access New Interest-Free Payment Plan for Genomic Test That May Help Them Avoid Chemotherapy

Melbourne, Australia, 15 March 2021: BREAST cancer patients who wish to have a genomic test that may help them to avoid chemotherapy can now take out interest-free payment plans of up to two years to pay for the test, following an exclusive arrangement between independent pharmaceutical company Specialised Therapeutics Australia (STA) and Latitude Finance.

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/

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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 Asia Executive Appointments

Singapore, 23 July 2020: Independent pharmaceutical company Specialised Therapeutics Asia (ST Asia) has appointed two senior executives to its Singapore team, as it drives commercialisation of new oncology products in the region.

Dr Bhuvana Ramaswamy will commence as Senior Medical Advisor for South East Asia in October, bringing extensive oncology, scientific and pharmaceutical industry expertise to the role.

Dr Ramaswamy will be joined by new Senior Business Manager Mr Kurt Sim, who has an extensive background commercialising oncology and haematology products throughout South East Asia, along with broad regulatory and market access expertise.

STA Chief Executive Officer Mr Carlo Montagner said these appointments would bolster the company's regional presence and were further evidence of its commitment to providing new therapies to patients throughout Australia, New Zealand and across South East Asia.

"These are complex regions with nuanced regulatory, medical and commercial requirements," Mr Montagner said.

"Our regulatory team has recently achieved several new oncology product approvals in these complex regions, including Singapore, Malaysia and Brunei, with more approvals expected in coming months.

"We are building on these tremendous efforts and ensuring we have the relevant scientific and commercial personnel, with the capability to work closely with

clinicians and deliver new approved therapies and technologies to South East Asian patients as rapidly as possible. Appointing senior people with intimate knowledge of these regions is imperative to executing this plan.

“We are confident these new executive appointments will enable STA to expeditiously execute its growth strategy and ensure patients have access to new therapies and technologies at the earliest opportunity.”

Originally from India, Dr Bhuvana Ramaswamy moved to Singapore 20 years ago, and has been heavily involved in a number of clinical trials at Singapore’s National Cancer Centre. She has held senior medical and scientific roles in the global pharmaceutical industry, including roles at Ipsen and Bristol Myer Squibb (BMS), developing relationships with oncologists across Singapore and Malaysia.

Mr Sim has acquired valuable commercial expertise in previous roles throughout the Asia Pacific, as a Regional Business Development Manager at Ipsen and in other commercial and sales management roles at global pharmaceutical companies including Roche, Wyeth and Mundipharma.

His valuable oncology and haematology networks in Singapore, Malaysia and Brunei are supported by extensive experience preparing contract agreements, regulatory access and named patient programs in numerous countries across the region.

Dr Ramaswamy and Mr Sim will be based at ST Asia’s Singapore headquarters.

Ends.

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to provide 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

- • Key appointments to drive commercialisation of new oncology products throughout South East Asia
- •Appointments to commence October 2020

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New Early Breast Cancer Drug Now Approved in Malaysia

Singapore, 17 July 2020: A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence is now approved for use in Malaysia.

The drug, NERLYNX (neratinib), is an oral medication taken by women with breast cancer who have had surgery, chemotherapy and prior trastuzumab-based therapy.

It has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients,2 with the greatest benefit seen in women who are also hormone-receptor positive (HR+) and who commence therapy within

12 months of completing trastuzumab-based therapy. For these women, the five-year risk of recurrence is reduced by up to 42%.[1]

NERLYNX is approved in Malaysia for " the extended adjuvant treatment of women with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago."

Nerlynx was also recently approved in Singapore by the HSA.

Independent pharmaceutical company, Specialised Therapeutics Asia (STA) is making NERLYNX available in South East Asia under exclusive license from Puma Biotechnology Inc.

STA Chief Executive Officer Mr Carlo Montagner said the latest approval in Malaysia represented a key commercial milestone and highlighted the company's expertise in navigating regulatory pathways in these complex regions.

"Our regulatory team has worked tirelessly to secure these approvals for NERLYNX in Singapore and now Malaysia," he commented.

"NERLYNX is the first drug in our portfolio to be approved in these regions. We are now rapidly progressing other portfolio products through relevant regulatory channels to enable patients across South East Asia access to therapies where there is an unmet medical need.

"In the case of NERLYNX, we look forward to seeing women throughout South East Asia benefit from this important therapy, that provides an opportunity to improve outcomes for early breast cancer patients."

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 trial of NERLYNX, ExteNET.[2]

Professor Chan said its availability in Malaysia, as well as Singapore, 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."

Data from the Malaysia National Cancer Registry Report (MNCRR) 2012-2016 demonstrates that the number of breast cancer cases being recorded in Malaysia is rising, with around 34 women in every 100,000 diagnosed with the disease between 2012 to 2016, compared to about 31 women between 2007 to 2011.[3]

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.[4]

About NERLYNX[5]

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 Australian TGA, the US Food and Drug Administration (FDA)4 and the European Medicines Agency (EMA)6 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).

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

Up to 20% of patients with breast cancer tumors over-express the HER2 protein (HER2-positive disease) and in the ExteNET study, 57% of patients were found to have tumors that were hormone-receptor positive. HER2-positive 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 recurring, up to 25%[7] of patients treated with trastuzumab experience recurrence within 10 years, the majority of which are metastatic recurrences.

About the ExteNET Study[2,8]

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 randomised 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%.[8]

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.[8]

Puma is conducting a Phase 2 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.

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 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.

- • NERLYNX® (neratinib) approved by Malaysia's National Pharmaceutical Regulatory Agency
- • Five-year follow up data show NERLYNX reduces risk of invasive disease recurrence by 42% in women with early-stage, HER2+/HR+ breast cancer and who commence therapy within 12 months of completing trastuzumab-based therapy [1]
- • NERLYNX expected to be available in Malaysia later this year via STA regional partner Zeullig Pharma

Additional information can be found at www.stbiopharma.com

Further Enquiries

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New Small Cell Lung Cancer Drug Accepted for TGA Evaluation Under Project Orbis

Singapore and Melbourne, Australia, 3 June 2020: A NOVEL marine-derived drug to treat Small Cell Lung Cancer (SCLC) has been granted a provisional designation by the Therapeutic Goods Administration (TGA), based on encouraging results from an international trial evaluating its safety and efficacy in several solid tumours, including SCLC.

Data from a key Phase 2 study of the drug Lurbinectedin demonstrated a 35%

overall response rate in second-line patients, with a median overall survival of 9.3 months (95% CI 6.3-11.8) which is a clinically meaningful advantage over current standard of care in patients in second-line SCLC therapy.[1]

These results also underpin a decision by the US Food and Drug Administration (FDA) granting Lurbinectedin a priority and accelerated review. Lurbinectedin will now be reviewed concurrently by the FDA and other international regulators, including the TGA, under the 'Project Orbis' initiative.

This multi-country collaboration between international regulators is designed to streamline approvals where there is a strong unmet medical need, predominantly in oncology and haematology. This project may enable cancer patients to receive expedited access to new therapies.

In tandem with the provisional designation, lurbinectedin is now being investigated in patients at five cancer centres in Sydney, Melbourne and Queensland. All study subjects are SCLC patients who have relapsed after being treated with standard platinum-based chemotherapy, with or without immunotherapy.

A principal investigator on the new Australian study, Associate Professor Tom John at the Peter MacCallum Cancer Centre, said patients had few treatment options after failure of first-line therapy.

Associate Professor John commented: "The initial Lurbinectedin data are encouraging, and we will be collecting local data to see if it matches that seen in the international study. There is still a significant medical unmet need in Small Cell Lung Cancer. We welcome new treatment options for this difficult to treat patient population."

Lurbinectedin is being made available in Australia and Singapore by independent pharmaceutical company Specialised Therapeutics Asia (STA) under exclusive license from Spanish biopharmaceutical company PharmaMar.

STA Chief Executive Officer Mr Carlo Montagner described the TGA's provisional designation for Lurbinectedin and review under the Project Orbis collaboration as "extremely encouraging".

"We welcome the provisional designation that acknowledges the encouraging

data demonstrated to date and the high unmet medical need in patients with refractory SCLC," he said.

"We look forward to progressing Lurbinectedin through relevant regulatory channels in South East Asia and Australia / New Zealand as expeditiously as possible."

In the interim, STA will continue to make this compound available to eligible patients under a named co-pay Patient Access Program in our region."

Up to 1900 Australians[2] and 1100 Singapore residents are diagnosed with SCLC every year, representing approximately 15% of all lung cancers.[3]

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 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 which takes its inspiration from the sea to discover molecules with antitumor activity. It is a

company that seeks innovative products to provide healthcare professionals with new tools to treat cancer. Its commitment to patients and to research has made it one of the world leaders 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. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

About lurbinectedin

Lurbinectedin (PM1183) is a synthetic compound currently under clinical investigation. It is a selective inhibitor of the oncogenic transcription programs on which many tumours are particularly dependent. Together with its effect on cancer cells, Lurbinectedin inhibits oncogenic transcription in tumour-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumour. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

About the Phase 2 basket study

The Phase 2 basket study of Lurbinectedin was a multicentre, single-arm phase II basket trial, designed to evaluate the safety and efficacy of Lurbinectedin in patients across advanced several solid tumours, including SCLC.

Treatment with Lurbinectedin induced a 35.2% overall response rate (ORR), which consisted of all partial responses (PRs) occurring in 37 of 105 patients. An additional 35 patients had stable disease, leading to a disease control rate of 68.6% (95% CI, 58.8%-77.3%).

Overall, 65% of patients had a decrease in tumour size and responses occurred in 5 of 8 patients who had failed prior immunotherapy. Twenty-eight patients (26.7%) had progressive disease and 5 patients were not evaluable.

The median duration of response was 5.3 months (95% CI, 4.1-6.4). The response rate was higher in patients with platinum-sensitive disease, where the ORR was 45% compared with 22.2% in patients with resistant disease.

Overall, the median progression-free survival (PFS) was 3.9 months (95% CI, 2.6-4.6) and the 6-month PFS rate was 33.6% (95% CI, 24.0-43.1). In the sensitive subgroup, the median PFS was 4.6 months (95% CI, 3.0-6.5) and the 6-month PFS rate was 44.6% (95% CI, 31.2-57.9). In the resistant population, the median PFS was 2.6 months (95% CI, 1.3-3.9) and the 6-month PFS rate was 18.8% (95% CI, 6.8-30.9).

At a median follow-up of 17.1 months, the median overall survival (OS) was 9.3 months (95% CI, 6.3-11.8) and the 12-month OS rate was 34.2% (95% CI, 23.2-45.1). The median OS was 11.9 months in sensitive patients versus 5.0 months in resistant patients.

The most common grade 1/2 adverse events (AEs) included fatigue (51.4%), nausea (32.4%), decreased appetite (21.0%), vomiting (18.1%), diarrhea (12.4%), constipation (9.5%), and neutropenia (5.7%). Grade 3/4 AEs included neutropenia (22.9%), anaemia (6.7%), fatigue (6.7%), thrombocytopenia (4.8%), febrile neutropenia (4.8%), pneumonia (1.9%), increased alanine aminotransferase level (1.9%) and skin ulcer (1.0%)

- • TGA has granted provisional designation for new drug Lurbinectedin based on encouraging Phase 2 results and high unmet medical need
- • A marketing application has now been accepted by the TGA under provisional evaluation pathway
- • Lurbinectedin has received priority review under the FDA’s accelerated approval pathway
- • Lurbinectedin to be considered under the ‘Project Orbis’ initiative, which has been designed to allow collaboration between the FDA and select international regulators, including the TGA
- • Lurbinectedin currently available to patients in Australia and Singapore via a named co-pay Patient Access Program

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New Early Breast Cancer Drug Available Now in Singapore

Singapore, 23 April 2020: A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence is now commercially available to Singapore patients.

The drug, NERLYNX (neratinib), is an oral medication taken by women with breast cancer who have had surgery, chemotherapy and prior trastuzumab-based therapy.

It has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients,2 with the greatest benefit seen in women who are also hormone-receptor positive (HR+) and who commence therapy within

12 months of completing trastuzumab-based therapy. For these women, the five-year risk of recurrence is reduced by up to 42%.[1]

NERLYNX is being made available in the region by independent pharmaceutical company, Specialised Therapeutics Asia (STA) under an exclusive sub-license agreement with Puma Biotechnology, Inc.

A number of patients in Singapore have already been treated with NERLYNX since it was made available via a named patient access program prior to regulatory approval.

Dr Yap Yoon Sim, medical oncologist at the National Cancer Centre, who was an investigator in the ExteNET trial which led to the approval of NERLYNX, said the introduction of NERLYNX provided breast cancer patients with a new option to further reduce their risk of recurrence.

“Certain patients with HER2+ breast cancer may still have a significant risk of relapse, even after being treated with standard chemotherapy and trastuzumab-based therapy,” Dr Yap said.

“This risk can vary from less than 10% to more than 30% during the first five years, depending on the size of the tumour and the number of lymph nodes affected.

“We know the risk of recurrence continues even five years post-diagnosis, especially in patients with hormone-receptor positive breast cancer.

“NERLYNX may now provide additional benefit in terms of reducing this risk of relapse, particularly to women with high-risk disease.

“Essentially it gives patients another opportunity to remain disease-free.”

STA Chief Executive Officer Mr Carlo Montagner said oncologists had welcomed the introduction and availability of NERLYNX, with more than 1600 women in Singapore diagnosed with breast cancer every year.

“We are pleased to be able to make this important therapy available to women in Singapore and further expect to ensure its availability in other parts of South-East Asia, including Malaysia and Brunei,” he said.

Singapore health data shows that breast cancer is the most common cancer that affects 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]

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 Australian TGA, the US Food and Drug Administration (FDA)4 and the European Medicines Agency (EMA)[5] 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).

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.[6]

About the ExteNET Study[2,7]

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 randomised 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.[7]

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 2 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.

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 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 Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. NERLYNX was granted marketing authorization by the European Commission in 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

- • NERLYNX® (neratinib) **now commercially available** in Singapore for HER2+ breast cancer patients following adjuvant trastuzumab-based therapy
- • Five-year follow up data show NERLYNX reduces risk of invasive disease recurrence by 42% in women with early-stage, HER2+/HR+ breast cancer and who commence therapy within 12 months of completing trastuzumab-based therapy[1]

Further Inquiries

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Specialised Therapeutics Signs Exclusive Deal for New Haematology Drug

Singapore, 18 December, 2019: Independent pharmaceutical company Specialised Therapeutics Asia (STA) has signed an exclusive license deal with US-based Onconova Therapeutics (NASDAQ: ONTX), securing commercialisation rights to a new therapy for the treatment of Myelodysplastic Syndrome (MDS).

The drug, known as rigosertib, is currently in a Phase 3 clinical trial to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who have progressed on, failed to respond to, or relapsed after first-line treatment. The trial is over 90% enrolled and has clinical trial sites open in Australia.

STA Chief Executive Officer, Mr Carlo Montagner, said patients with high-risk MDS had limited treatment options following currently available first-line treatment.

“There is no currently approved treatment following failure of standard chemotherapy with hypomethylating agents. Patients are left with the option of entering clinical trials if available, or supportive care,” he said.

“If approved, rigosertib would address a clear unmet medical need and may be a valuable inclusion to the STA therapeutic portfolio.”

“We are delighted to enter into this collaboration with Onconova and look forward to the results of the ongoing phase III INSPIRE trial of intravenous (IV) rigosertib.”

MDS includes a group of diseases which impact the production of normal blood cells in the bone marrow. MDS is more common in elderly people, with 90% of patients diagnosed over age 60, although it can present at any age.[1]

Onconova Therapeutics’ President and Chief Executive Officer Dr Steven Fruchtman commented: “We are pleased to partner with Specialised Therapeutics Asia, which has a strong track record of commercialising new products in

oncology and haematology across Australia and New Zealand, We look forward to working together and following a successful readout of the ongoing INSPIRE Trial, potentially providing rigosertib as a new therapeutic option for patients diagnosed with MDS.”

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 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.

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About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company discovering and developing novel small molecule drug candidates to treat cancer, with a focus on Myelodysplastic Syndromes (MDS). Using a proprietary chemistry platform, Onconova has created a pipeline of targeted agents designed to work against specific cellular pathways that are important in cancer cells. Advanced clinical trials with the Company’s lead compound, rigosertib, are aimed at what the Company believes are unmet medical needs of patients with MDS. Onconova has conducted trials with two other research compounds and has a pre-clinical program with a CDK4/6 and Ark5 inhibitor, ON 123300.

For more information, please visit http://www.onconova.com.

About Myelodysplastic Syndromes

MDS is a group of blood disorders that affect bone marrow function, whereby the bone marrow cells appear dysplastic and their capacity to produce cells is defective. As a result, patients with MDS have low blood cell counts and require frequent blood transfusions. In approximately one-third of patients, higher-risk MDS can progress to acute myeloid leukaemia (AML).

The Leukemia Foundation of Australia estimates that an incidence of between four to five per 100,000 of the population. However, in patients over the age of 60, this increases to anything from 20 to 50 per 100,000.[1]

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model described rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in first-line and refractory higher-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About the INSPIRE Phase 3 Clinical Trial

The INternational Study of Phase 3 IV RigosErtib, or INSPIRE, clinical trial was finalised following guidance received from the U.S. Food and Drug Administration and European Medicines Agency. INSPIRE is a global, multi-center, randomised, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who had progressed on, failed to respond to, or relapsed

after previous treatment with a hypomethylating agent (HMA) within nine cycles over the course of one year after initiation of HMA treatment. This time frame optimises the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. Patients are randomised at a 2:1 ratio into two study arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. The trial continued beyond the pre-specified interim analysis and is nearing its conclusion. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

- • STA secures exclusive commercialisation rights for AU and NZ
- • Rigosertib is a promising new compound to treat Myelodysplastic Syndrome, which has limited treatment options

Further Inquiries

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New Early Breast Cancer Drug Approved by Singapore Health Sciences Authority

Singapore, 3 December, 2019: A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence has received approval in Singapore – at least six months ahead of its expected schedule.

The drug, NERLYNX (neratinib), is an oral medication taken by women with breast cancer who have had surgery, chemotherapy and prior trastuzumab-based therapy.

It has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients,[2] with the greatest benefit seen in women who are also hormone-receptor positive (HR+) and who commence therapy within 12 months of completing trastuzumab-based therapy. For these women, the five-year risk of recurrence is reduced by up to 42%.[1]

NERLYNX is being made available in the region by independent pharmaceutical company, Specialised Therapeutics Asia (STA) under exclusive license from Puma Biotechnology Inc.

Already 13 women in Singapore have been treated with NERLYNX since it was made available recently via a special access program. The number of patients on therapy is now expected to rise.

The HSA approval is **"for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy"**.

STA Chief Executive Officer Mr Carlo Montagner said the decision to approve NERLYNX in Singapore was a key milestone for the company.

"NERLYNX is the first drug in our portfolio to be approved by the HSA for commercialization in Singapore," he said.

“We look forward to extending the reach of this medicine, with regulatory dossiers also submitted in Malaysia, Brunei and the Philippines.”

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 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 that affect 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]

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.

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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

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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]

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Puma is conducting a Phase 2 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.

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 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.

- • NERLYNX® (neratinib) now approved in Singapore for HER2+ breast cancer patients following adjuvant trastuzumab-based therapy
- • NERLYNX is the first therapy in the Specialised Therapeutics' portfolio approved in SE Asia
- • Five-year follow up data show NERLYNX reduces risk of invasive disease recurrence by 42% in women with early-stage, HER2+/HR+ breast cancer and who commence therapy within 12 months of completing trastuzumab-based therapy [1]

Additional information can be found at www.stbiopharma.com

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7. Martin M et. Al. Lancet Oncology 2017; 1-13

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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