Specialised Therapeutics Enters into a New Supply and Distribution Agreement with Incyte to Launch Two New Cancer Therapies

Singapore, 22 October 2021: Independent pharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) will partner with Incyte Biosciences International Sàrl, the Swiss-based affiliate of Incyte (NASDAQ:INCY), to launch and distribute two new medicines for its haematology and oncology portfolios, tafasitamab (sold as Monjuvi® in the United States and Minjuvi® in Europe) and pemigatinib (Pemazyre®).

Under the terms of the agreement, Incyte will be responsible for the development, manufacture and supply of both products and ST will be responsible for regulatory, distribution and local marketing related activities in Australia, New Zealand and Singapore.

Pemigatinib is approved in the United States, Europe and Japan for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Tafasitamab in combination with lenalidomide is approved in the United States and Europe for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

ST Chief Executive Officer Mr Carlo Montagner said the new products were synergistic with the company's strong oncology and haematology portfolios, and the new agreement was further endorsement of ST's regional capabilities.

"We are proud to have been selected to partner with a world-leading biotech of Incyte's calibre and look forward to these important products in our key regions," he said.

“Both pemigatinib and tafasitamab address strong unmet needs in rare patient populations. We have extensive experience and a successful track record of working with clinicians and other stakeholders to bring innovative therapies to small patient populations where there is high unmet clinical need. Our teams look forward to working closely with Incyte to ensure all eligible patients have access to these therapies at the earliest opportunity.”

Incyte CEO Hervé Hoppenot said the latest collaboration and partnership provided an important strategic opportunity to further serve the global oncology community, offering innovative new medicines to patients with high unmet needs in Australia, New Zealand and Singapore.

“ST’s expertise in these regions, navigating complex regulatory channels to bring new therapies and technologies to patients with rare cancers, is complementary to our own commitment to positively impact the lives of patients with serious unmet medical needs,” he said. “We look forward to a successful and mutually beneficial partnership, working together with a shared goal of improving patient outcomes.”

Regulatory activities for both products are currently in progress.

Ends.

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST) 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. ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company’s broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com

About Tafasitamab

Tafasitamab is a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

In January 2020, MorphoSys and Incyte entered into a Collaboration and License agreement to further develop and commercialize tafasitamab globally. Monjuvi® is being co-commercialized by Incyte and MorphoSys in the United States. Incyte has exclusive commercialization rights outside the United States.

In the United States, Monjuvi® (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional approval, in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

 Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in the EU.

XmAb® is a trademark of Xencor, Inc.

About Pemigatinib

Pemigatinib (Pemazyre®) is a kinase inhibitor indicated in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Japan, Pemazyre is approved for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy.

In Europe, Pemazyre is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Pemazyre is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 that, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations.

Pemazyre is marketed by Incyte in the United States, Europe and Japan. Incyte has established various license or distribution agreements for Pemazyre in certain geographies and retains all other rights to develop and commercialize pemigatinib outside of the United States.

Pemazyre is a trademark of Incyte.

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

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

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

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

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

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

"We are delighted to make this important new therapy available to Australian

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

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

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

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

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

Ends.

About Specialised Therapeutics Asia

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

ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology,

ophthalmology and supportive care.

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

About ILUVIEN

ILUVIEN (fluocinolone acetonide intravitreal implant) delivers 0.19 mg fluocinolone acetonide via a sustained release intravitreal implant indicated to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Each ILUVIEN implant with its continuous microdosing delivery is designed to release submicrogram levels of fluocinolone acetonide, a corticosteroid, for 36 months, enabling the physician to treat this persistent disease consistently every day. ILUVIEN is contraindicated in the presence of pre-existing glaucoma or active or suspected ocular or periocular infection. The most frequently reported adverse drug reactions included cataract operation, cataract and increased intraocular pressure. www.ILUVIEN.com

About Diabetic Macular Oedema (DME)

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

About Alimera Sciences, Inc.

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

information, please visit www.alimerasciences.com.

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

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

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

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

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

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

"Track and trace technologies enable us and our partners to ensure safe drug distribution chains, and to implement any product recalls as rapidly as possible," Mr Montagner said.

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

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

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

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

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

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

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

About Specialised Therapeutics Asia

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

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

approved for use in Australian patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Puma Biotechnology’s CEO and President Alan H. Auerbach added: “Reducing the risk of disease recurrence remains a need for patients, despite advances in the treatment of early-stage HER2-positive breast cancer. We are pleased that our partner STA will be bringing this new medicine to patients throughout Australia and would like to express our appreciation to the patients, caregivers and physicians who contributed to the neratinib clinical development program and more specifically, the ExteNET trial. We are committed to continuing to expand NERLYNX accessibility to patients around the world.”

Ends.

About NERLYNX

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER[4.5,6]

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

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

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

Click on this link for AU Product Information:

https://www.stabiopharma.com/assets/files/d-nerlynx_pi.pdf

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

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

About HER2+ Breast Cancer

Approximately 15−20% of breast cancer tumours over-express the HER2 protein. HER2+ breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early-stage HER2-positive breast cancer returning after surgery, up to 25% of patients treated with trastuzumab-based adjuvant therapy experience recurrence.[4]

About the ExteNET Study[1,6]

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

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

The primary endpoint of the trial was invasive disease free survival (iDFS). The trial demonstrated that after a median follow up of 5.2 years, treatment with neratinib resulted in a 27% reduction of risk of invasive disease recurrence or

death versus placebo (hazard ratio = 0.73, p = 0.008). The 5-year iDFS rate for the neratinib arm was 90.2% and the 5-year iDFS rate for the placebo arm was 87.7%.[7]

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

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

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

About Specialised Therapeutics Asia

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.

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2. Australian Approved Product Information, March 2019
3. Gnant M, et al. SABCS 2018 P2-13-01
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5. NERLYNX (neratinib) U.S. Food and Drug Administration Prescribing Information
6. NERLYNX (neratinib) European Medicines Agency Summary of Product Characteristics
7. Martin M, et. al. Lancet Oncol. Dec 2017;18(12):1688-1700

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

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

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

NERLYNX has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients.[1] The greatest benefit was observed in women who were also hormone-receptor positive (HR+) and treated within 12 months following completion of trastuzumab-based adjuvant therapy. Their five-year risk of recurrence or death was reduced by 42%. In these patients, invasive disease-free survival (iDFS) was 90.8% in the patients treated with neratinib, compared with 85.7% in those receiving placebo (hazard ratio = 0.58; 95% CI: 0.41−0.82; p = 0.002).

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

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

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

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

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

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

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

Singapore health data shows that breast cancer is the most common cancer in

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

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

About NERLYNX

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4.[4,5]

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

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.

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

World-First Approval for Multiple Myeloma Drug Aplidin®

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Ends.

About APLIDIN® (plitidepsin)

Plitidepsin is an anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including combination studies in relapsed or refractory multiple myeloma, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma.

About Multiple Myeloma in Australia

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

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

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

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide innovative specialist therapies and technologies to patients throughout South East Asia, as

well as in Australia and New Zealand. ST Asia's existing product portfolio spans oncology, haematology, neurology, urology and ophthalmology. Additional information can be found at www.stbiopharma.com

About PharmaMar

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

Further Inquiries

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Specialised Therapeutics to Collaborate with Pharmacy Phusion to Improve Patient Outcomes

Singapore, 2 November 2018: Independent pharmaceutical company Specialised Therapeutics (ST) has struck a new agreement with specialty pharmacy services group Pharmacy Phusion to assist with the distribution and patient support for a new medicine that treats HER2 overexpressing early-stage breast cancer.

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

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

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

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

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

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

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

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

Pharmacy Phusion's Group Professional Manager Mark Silcock said the group

works across a range of complex therapy areas, but all expert pharmacists engaged in customer support programs are experienced and uniquely positioned to support patients prescribed new and often complex medicines.

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

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

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

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

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

Ends.

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About Specialised Therapeutics Asia

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

ST collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing therapies and technologies to patients affected by a range of diseases. ST remains committed to making new and novel

therapies available to patients in its key regions of Australia, New Zealand and throughout South-East Asia, targeting diseases where there remains an unmet medical need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com.

Specialised Therapeutics Celebrates 10 Years and Unveils Expansion Plan

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

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

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

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

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

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

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

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

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

Ends.

Media Inquiries:
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About Specialised Therapeutics Australia

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

Specialised Therapeutics Asia Initiates Early Access Program for Neratinib

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

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

relevant regulatory authorities.

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

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

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

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About Neratib[1]

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

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

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

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

About Special Access Programs

Special Access Programs enable pharmaceutical companies a means of providing ethical access to off-label or unapproved medicines to assist patients where there is an unmet medical need. Enrolment in any access program is only provided following request from an appropriate medical professional. Special Access Programs are strictly overseen to ensure full compliance, and are opened when no alternative treatment options are available.

About Specialised Therapeutics Asia

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

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

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Federal Government Rejects Funding Bid for Novel Breast Cancer Test That May Spare Women from Chemotherapy

Oncotype DX® breast cancer assay may spare thousands of women from chemotherapy
Medical Services Advisory Committee has now rejected five funding applications for Oncotype DX

Melbourne, Australia, 4 October 2017: THE Federal Government's peak advisory committee for Medicare funding has rejected calls from doctors, patients and the pharma industry to fund a novel breast cancer test that may spare thousands of Australian women from enduring unnecessary chemotherapy.

The Health Department's Medical Services Advisory Committee (MSAC) recommended against funding the expensive Oncotype DX breast cancer assay for Australian women – despite it being reimbursed and freely available to women in many other countries, including the United States, Canada, the United Kingdom and throughout Europe.

This genetic test identifies those women who could safely avoid chemotherapy, by analysing the activity of specific cancer genes taken from a single sample of tumour tissue. It is suitable for breast cancer patients who have hormone receptor positive, HER2 negative, early stage breast cancer, which is a common form of breast cancer affecting thousands of Australian women.

The test provides a prognosis of the likelihood the cancer will recur. It is also able to provide medical teams with predictive information, identifying tumours that would be more sensitive to chemotherapy.

Specialised Therapeutics Australia has made the test available in Australia since 2014 to those women who are able to afford the $4500 out of pocket cost. Since 2014, more than 1,000 men and women diagnosed with breast cancer have paid for an ODX test allowing them and their medical team to make a more informed decision about their treatment.

In the US, Canada, the UK and Europe, the Oncotype DX test is reimbursed, widely available and consistently shown to be cost-effective. It has spared many patients from enduring unnecessary and debilitating chemotherapy.

Respected Australian surgical oncologist and specialist breast surgeon, Professor Bruce Mann said he was “very disappointed” by the decision, noting the test had been shown to change treatment decisions in many cases. He said that most frequently, it enabled patients to avoid chemotherapy. But sometimes, test results indicated that chemotherapy was the best treatment path.

“Many breast cancer patients simply cannot afford the high costs of this test and so are making treatment decisions without all potentially available information,” Professor Mann said.

“Having access to funded tests would allow limited health resources to be directed towards those who will benefit most.”

Australian breast surgeon Miss Jane O’Brien said that while the test frequently helped identify those women who could avoid unnecessary chemotherapy, it was also able to identify those for whom chemotherapy should be recommended.

“Without Oncotype, some patients may face the prospect of being under-treated,” she said.

“I have had patients who have taken the test and been advised to proceed with chemotherapy, when perhaps medical oncologists would have been confident in recommending anti-hormone therapy alone, based on the standard criteria that we have historically used. I think it is a great pity this test is not widely funded for all appropriate Australian patients.”

The Oncotype DX breast cancer assay measures the expression of 21 cancer-related genes to provide a Recurrence Score® result, a number between 0 and 100.

A low Recurrence Score result is associated with a better prognosis and the likelihood that there would be little to no benefit in being treated with chemotherapy. Conversely, a high result would indicate a poorer prognosis, however chemotherapy is likely to be effective and reduce the risk of recurrence.

The Oncotype DX breast cancer assay is suitable for women diagnosed with hormone-receptor positive, HER-2 negative breast cancer. The test is performed on tumour tissue removed during original surgery and patients are advised to have the test soon after surgery and before commencing follow up treatment.

The Oncotype DX test was developed by Genomic Health, Inc. (NASDAQ: GHDX) a world leading provider of genomic-based diagnostic tests that optimise treatment for early stage cancer. The company is based in California in the USA.
The Oncotype DX breast cancer assay is made available in Australia by international biopharmaceutical company Specialised Therapeutics Australia at a cost of $4,500.

Specialised Therapeutics' Chief Executive Officer Mr Carlo Montagner said he was dismayed and frustrated by the latest MSAC decision, which follows five funding applications for Oncotype DX in Australia.

"This simply means that Australian women continue to be at a disadvantage," he said. "This test is widely available and reimbursed for women in most developed countries, including the United States and the United Kingdom.

"It seems that in Australia, only the 'haves' of our society can benefit from this cutting edge technology. What a pity, in this age of personalised medicine and especially at a time when the Government has acknowledged a commitment to innovation. Our belief in this technology is validated by clinical data and the experience of doctors and patients from around the world. We are lagging behind."

Specialised Therapeutics Australia will now seek to meet with health department authorities to reconsider the funding application.

Ends.

About the Specialised Therapeutics Group

The Specialised Therapeutics (ST) group of companies 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 in Australia, New Zealand and throughout South East Asia. ST is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Further information can be found at www.STAbiopharma.com

About Oncotype DX®

The Oncotype DX portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumour in order to optimise cancer treatment decisions. The company's flagship product, the Oncotype DX Breast Recurrence Score® test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. With more than 800,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalised medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com or www.MyBreastCancerTreatment.org.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care, including addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ® Genomic Intelligence Platform™, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of

Oncotype DX® gene expression tests that have been used to guide treatment decisions for more than 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select™ test. The company is based in Redwood City, California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.