New Therapy for Rare Gastrointestinal Stromal Tumours Approved in Singapore

- *Singapore's Health Sciences Authority (HSA) has approved QINLOCK® (ripretinib) for the treatment of patients with 4th line GIST*
- *QINLOCK significantly reduced the risk of disease progression or death by 85% and showed clinically meaningful overall survival in the INVICTUS Phase 3 Study[1,2]*

Singapore, 8 May 2023: Independent biopharmaceutical company Specialised Therapeutics Asia (ST) is pleased to announce that a new therapy to treat rare gastrointestinal stromal tumours (GIST) shown to improve survival has been approved for use in Singapore.

The therapy, QINLOCK (ripretinib) is now approved by the Health Sciences Authority (HSA) "***for the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib, sunitinib, and regorafenib***".

Singapore-based senior consultant in medical oncology Dr Richard Quek said QINLOCK represented a major treatment advancement for patients with advanced GIST.

"Since 2013, despite multiple attempts and studies, no therapy was shown to be effective for 4th line GIST patients whose cancers have progressed on existing treatment, until the discovery of QINLOCK," Dr Quek said.

In the pivotal INVICTUS study that led to QINLOCK's approval, QINLOCK was shown to significantly delay cancer progression.

“This approval in Singapore clearly provides an opportunity for us to improve the outcomes of our GIST patients who are refractory to the current existing treatment.”

QINLOCK is an oral medication used to treat GIST in people who have received at least three prior treatments. It belongs to a drug class called tyrosine kinase inhibitors and works by blocking specific tumour proliferation pathways.[2]

A pivotal Phase 3 clinical trial of QINLOCK – the INVICTUS study – demonstrated that QINLOCK was able to significantly reduce the risk of disease progression by 85% (hazard ratio of 0.15, $p<0.0001$) with a median progression-free survival of 6.3 months in patients administered QINLOCK, compared to 1.0 month in the placebo arm.[1] QINLOCK was associated with clinically meaningful overall survival of 15.1 months vs 6.6 months and reduced the risk of death by 64% (hazard ratio of 0.36). The objective response rate by Blinded Independent Central Review using modified Response Evaluation Criteria in Solid Tumors (RECIST) was 9.4% with QINLOCK vs 0.0% with placebo ($p=0.0504$).[1,3]

In addition, in a long-term follow up analysis of the INVICTUS trial, patients in the QINLOCK arm demonstrated a median overall survival of 18.2 months compared to 6.3 months in the placebo arm and reduced the risk of death by 59% (hazard ratio of 0.41).The objective response rate was 11.8% with QINLOCK vs 0.0% with placebo.[3]

ST Chief Executive Officer Carlo Montagner said the Singapore approval followed the recent approval of QINLOCK in New Zealand, as well as regulatory and reimbursement approval in Australia.

“Achieving these critical regulatory milestones is testament to the dedication of our regulatory teams to make QINLOCK available to all eligible patients in Singapore who are impacted by this rare gastrointestinal cancer.”

ST commercialises QINLOCK in Singapore under an exclusive distribution agreement from US based Deciphera Pharmaceuticals.

Further Inquiries can be directed to ST Senior Manager Communications and Corporate Affairs Emma Power on + 65 31589910 epower@stbiopharma.com

About GIST

Gastrointestinal stromal tumour (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST growth usually begins in the connective tissue in the wall of the affected organ and grows outwards. The common location of GIST is in the stomach (50 to 60%) and small intestines (30 to 40%) but can occur in any site in the digestive system. Other possible GIST sites are the oesophagus, rectum, and colon. GIST cases are rare and estimated to cause between 0.1% and 3% of GI cancer. The risk of GIST diagnosis increases with age, with GIST incidence peaking among people in their fifties and sixties.[4]

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRA 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. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.[5,6]

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients in Australia, New Zealand and across 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. Our mission is to provide therapies that would otherwise not be available to communities in our regions. 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 the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomised, 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 at least imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK once daily (n=85) or placebo (n=44). The primary efficacy endpoint was 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 in the QINLOCK arm 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, $p<0.0001$) compared to placebo.[1] Secondary endpoints included Objective Response Rate (ORR) as determined by independent radiologic review using modified RECIST and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p=0.0504$), which was not statistically significant.[1] QINLOCK 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).[1] In a long-term follow up of 19 months after the primary analysis, QINLOCK also demonstrated a median OS of 18.2 months compared to 6.3 months in the placebo arm and reduced the risk of death by 59% (hazard ratio of 0.41).[3] The most common (>2%) grade 3 or 4 treatment related adverse events in the QINLOCK group included lipase increase (5%), hypertension (4%), fatigue (2%), and hypophosphataemia (2%); and in the placebo group, anaemia (7%), fatigue (2%), diarrhoea (2%), decreased appetite (2%), dehydration (2%), hyperkalaemia (2%), acute kidney injury (2%), and pulmonary oedema (2%).[1,4]

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Global Sarcoma Therapy Now Approved for New Zealand Patients

Singapore and Auckland, New Zealand, 17 February 2023: Independent biopharmaceutical company Specialised Therapeutics (ST) is pleased to announce that its portfolio therapy to treat rare soft tissue sarcomas has now been

approved in New Zealand.

New Therapy to Treat Rare Gastrointestinal Stromal Tumour Approved for New Zealand Patients

Singapore and New Zealand, 20 January 2023: Independent biopharmaceutical company Specialised Therapeutics Asia (ST) is pleased to announce that a new therapy to treat rare gastrointestinal stromal tumour (GIST) shown to improve survival has now been approved in New Zealand.

New Treatment for Rare Cancer Cholangiocarcinoma Approved in Australia

Melbourne, Australia 15 September 2022: A NEW targeted therapy to treat a rare bile duct cancer called cholangiocarcinoma has been approved for use in Australia.

New Therapy for Rare Gastrointestinal Stromal Tumours Accepted in Singapore for Regulatory Evaluation

Singapore, 12 July 2022: A novel therapy to treat rare gastrointestinal stromal tumours (GIST) has been accepted for evaluation by Singapore's Health Sciences Authority.

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.

Minjuvi® and Monjuvi® are registered trademarks of MorphoSys AG. 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

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.

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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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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.

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 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, over 25% 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 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.[7]

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.

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.

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