New Early-Breast Cancer Drug to be Made Available in Australia, New Zealand and South East Asia following License Deal

Singapore, 23 November 2017:

A NEW breast cancer drug shown to reduce the risk of cancer recurrence will soon be made available in Australia, New Zealand and throughout South-East Asia, following a key license deal between Specialised Therapeutics Asia (ST Asia) and US biopharmaceutical company Puma Biotechnology, Inc. (NASDAQ: PBYI).

Under the terms of the exclusive arrangement, Specialised Therapeutics will market the drug NERLYNX® (neratinib) throughout the Asia-Pacific, beginning with Australia, Singapore, Malaysia and Brunei.It will be available to women with early-stage, HER2+ breast cancer following standard of care adjuvant chemotherapy and 12 months of trastuzumab-based therapy.

Commercial terms of the agreement are not being disclosed, but Puma will receive an upfront payment as well as milestones and other payments on NERLYNX sales in all ST Asia regions.

NERLYNX is the first treatment to be FDA approved for extended adjuvant therapy in early-stage HER2+ breast cancer following adjuvant trastuzumab-based therapy.

Results from a double blind, placebo-controlled, randomised Phase 3 study showed that NERLYNX reduces the risk of invasive disease recurrence or death by 27% compared to placebo after a median follow up of 5.2 years. The 5-year invasive disease-free survival (iDFS) rate for the NERLYNX arm was 90.2% compared to 87.7% in the placebo arm ($p=0.008$).[1]

For the pre-defined subgroup of patients with hormone receptor positive disease, approximately 57% of the overall study population, the results of the trial demonstrated that at 5 years, treatment with neratinib resulted in a 40%

reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.60, p = 0.002).[3] In this sub-group, the 5-year iDFS rate for the neratinib arm was 91.2% compared to 86.8% in the placebo arm.[1]

The safety results showed the most frequently observed adverse event for the NERLYNX-treated patients was diarrhoea, with approximately 40% of the NERLYNX-treated patients experiencing grade 3 or higher diarrhoea (1 patient (<1%) had grade 4 diarrhoea). Patients who received NERLYNX in this trial did not receive any prophylaxis with anti-diarrhoeal agents.[1,2]

Principal trial investigator, Professor Arlene Chan, said the availability of NERLYNX in Australia and other regions was an important step forward in further reducing recurrence in HER2+ early breast cancer.

“This is a drug that provides a potential cure for some women who may otherwise have had a recurrence,” she said.

“Despite the clear proven benefit of standard of care chemotherapy and trastuzumab therapy, one in four women diagnosed with early-stage HER2+ breast cancer can still have a relapse within five years.

“This drug will now prevent some of those women from experiencing that recurrence.

“My hope and expectation is that with longer follow up, not only will recurrence rates be reduced, but they will show that the use of NERLYNX will improve overall survival.”

Specialised Therapeutics Chief Executive Officer Carlo Montagner said NERLYNX was a valuable inclusion to the company’s expanding oncology portfolio.

“We are thrilled to be able to provide this therapy to women in our regions, working in collaboration with our new international partner, Puma Biotechnology,” he said.

“We plan to expedite access to this important medicine, with a Special Access Program to open in Australia in Q1 2018. This will provide early subsidised access for appropriate patients. In tandem, we will file for TGA registration and seek regulatory approval to market in other regions, including Singapore, Brunei,

Malaysia and New Zealand."

President and CEO of Puma Biotechnology Alan H. Auerbach said this license agreement demonstrates the commitment to bringing NERLYNX to patients around the world.

"We are confident this new partnership with ST Asia will ensure all appropriate patients in the region can access this new medicine at the earliest opportunity," he said.

NERLYNX is an oral medication taken after chemotherapy and after 12 months of treatment with a trastuzumab-based therapy, which is the global standard of care.

About NERLYNX[4]

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

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

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

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

About HER2+ Breast Cancer

Approximately 20% to 25% of breast cancer tumours over-express the HER2 protein. HER2+ breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early-stage HER2-positive breast cancer returning after surgery, up to 24% of patients treated with trastuzumab experience recurrence.[1]

About the ExteNET Study[1, 2]

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

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

The primary endpoint of the trial was invasive disease free survival (iDFS). The trial demonstrated that after a median follow up of 5.2 years, treatment with neratinib resulted in a 27% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.73, p = 0.008). The 5-year iDFS rate for the neratinib arm was 90.2% and the 5-year iDFS rate for the placebo arm was 87.7%.

A secondary endpoint of the trial was invasive disease free survival including ductal carcinoma in situ (iDFS-DCIS). The trial demonstrated that treatment with neratinib resulted in a 29% reduction of risk of disease recurrence including DCIS or death versus placebo (hazard ratio = 0.71, p = 0.004). The 5-year iDFS-DCIS rate for the neratinib arm was 89.7% and the 5-year iDFS-DCIS rate for the placebo arm was 86.8%.

For the pre-defined subgroup of patients with hormone receptor positive disease,

approximately 57% of the overall study population, the trial demonstrated that at 5 years, treatment with neratinib resulted in a 40% reduction of risk of invasive disease recurrence or death versus placebo. In this sub-group, the 5-year iDFS rate for the neratinib arm was 91.2% compared to 86.8% in the placebo arm (hazard ratio = 0.60, p = 0.002).[3]

The safety results showed the most frequently observed adverse event for the neratinib-treated patients was diarrhoea, with approximately 40% of the neratinib-treated patients experiencing grade 3 or higher diarrhoea (1 patient (<1%) had grade 4 diarrhoea).

Puma is conducting the Phase 2 CONTROL study investigating a structured prophylactic regimen of loperamide for the first 1-2 cycles of neratinib therapy. Emerging data suggest that loperamide prophylaxis reduces the incidence, severity and duration of neratinib-associated diarrhoea as compared with events observed in ExteNET.

About Puma Biotechnology, Inc.

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialisation of innovative products to enhance cancer care. The Company in-licenses the global development and commercialisation rights to three drug candidates — PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. NERLYNX is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX.

Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand.

ST Asia and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases. ST Asia is committed to making new and novel therapies available to patients around the world, targeting diseases where there remains an unmet medical need. STA's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stabiopharma.com

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- Specialised Therapeutics Asia to make NERLYNX® (neratinib) available in Australia, New Zealand and South-East Asia for women with early-stage, HER2+ breast cancer following exclusive license agreement
- Five-year follow up data shows NERLYNX reduces risk of invasive disease recurrence by 27% in women with early-stage, HER2+ breast cancer

- Special Access Program to open in Australia Q1 2018 followed by other countries in the territory

References:

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