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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