New Early Breast Cancer Drug Available Now in Singapore

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

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

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

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

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

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

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

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

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

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

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

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

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

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

About NERLYNX[4]

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

NERLYNX is the first HER2-targeted medication approved by the Australian TGA, the US Food and Drug Administration (FDA)4 and the European Medicines Agency (EMA)[5] as extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer, for patients who have previously been treated with trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).

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

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

About HER2+ Breast Cancer

Approximately 20% to 25% of breast cancer tumours over-express the HER2 protein. HER2+ breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early-stage HER2-positive breast cancer returning after surgery, up to 24% of patients treated with trastuzumab experience recurrence.[6]

About the ExteNET Study[2,7]

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

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

The primary endpoint of the trial was invasive disease free survival (iDFS). The trial demonstrated that after a median follow up of 5.2 years, treatment with neratinib resulted in a 27% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.73, p = 0.008). The 5-year iDFS rate for the neratinib arm was 90.2% and the 5-year iDFS rate for the placebo arm was 87.7%.[7]

An additional five-year sub-group analysis demonstrated a 42% risk reduction in

women who were HR+ and who had commenced neratinib therapy within 12 months of completing treatment with trastuzumab.[7]

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

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

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies throughout South East Asia, as well as in Australia and New Zealand. STA and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.stbiopharma.com

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization

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

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

Further Inquiries

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