

# New Early Breast Cancer Drug Approved by Singapore Health Sciences Authority

**Singapore, 3 December, 2019:** A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence has received approval in Singapore – at least six months ahead of its expected schedule.

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,<sup>2</sup> 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%.<sup>1</sup>

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

Already 13 women in Singapore have been treated with NERLYNX since it was made available recently via a special access program. The number of patients on therapy is now expected to rise.

The HSA approval is **“for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy”**.

STA Chief Executive Officer Mr Carlo Montagner said the decision to approve NERLYNX in Singapore was a key milestone for the company.

“NERLYNX is the first drug in our portfolio to be approved by the HSA for commercialization in Singapore,” he said.

“We look forward to extending the reach of this medicine, with regulatory dossiers also submitted in Malaysia, Brunei and the Philippines.”

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 trial of NERLYNX, ExteNET.<sup>2</sup>

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 that affect 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.<sup>3</sup>

## About NERLYNX<sup>4</sup>

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)<sup>4</sup> and the European Medicines Agency (EMA)<sup>5</sup> 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.<sup>6</sup>

## About the ExteNET Study<sup>2,7</sup>

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%.<sup>7</sup>

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.<sup>7</sup>

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.

- • NERLYNX<sup>®</sup> (neratinib) now approved in Singapore for HER2+ breast cancer patients following adjuvant trastuzumab-based therapy
- • NERLYNX is the first therapy in the Specialised Therapeutics' portfolio approved in SE Asia
- • 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 <sup>1</sup>

Additional information can be found at [www.stbiopharma.com](http://www.stbiopharma.com)

## Further Inquiries

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