# 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.

Additional information can be found at www.stbiopharma.com.

# Further Inquiries

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