

New Early Breast Cancer Drug to Reduce Risk of Recurrence or Death Now Available in Malaysia

- *NERLYNX[®] (neratinib) is approved by Malaysia's National Pharmaceutical Regulatory Agency (NPRA)*
- *Leading regional breast cancer oncologists say the availability of NERLYNX (neratinib) is a 'huge step forward' for Malaysian women who have been diagnosed with HER2+ early-stage breast cancer*
- *Five-year follow-up data shows NERLYNX reduces the 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 therapy¹*

Singapore, 29 March 2022: A NEW drug shown to significantly reduce the risk of cancer recurrence or death in an aggressive form of breast cancer is now available in Malaysia.

The drug, NERLYNX (neratinib) is an oral medication taken for 12 months by women who have been diagnosed with early stage HER2-positive (HER2+) breast cancer and who have received prior trastuzumab-based therapy.

It is approved in Malaysia **“for the extended adjuvant treatment of women with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago”.**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 is reduced by 42% after completing 12 months of NERLYNX therapy.¹

Malaysian breast cancer oncologist Dr Mastura Md Yusof from Cancer Centre at Pantai Hospital Kuala Lumpur said around 2500 women were diagnosed with early-stage breast cancer every year in Malaysia. She describes the availability of NERLYNX as “very welcome for many women and their families”.

“As oncologists treating these patients on the field, we welcome any new therapy that can give benefits to patients,” Dr Mastura said. “We know about thirty percent of early-stage breast cancer patients will relapse in the first three years after standard treatment. Any further treatment that we can provide to further reduce the risk of recurrence in some of these women must be considered.

“Malaysian women typically are very hardworking, and frequently are the main income generators in many households. If they develop breast cancer, we must give them the best shot at life so they can continue to live with dignity, and contribute to their family, work and society.”

NERLYNX is being made available by independent pharmaceutical company, Specialised Therapeutics (ST), in partnership with Zuellig Pharma Sdn Bhd, who will be distributing NERLYNX in Malaysia.

ST Chief Executive Officer Carlo Montagner said NERLYNX represented a new stage of treatment for Malaysian women.

“This is the first time Malaysian women are being presented with an opportunity for *extended*-adjuvant therapy that will reduce the risk of disease recurrence,” he said.

“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.”

Ends.

About NERLYNX

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal

transduction through the epidermal growth factor receptors, HER1, HER2 and HER4.²

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). NERLYNX is also the first anti-HER2 treatment to be European Commission (EC) approved as extended adjuvant therapy for early-stage HR+ / HER2-positive breast cancer following adjuvant trastuzumab-based therapy.²

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.²

About HER2+ Breast Cancer

Up to 20% of patients with breast cancer tumors over-express the HER2 protein (HER2-positive disease) and in the ExteNET study, 57% of patients were found to have tumors that were hormone-receptor positive. 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.³

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics (ST) is an international biopharmaceutical company providing new specialist therapies and technologies

to patients throughout Southeast Asia, as well as in Australia and New Zealand. ST 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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