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

- *NERLYNX® (neratinib) is approved by the Food and Drug Administration of the Philippines*
- *Leading regional breast cancer oncologists say the availability of NERLYNX is a 'great step forward' for women in the Philippines 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 therapy* [1]

Singapore, 8 July 2022: A NEW drug shown to significantly reduce the risk of cancer recurrence or death in an aggressive form of breast cancer is now approved by the Food and Drug Administration of the Philippines.

The drug, NERLYNX (neratinib) is an oral medication taken daily 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 has been approved by the Food and Drug Administration of the Philippines **"for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy."**

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]

Chair of the Philippines' Cardinal Santos Medical Center, Dr Ma. Luisa Abesamis-Tiambeng, said the NERLYNX approval was "a great step forward" for women in the Philippines who have been diagnosed with early breast cancer that is both HER2+ and HR+.

Dr Tiambeng commented: "We know that one in four women with this type of breast cancer are still at risk of recurrence, despite treatment with chemotherapy and trastuzumab-based therapy following their initial breast surgery. Following this important approval by the Food and Drug Administration of the Philippines, NERLYNX presents a new opportunity for women in this region to have extended adjuvant therapy to further reduce their chance of a relapse."

NERLYNX is being made available by independent pharmaceutical company, Specialised Therapeutics (ST).

ST Chief Executive Officer Carlo Montagner said NERLYNX was the first therapy in the company's therapeutic portfolio to achieve approval in the Philippines.

"There are regulatory nuances in every territory in which we operate, and this latest approval is a testament to the skill of our regulatory team, who are navigating complex jurisdictions," he said.

"From a patient perspective, this is the first time the women in the Philippines are being presented with an opportunity for *extended*-adjuvant therapy that will reduce the risk of disease recurrence.

"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 U. S Food and Drug Administration (FDA) for the extended adjuvant treatment of adult patients with early-stage HER2+ breast cancer, who have previously been treated with trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).[7] NERLYNX is also the first anti-HER2 treatment to be approved by the European Commission (EC) for the extended adjuvant treatment of adult patients with early-stage HR+ / HER2+ breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.[8]

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 tumours over-express the HER2 protein (HER2+ disease) and in the ExteNET study, 57% of patients were found to have tumours that were HR+. 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+ breast cancer returning after surgery, up to 25% of patients treated with trastuzumab-based adjuvant therapy experience recurrence within 10 years, the majority of which are metastatic recurrences.[3]

About the ExteNET Study[1,3,4]

The ExteNET trial was a double-blind, placebo-controlled, Phase III study of neratinib versus placebo after adjuvant treatment with trastuzumab and chemotherapy in patients with early-stage HER2+ breast cancer.

The ExteNET study randomised 2,840 patients in 41 countries with early-stage HER2+ 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) with a 34% reduction in the risk of recurrence and a 2.3% absolute benefit versus placebo at 2 years (HR=0.66; 95% CI: 0.49, 0.90 p=0.008). 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%.[1] In the overall survival (OS) analysis after a median follow-up of 8.0 years (range, 0-9.8 years), 53 (7.9%) of 670 patients in the neratinib group and 68 (10.2%) of 664 patients in the placebo group of the HR+/≤ 1-year population had died. The hazard ratio of OS was 0.79 (95% CI, 0.55-1.13), and the estimated 8-year OS rates were 91.5% (95% CI, 88.9%-93.5%) in the neratinib group and 89.4% (95% CI, 86.6%-91.6%) in the placebo group of the HR+/≤ 1-year population, giving an absolute between-group difference of 2.1%.[4]

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.[5]

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]

A Phase II CONTROL study investigated various prophylactic antidiarrhoeal regimens for the first 1-2 cycles of neratinib therapy. Data suggest that prophylactic management reduces the incidence, severity and duration of neratinib-associated diarrhoea as compared with events observed in ExteNET.[6]

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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