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ASIA EDITION

Malaysia approves new early breast cancer drug

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NERLYNXÃ?Â® (neratinib) reduces the reoccurrence risk of the disease for five years up to 42% in patients who have undergone surgery, chemotherapy, prior to trastuzumab-based therapy and HER2+ early breast cancer patients



A NEW breast cancer drug NERLYNX® (neratinib) shown to significantly reduce the risk of cancer recurrence is now approved for use by the National Pharmaceutical Regulatory Agency in Malaysia.

The drug is an oral medication taken post-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, 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%.

NERLYNX 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."

Nerlynx was also recently approved in Singapore by the Health Sciences Authority (HSA).

Independent pharmaceutical company, Specialised Therapeutics Asia (STA) is making NERLYNX available inSouth East Asia under exclusive license from Puma Biotechnology Inc.

STA Chief Executive Officer Mr Carlo Montagner said the latest approval in Malaysia after Singapore represents a key commercial milestone and highlights the company's expertise in navigating regulatory pathways in these complex regions.

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 trial of NERLYNX, ExteNET. "Despite the clear proven benefit of the standard of care chemotherapy and trastuzumab therapy, women diagnosed with early-stage HER2+ breast cancer are still at risk of disease recurrence. Its availability inMalaysia, as well as Singapore, would be "a huge step forward" to further reduce the risk of cancer recurrence in local women diagnosed with HER2+ early breast cancer" says Professor Chan.