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Medicines Update: Nerlynx - Puma Biotechnology

A new medicine shown to significantly reduce the risk of cancer recurrence or death in an aggressive form of breast cancer has been approved by the TGA for use in Australian patients. Nerlynx (neratinib) is an oral medication taken for 12 months by women with early stage HER2-positive (HER2+) breast cancer. It is indicated 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 or death is reduced by 42% after completing 12 months of Nerlynx therapy.

Professor Arlene Chan AM, from the Breast Cancer Research Centre Western Australia, 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.

Diarrhoea was the most common side effect of the medication, but evidence was being gathered that anti-diarrhoeal medications can substantially reduce these side effects.

A reimbursement application has been submitted to the Pharmaceutical Benefits

Advisory Committee and is currently under evaluation.