

# Specialised Therapeutics Asia Initiates Early Access Program for Neratinib

**Singapore, 5 April 2018:** Specialised Therapeutics Asia today announces the initiation of an early access program for neratinib, an extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer.

Under this Special Access Program (SAP) select patients in Australia will be provided access to the medicine, where appropriate and when permitted by relevant regulatory authorities.

The SAP protocol allows for neratinib to be available to patients with HER2 overexpressing cancers.

In all cases, the patient must have a special clinical need that cannot be met by currently approved and available medicines.

Specialised Therapeutics' neratinib Special Access Program follows the signing of a key license agreement with Puma Biotechnology Inc. (NASDAQ:PBYY) in November 2017, providing exclusive rights to commercialise neratinib in Australia, New Zealand and in South East Asia.

Ends.

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## About Neratinib<sup>1</sup>

Neratinib (NERLYNX<sup>TM</sup>) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4.

Neratinib is the first HER2-targeted medication approved by the US Food and Drug Administration (FDA) as extended adjuvant treatment for early-stage HER2-

positive (HER2+) breast cancer, for patients who have previously been treated with the medicine trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).

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.

Neratinib 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.

### **About Special Access Programs**

Special Access Programs enable pharmaceutical companies a means of providing ethical access to off-label or unapproved medicines to assist patients where there is an unmet medical need. Enrolment in any access program is only provided following request from an appropriate medical professional. Special Access Programs are strictly overseen to ensure full compliance, and are opened when no alternative treatment options are available.

### **About Specialised Therapeutics Asia**

Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand.

ST Asia 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. ST Asia is committed to making new and novel therapies available to patients around the world, targeting diseases where there remains an unmet medical need. STA's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at [www.stabiopharma.com](http://www.stabiopharma.com)

Further enquiries: ST Asia Communications Manager Emma Power is available on +61 419 149 525.

**References:**

1. NERLYNX<sup>®</sup> (neratinib) US Product Information (approved) [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/208051s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf)