

## **Puma biotech and Specialised Therapeutics signs agreement to commercialize NERLYNX®**

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Puma Biotechnology and Specialised Therapeutics Asia Enter into Exclusive Licensing Agreement to Commercialize NERLYNX® (neratinib) in Australia, New Zealand and South East Asia

Biopharma company Puma Biotechnology and Specialised Therapeutics Asia have entered into an exclusive agreement under which Specialised Therapeutics will commercialize NERLYNX® (neratinib) throughout South East Asia, beginning with Australia, Singapore, Malaysia, Brunei and New Zealand.

Specialised Therapeutics Asia is international biopharmaceutical company with strategic focus and expertise in Australia, New Zealand and South East Asia. Currently, Specialised Therapeutics markets Abraxane® and other oncology products in these countries.

NERLYNX is not approved currently for commercialization outside of the United States. Specialised Therapeutics will be responsible for seeking the requisite regulatory approvals and, once approved, for commercializing NERLYNX in those countries.

Puma will receive upfront and milestone payments of up to \$4.5 million throughout the term of this agreement, as well as significant double digit royalties on NERLYNX sales in all regions in which Specialised Therapeutics commercializes NERLYNX.

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets.

Approximately 20% to 25% of breast cancer tumors over-express the HER2 protein. HER2-positive 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 experience recurrence.

Alan H. Auerbach, Chief Executive Officer and President of Puma said, "Our new agreement with Specialised Therapeutics demonstrates our commitment to bringing NERLYNX to patients around the world while continuing to focus our commercial resources on the U.S. market. We are confident this new partnership will help patients in our new partner's regions access NERLYNX at the earliest opportunity."

Carlo Montagner, Chief Executive Officer of Specialised Therapeutics said, "We are thrilled to be selected as Puma's first international partner able to provide this therapy to women in our region. We plan to expedite access to this important therapy with a Special Access Program, which we expect to open in Australia in the first quarter of 2018. In tandem, we plan to file for Therapeutic Goods Administration (TGA) registration and to seek regulatory approval to market in other countries, including Singapore, Malaysia, Brunei and New Zealand. We expect to have regulatory approval for NERLYNX in Australia by the second quarter of 2019."