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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

## Release Date:

Wednesday, November 22, 2017 6:15 am PST

## Terms:

## Dateline City:

LOS ANGELES

LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, and Specialised Therapeutics Asia, an international biopharmaceutical company with strategic focus and expertise in Australia, New Zealand and South East 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. 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.

“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,” stated Alan H. Auerbach, Chief Executive Officer and President of Puma. “We are confident this new partnership will help patients in our new partner’s regions access NERLYNX at the earliest opportunity.”

“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,” said Carlo Montagner, Chief Executive Officer of Specialised Therapeutics. “We expect to have regulatory approval for NERLYNX in Australia by the second quarter of 2019.”

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.

## About HER2-Positive Breast Cancer

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.

## IMPORTANT SAFETY INFORMATION

### NERLYNX® (neratinib) tablets, for oral use

**INDICATIONS AND USAGE:** NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

**CONTRAINDICATIONS:** None

### WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.

- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

**ADVERSE REACTIONS:** The most common adverse reactions ( $\geq 5\%$ ) were diarrhea, 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.

**To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and [www.NERLYNX.com](http://www.NERLYNX.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

#### **DRUG INTERACTIONS:**

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H<sub>2</sub>-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

#### **USE IN SPECIFIC POPULATIONS:**

- **Lactation:** Advise women not to breastfeed.

**Please see [Full Prescribing Information](#) for additional safety information.**

The recommended dose of NERLYNX is 240 mg (six 40 mg tablets) given orally once daily with food, continuously for one year. Antidiarrheal prophylaxis should be initiated with the first dose of NERLYNX and continued during the first 2 months (56 days) of treatment and as needed thereafter.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at [www.NERLYNX.com](http://www.NERLYNX.com) or 1-855-816-5421.

#### **About Puma Biotechnology**

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. NERLYNX<sup>®</sup> (neratinib) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

Further information about Puma Biotechnology can be found at [www.pumabiotechnology.com](http://www.pumabiotechnology.com).

#### **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, including 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. ST Asia'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)

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding the commercialization and commercial availability of NERLYNX<sup>®</sup> in South East Asia, including in Australia, Singapore, Malaysia, Brunei and New Zealand; the registration of, and regulatory approval of, NERLYNX in the region and these countries; the expected milestone payments and royalties payable under the agreement with Specialised Therapeutics; the benefits of NERLYNX and neratinib; the Company's clinical trials; and the announcement of data relative to those trials. All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has only recently commenced commercialization and shipment of its only FDA approved product; the Company's dependence upon the commercial success of NERLYNX (neratinib); the Company's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company's ability to achieve or sustain profitability; the Company's ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company's operations; the effectiveness of sales and marketing efforts; the

Company's ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company's drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company's products; the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; risks pertaining to securities class action, derivative and defamation lawsuits; the Company's dependence on licensed intellectual property; and the other risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

**Language:**

English

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