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## **Puma Biotechnology's Licensing Partner Specialised Therapeutics Asia Receives Regulatory Approval to Commercialize NERLYNX® (neratinib) for Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer**

### **Release Date:**

Monday, March 18, 2019 5:45 am PDT

### **Terms:**

### **Dateline City:**

LOS ANGELES

- *Neratinib becomes the first anti-HER2 treatment to be approved in Australia, as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy.*
- *Treatment with neratinib in the approved indication resulted in a 34% reduction in the risk of invasive disease recurrence or death versus placebo after patients completed one year of therapy following a trastuzumab-based regimen.*
- *Further, five-year data shows neratinib reduces the risk of invasive disease recurrence or death by 42% in women with early-stage, HER2+/HR+ breast cancer.*
- *Neratinib addresses an unmet medical need, as up to 25% of HER2-positive early stage breast cancer patients treated with trastuzumab-based adjuvant therapy experience a recurrence.*

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI) announced that its licensing partner Specialised Therapeutics Asia (STA) has received marketing authorization from Australia's Therapeutic Goods Administration (TGA) to commercialize *NERLYNX® (neratinib) in Australia for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab based therapy*. STA has submitted regulatory applications to gain approval to introduce NERLYNX in Singapore. Further applications are planned by STA in other countries in South East Asia, including Malaysia, Brunei, Vietnam and Thailand.

TGA approval was based on the Phase III ExteNET trial, a multicenter, randomized, double-blind, placebo-controlled trial of neratinib following adjuvant trastuzumab treatment. Women (n=2,840) with early-stage HER2-positive breast cancer and within two years of completing adjuvant trastuzumab were randomized to receive either neratinib (n=1420) or placebo (n=1420) for one year.

The results of the ExteNET trial demonstrated that after two years of follow-up, invasive disease-free survival (iDFS) was 94.2% in patients treated with neratinib compared with 91.9% in those receiving placebo (HR 0.66; 95% CI: 0.49, 0.90, p=0.008).

The most common adverse reactions (>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, weight loss, and urinary tract infection. The most common adverse reaction leading to discontinuation was diarrhea, which was observed in 16.8% of neratinib-treated patients. Hepatotoxicity or increases in liver transaminases led to drug discontinuation in 1.7% of neratinib-treated patients.

"TGA approval marks the first time Australian women are being presented with an opportunity for *extended*-adjuvant therapy that will reduce the risk of disease recurrence in patients who would otherwise have had a relapse," said Carlo

Montagner, Chief Executive Officer of Specialised Therapeutics. “We are pleased to be at the forefront of this new treatment paradigm and look forward to changing outcomes for these women and their families.”

Puma Biotechnology’s CEO and President, Alan H. Auerbach, added, “Reducing the risk of disease recurrence remains a need for patients, despite advances in the treatment of early stage HER2-positive breast cancer. We are pleased that our partner STA will be bringing this new medicine to patients throughout Australia and would like to express our appreciation to the patients, caregivers and physicians who contributed to the neratinib clinical development program and, more specifically, the ExeNET trial. We are committed to continuing to expand NERLYNX accessibility to patients around the world.”

### **About HER2-Positive Breast Cancer**

Approximately 20 to 25 percent 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.

### **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. Puma in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. NERLYNX was granted marketing authorization by the European Commission for the extended adjuvant treatment of hormone receptor-positive HER2-positive early stage breast cancer in September 2018. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

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

### **Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication**

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

**INDICATIONS AND USAGE:** NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with 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 (≥ 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 H2-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.**

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and health care 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.

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.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding the worldwide expansion of NERLYNX. All forward-looking statements 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 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 Annual Report on Form 10-K for the year ended December 31, 2018. 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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