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# News Release

## Puma Biotechnology Announces Top Line Results of the Phase III NALA Trial of Neratinib in Patients with HER2-Positive Metastatic Breast Cancer

**LOS ANGELES, Calif., Dec. 17, 2018 –** Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced top line results from the Phase III NALA trial of the Company's lead drug candidate PB272 (neratinib) in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments (third-line disease) in the setting of metastatic disease. The Phase III NALA trial is a randomized controlled trial of neratinib plus capecitabine versus Tykerb® (lapatinib) plus capecitabine in patients with third-line HER2-positive metastatic breast cancer. The trial enrolled 621 patients who were randomized (1:1) to receive either neratinib plus capecitabine or lapatinib plus capecitabine. The trial was conducted globally at sites in North America, Europe, Asia-Pacific and South America. The co-primary endpoints of the trial are centrally confirmed progression free survival (PFS) and overall survival (OS). An alpha level of 1% was allocated to the PFS and 4% allocated to OS. The study was to be considered positive if either of the co-primary endpoints was positive. Puma reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the design of the Phase III clinical trial and the European Medicines Agency (EMA) also provided follow-on scientific advice (SA) consistent with that of the FDA regarding the Company's Phase III trial design and endpoints used in the trial.

For the primary analysis of centrally confirmed PFS, treatment with neratinib plus capecitabine resulted in a statistically significant improvement in centrally confirmed PFS (p=0.0059) compared to treatment with lapatinib plus capecitabine. For the primary analyses of OS, neratinib plus capecitabine resulted in an improvement in OS that did not achieve statistical significance but trended positively in favor of the neratinib plus capecitabine arm of the study (p=0.21). For the secondary endpoint of time to intervention for symptomatic central nervous system disease (also referred to as brain metastases), the results of the trial showed that treatment with neratinib plus capecitabine led to an improvement over the combination of lapatinib plus capecitabine (p=0.043).

The safety profile of neratinib in the Phase III NALA study was consistent with previous clinical trials of neratinib.

Full results of the trial will be submitted to health authorities around the world, including the U.S. Food and Drug Administration and European Medicines Agency. Results of the trial will be submitted for presentation at a major medical conference in 2019.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are highly encouraged by these results from the NALA trial with the combination of neratinib plus capecitabine in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments. We look forward to working with the regulatory authorities in the hope of bringing another potential treatment option to patients with HER2-positive metastatic breast cancer as soon as possible."

## Conference Call

Puma Biotechnology will host a conference call at 1:30 p.m. PST/4:30 p.m. EST on Monday, December 17, 2018, to discuss the results of its NALA trial. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (international). Please dial in at least ten minutes in advance and inform the operator that you would like to join the "Puma Biotechnology Conference Call." A live webcast of the conference call may be accessed on the Investors section of the Puma Biotechnology website at http://www.pumabiotechnology.com. A replay of the call will be available approximately one hour after completion of the call and will be archived on Puma's website for 30 days.

### 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.

### 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 inpatients 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 or FDA at 1-800-FDA-1088 or 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 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.
Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

**Important EU NERLYNX® (neratinib) Safety Information**

**All suspected adverse reactions should be reported in accordance with the national reporting system.**

The adverse reactions described in this section were identified in the randomized Phase 3 clinical trial (n=2840). The most common adverse reactions of any grade were diarrhoea (93.6%), nausea (42.5%), fatigue (27.3%), vomiting (26.8%), abdominal pain (22.7%), rash (15.4%), decreased appetite (13.7%), abdominal pain upper (13.2%), stomatitis (11.2%), and muscle spasms (10.0%).

The most common Grade 3-4 adverse reactions were diarrhoea (Grade 3, 36.9% and Grade 4, 0.2%) and vomiting (Grade 3, 3.4% and Grade 4, 0.1%).

Adverse reactions reported as serious included diarrhoea (1.9%), vomiting (1.3%), dehydration (1.1%), nausea (0.5%), alanine aminotransferase increased (0.4%), aspartate aminotransferase increased (0.4%), abdominal pain (0.3%), fatigue (0.3%) and decreased appetite (0.2%).

**For full European prescribing information, please refer to the NERLYNX (neratinib) Summary of Product Characteristics on the European Medicines Agency website (http://www.ema.europa.eu/ema/).**

**Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding the submission of results of the NALA trial to regulatory authorities and timing for presentation of the full results of the NALA trial. All forward-looking statements involve risks and uncertainties that could cause Puma'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 Puma with the Securities and Exchange Commission from time to time, including Puma's Annual Report on Form 10-K for the year ended December 31, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

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