News Release

Puma Biotechnology Presents Interim Results of Phase II CONTROL Trial of Neratinib in Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer at the 2017 San Antonio Breast Cancer Symposium

LOS ANGELES, Calif., Dec. 6, 2017 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, will present updated interim results from a Phase II clinical trial of Puma's drug neratinib at the 2017 San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled, "Effects of adding budesonide or colestipol to loperamide prophylaxis on neratinib-associated diarrhea in patients with HER2-positive early stage breast cancer: the CONTROL trial," will be presented at a poster session on December 7 at 5:00 p.m. CST. A full copy of the poster is available on the Puma Biotechnology website.

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.

The main adverse event seen to date in clinical trials of neratinib is diarrhea and, more specifically, grade 3 diarrhea. In the Phase III ExteNET trial of neratinib as extended adjuvant treatment of HER2-positive early stage breast cancer that has previously been treated with adjuvant Herceptin, 95.4% of the patients experienced all grade diarrhea and 39.8% of the patients experienced grade 3 or higher diarrhea (there was one event of grade 4 diarrhea). The CONTROL trial is an international, open-label, Phase II study investigating the use of loperamide prophylaxis with or without other agents in the reduction of neratinib-associated diarrhea that has a primary endpoint of the incidence of grade 3 diarrhea.

In the CONTROL trial, patients with HER2-positive early stage breast cancer who had completed trastuzumab-based adjuvant therapy received neratinib daily for a period of one year. The trial initially tested high dose loperamide prophylaxis given for the first 2 cycles (56 days) of treatment (12 mg on days 1-14, 8 mg on days 15-56 and as needed thereafter). The CONTROL trial was then expanded to include two additional cohorts. One cohort received the combination of loperamide and budesonide and the other cohort received the combination of loperamide plus colestipol. Budesonide is a locally acting corticosteroid that the Company believes targets the inflammation identified in a preclinical model of neratinib-induced diarrhea and colestipol is a bile acid sequestrant that the Company believes targets potential bile acid malabsorption that could result from such inflammation.

The interim analysis of the trial presented in the poster included a total of 137 patients who received neratinib plus loperamide prophylaxis, 64 patients who received neratinib plus loperamide prophylaxis for 2 cycles and budesonide for 1 cycle, and 120 patients who received neratinib plus loperamide prophylaxis for 1 cycle and colestipol for 1 cycle.

The results of the trial showed that the incidence of grade 3 diarrhea for the 137 patients who received the loperamide prophylaxis was 30.7%. For the 137 patients who received the loperamide prophylaxis, the median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 3 days. For the 137 patients who received loperamide prophylaxis, 20.4% discontinued neratinib due to diarrhea.

For the 64 patients who received the combination of loperamide plus budesonide, the results of the trial showed that the incidence of grade 3 diarrhea was 26.6%. The median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 2 days. For the 64 patients who received loperamide plus budesonide prophylaxis, 10.9% discontinued neratinib due to diarrhea.

For the 120 patients who received the combination of loperamide plus colestipol, the results of the trial showed that the incidence of grade 3 diarrhea was 10.8%. The median number of grade 3 diarrhea episodes per patient was 1 and the median cumulative duration of grade 3 diarrhea was 3 days. For the 120 patients who received loperamide plus colestipol prophylaxis, 1.7% discontinued neratinib due to diarrhea. Further information is provided in Table 1 below:

Table 1: Characteristics of Treatment-Emergent Diarrhea

Study	**CONTROL**			**ExteNET**
	Loperamid (n=137)	**Loperamide + budesonide (n=64)**	**Loperamide + colestipol (n=120)**	**Loperamide prn (n=1408)**
Diarrhea, %				
Any grade	79.6	86.0	66.7	95.4
Grade 1	24.8	25.0	30.0	22.9
Grade 2	24.1	34.4	25.8	32.5
Grade 3[a]	30.7	26.6	10.8	39.8
Grade 4	0	0	0	0.1
Median cumulative duration, days				
Any grade	14.0	24.0	16.0	59.0
Grade ≥2	5.0	6.0	3.5	10.0
Grade ≥3[a]	3.0	2.0	3.0	5.0
Median diarrhea episodes/patient				
Any grade	2.0	9.0	2.5	8.0
Grade ≥2	2.0	3.0	1.0	3.0
Grade ≥3[a]	1.0	1.0	1.0	2.0
Action taken, %				
Dose hold	15.3	18.8	9.2	33.9
Dose reduction	7.3	3.1	4.2	26.4
Discontinuation	20.4	10.9	1.7	16.8
Hospitalization	1.5	0	0	1.4
Duration of neratinib treatment, months				
Median	11.5	11.9	3.7	11.6

[a] No grade 4 events in the CONTROL study; one grade 4 event in the ExteNET study.

Hope S. Rugo, MD, USCF Helen Diller Family Comprehensive Cancer Center, San Francisco, California, said, "We are pleased to see the maturation of the data supporting observations of a reduction in incidence, severity and duration of neratinib-associated diarrhea with loperamide prophylaxis, loperamide plus budesonide prophylaxis or the loperamide plus colestipol prophylaxis. Along with the continued reduction in the incidence and severity of grade 3 diarrhea with neratinib, diarrhea appears to be acute, self-limiting and manageable. The addition of budesonide or colestipol to loperamide prophylaxis appears to greatly improve the tolerability of neratinib and we look forward to the completion of the colestipol cohort."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased to see the reductions in the incidence of severe neratinib-related diarrhea in the CONTROL trial when using the loperamide, loperamide plus budesonide or loperamide plus colestipol regimens. The severe diarrhea appears to become more acute, whereby it does not typically recur after the first month. We are also very encouraged by the improvements in tolerability that have been seen to date in the budesonide and the colestipol cohorts. This is a marked improvement in tolerability over what was seen in the ExteNET trial and we look forward to continuing to monitor this in the loperamide plus colestipol cohort."

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 (≥ 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.

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 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® (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 are 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.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding 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.

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