News Release

Puma Biotechnology Presents Results of Patient Reported Outcomes in Phase II CONTROL Trial of Neratinib in Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer at the 2018 San Antonio Breast Cancer Symposium

LOS ANGELES, Calif., Dec. 6, 2018 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, is presenting updated results from a Phase II clinical trial of Puma's drug neratinib at the 2018 San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled, "The impact of neratinib with or without anti-diarrheal prophylaxis on health-related quality of life in HER2-positive early stage breast cancer: Analyses from the ExteNET and CONTROL trials." is being presented by Dr. Suzette Delaloge, Institut Gustave Roussy, Paris, France, at a poster session on December 6 from 7:00 - 9:00 a.m. CST. A full copy of the poster is available on the Puma Biotechnology website at www.pumabiotechnology.com.

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. NERLYNX was granted marketing authorization in September 2018 by the European Commission for extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab based therapy.

Diarrhea is the main side effect of neratinib. In ExteNET, where antidiarrheal prophylaxis was not mandated by the study protocol, grade 1/2 diarrhea was reported in 55% and 34% of patients in the neratinib and placebo groups, respectively, and grade 3 diarrhea occurred in 40% and 2%, respectively. Because neratinib-induced diarrhea occurs early in the course of treatment, a structured high dose regimen of loperamide prophylaxis given for one or two cycles has been introduced to better manage this side effect. The Phase II CONTROL study, conducted in the exact same setting as ExteNET, investigated the effectiveness of anti-diarrheal prophylaxis with loperamide alone or in combination with budesonide or colestipol in the prevention of neratinib-associated diarrhea.

Both ExteNET and CONTROL assessed patient-reported outcomes using the Functional Assessment of Cancer Therapy for Breast Cancer (FACT-B), a validated instrument for the assessment of health-related quality of life (HRQoL) in breast cancer. Total scores of FACT-B range from 0-144, with higher scores indicating better HRQoL. A change of 7-8 points in the FACT-B total score is considered clinically meaningful. Preliminary HRQoL findings from the CONTROL study were presented in 2017 and are posted on Puma's website at www.pumabiotechnology.com/pr20171206.html. The poster presented at SABCS reports more detailed and mature HRQoL data from CONTROL, and compares it to the HRQoL findings from the ExteNET study.

In ExteNET, 17% of patients in the neratinib group and less than 1% of patients in the placebo group discontinued treatment because of diarrhea. In CONTROL, 20% of patients in the loperamide cohort, 11% in the budesonide plus loperamide cohort, and 4% in the colestipol plus loperamide cohort discontinued treatment due to diarrhea.

The poster presentation demonstrates that in both studies decreases in FACT-B total scores seen in early months were followed by recovery towards baseline levels. Decreases in FACT-B total scores observed did not cross a clinically meaningful threshold at any time point.

In the ExteNET study, a transient decrease in FACT-B total score was observed with neratinib at month 1 (mean change from baseline, –4.6 points) followed by recovery towards baseline. Decreases were also evident in the placebo group, with mean changes from baseline ranging from –3.5 to –1.7 points during study treatment. After month 3, mean changes from baseline were similar in neratinib and placebo arms. None of these changes reached clinically meaningful thresholds (7–8 points) at any time point.

The presentation also shows that in the CONTROL study, FACT-B total scores decreased from baseline in all cohorts; mean changes from baseline ranged from –6.0 to –1.5 points over the course of study treatment. In the cohorts that had completed follow-up (loperamide, budesonide plus loperamide), the largest decreases in FACT-B total scores were evident during months 1 and 3 followed by recovery towards baseline levels. None of these changes reached clinically meaningful thresholds (7–8 points) at any time point.

An evaluation of each of the FACT-B subscales (n=5) were evaluated and this analysis suggested that physical well-being (PWB) was the only subscale where the clinically important difference (CID) threshold was crossed in both trials. In the ExteNET study, in the neratinib arm, FACT-B PWB decreased at month 1 before improving at later visits. The mean change from baseline at month 1 with neratinib was –2.9 points and was greater than clinically meaningful thresholds (2–3 points); changes at later time-points were all less than the clinically meaningful threshold.

In the CONTROL study, decreases in FACT-B PWB were observed in all CONTROL cohorts throughout study treatment, with largest changes from baseline observed at month 1. In the loperamide alone and colestipol plus loperamide cohorts, changes reached clinically meaningful thresholds (2–3 points) at 4 out of 5 study visits, whereas in the budesonide plus loperamide cohort, changes crossed the CID threshold during months 1 and 3 only.

Suzette Delaloge, MD, Institut Gustave Roussy, Paris, France, said “Diarrhea is the main side effect of neratinib and can be bothersome in some patients. Although this is not a direct comparison, the confrontation of Extenet and Control data teach us how to prevent grade 3 diarrhea and how to allow better quality of life, together with better adherence of patients to this therapy."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, “We are pleased with the HRQoL data from ExteNET and CONTROL. We look forward to additional data from the CONTROL trial, which may continue to improve HRQoL and adherence to treatment.”

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. 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.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the benefits of NERLYNX® and neratinib, Puma's clinical trials and the announcement of data relative to those trials. 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 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, 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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