News Release

Puma Biotechnology Presents Results from the Phase II SUMMIT Trial of Neratinib for ERBB2 (HER2) Mutant, HER2 Non-Amplified, Metastatic Breast Cancer at the 2019 San Antonio Breast Cancer Symposium

LOS ANGELES, Calif., Dec. 11, 2019 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced that results from an ongoing Phase II clinical trial of Puma's drug neratinib are being presented at the 2019 San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled, "Neratinib + trastuzumab + fulvestrant for HER2-mutant, hormone receptor-positive, metastatic breast cancer: updated results from the phase 2 SUMMIT 'basket' trial," are being presented at a poster Session by Hans Wildiers, M.D., Ph.D., University Hospitals Leuven, Belgium, an investigator of the trial. A copy of this poster presentation is available on the Puma 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. 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 August 2018.

The Phase II SUMMIT basket trial is an open-label, multicenter, multinational study to evaluate the safety and efficacy of neratinib administered daily to patients who have solid tumors with activating HER2 or HER3 mutations. In the HER2-mutant, HR-positive breast cancer cohort, 28 patients received 240 mg of neratinib daily in combination with trastuzumab and fulvestrant. In this cohort, patients had received a median of 4 prior lines of therapy in the metastatic setting (range 0-10 prior regimens) before entering the trial. All patients had been previously treated with an endocrine agent prior to entering the study, including 17 patients (61%) who had received prior fulvestrant. Further, 15 patients (54%) received prior cyclin-dependent kinase 4/6 (CDK4/6) -inhibitor therapy. Twenty-one patients (75%) had received prior chemotherapy.

The interim efficacy summary of the breast cohort that received neratinib in combination with trastuzumab and fulvestrant showed that for the 17 efficacy evaluable patients, 9 patients (53%) experienced a confirmed objective response, all of which were classified as partial responses, and 10 patients (59%) experienced clinical benefit (clinical benefit is defined as confirmed complete response or partial response or stable disease for at least 24 weeks). The median duration of response has not been reached and the median progression-free survival was 9.8 months. At the time of data cut-off, five patients continued to receive treatment.

The safety profile observed in patients treated with the combination of neratinib plus trastuzumab plus fulvestrant in the SUMMIT study was consistent with that observed previously in metastatic patients with HER2 amplified tumors. All patients received anti-diarrheal prophylaxis with loperamide alone. The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 28 safety evaluable patients enrolled in this cohort, 10 patients (36%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for those patients was 5.5 days. No patient permanently discontinued neratinib due to diarrhea.

Prof. Dr. Hans Wildiers said, "The combination of neratinib plus trastuzumab plus fulvestrant therapy demonstrates encouraging clinical activity with durable responses in this heavily pretreated metastatic breast

cancer patient population with activating HER2 mutations and hormone receptor-positive disease. We look forward to continuing to enroll this cohort of SUMMIT."

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are very pleased with the activity seen with neratinib in combination with trastuzumab and fulvestrant in this cohort of patients with HER2-mutated breast cancer. We are in the process of expanding this HR-positive breast cancer cohort in SUMMIT with the intent of using this data to support future registration. We look forward to enrolling additional patients into this HR-positive breast cancer cohort in order to generate the additional data required to support approval of this combination therapy."

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 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 August 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

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, 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. When patients require gastric acid reducing agents, use an H2-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after H2-receptor antagonists.
- 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.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the development of combinations involving neratinib. 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 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, 2018. 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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