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 2018 San Antonio Breast Cancer Symposium

LOS ANGELES, Calif., Dec. 6, 2018 – 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 2018 San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled, "Neratinib + fulvestrant for HER2-mutant, HR-positive, metastatic breast cancer: Updated results from the phase 2 SUMMIT trial," are being presented at a Spotlight Session by Lillian M. Smyth, M.D., Breast Medicine Service and Early Drug Development Service, Memorial Sloan Kettering Cancer Center, an investigator of the trial.

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 September 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, 47 patients received 240 mg of neratinib daily in combination with fulvestrant at the labeled dose. In this cohort, 43 patients (92%) had HER2-non-amplified disease, and patients had received a median of 3 prior lines of therapy in the metastatic setting (range 0-11 prior regimens) before entering the trial. All patients had been previously treated with an endocrine agent prior to entering the study, including 25 patients (53%) who had received prior fulvestrant. Further, 20 patients (43%) received prior cyclin-dependent kinase 4/6 (CDK4/6) -inhibitor therapy.

The efficacy summary of the breast cohort that received neratinib + fulvestrant is shown in Table 1 below. The interim efficacy results from the trial showed that for the 47 efficacy evaluable patients, 14 patients (30%) experienced an objective response, which included 4 patients with a complete response and 10 patients with partial responses, and 22 patients (47%) 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 was 9.2 months and the median progression free survival was 5.4 months. Subgroup analysis demonstrated that patients who had received prior fulvestrant or CDK4/6 inhibitor targeted therapy prior to entering the trial also benefited from treatment of neratinib + fulvestrant. Of note, 6 patients (30%) with prior CDK4/6-inhibitor exposure demonstrated confirmed responses, with the duration of responses ranging from 4.5–14.8 months. Four patients were still on treatment at the time of data reporting.

Table 1: HER2-Mutant, HR-Positive Metastatic Breast Cancer
Phase II SUMMIT Trial Efficacy Summary

	Neratinib + Fulvestrant		
		Subgroups	
Efficacy Endpoint[a]:	**All Patients (n=47)**	**Prior Fulvestrant (n=25)**	**Prior CDK4/6 Inhibitor-Based Therapy (n=20)**
Objective response (confirmed)[b] – n	14	4	6
CR	4	0	1
PR	10	4	5
Objective response rate (95% CI)	**30** (17–45)	**16** (5–36)	**30** (12–54)
Median[c] DOR, months (95% CI)	**9.2** (5.5–16.6)		
DOR for each responder		9.2; 9.3*; 14.8*; 16.6	4.5; 7.3; 9.2*; 9.3*; 11.2*; 14.8*
Clinical benefit[d] – n	22	9	8
CR or PR	14	4	6
SD	8	5	2
Clinical benefit rate (95% CI)	**47** (32–62)	**36** (18–58)	**40** (19–64)
Median[c] PFS (95% CI) time to event, months	**5.4** (3.7–9.2)	**3.7** (3.5–6.9)	**4.1** (1.9–10.9)
	Patients with RECIST v1.1 Measurable Disease		
		Subgroups	
Efficacy Endpoint[a]:	**All Patients (n = 39)**	**Prior Fulvestrant (n = 21)**	**Prior CDK4/6 Inhibitor-Based Therapy (n=15)**
Objective response (confirmed)[b] – n	12	4	5
CR	2	0	0
PR	10	4	5
Objective response rate (95% CI)	**31** (17–48)	**19** (5–42)	**33** (12–62)
Median[c] DOR, months (95% CI)	**9.0** (4.5–16.6)		
DOR for each responder		9.2; 9.3*; 14.8*; 16.6	4.5; 7.3; 9.2*; 9.3*; 14.8*
Clinical benefit[d] – n	18	8	6
CR or PR	12	4	5
SD	6	4	1
Clinical benefit rate (95% CI)	**46** (30–63)	**38** (18–62)	**40** (16–68)
Median[c] PFS (95% CI) time to event, months	**5.4** (3.5–10.3)	NA	NA

[a] Response is based on investigator tumor assessments per RECIST v1.1 or modified PERCIST for patients with only PET-evaluable lesions.

[b] Overall objective response (ORR) is defined as either a complete or partial response that is confirmed no less than 4-weeks after the criteria for response are initially met.

[c] Kaplan-Meier analysis

[d] Clinical benefit rate (CBR) is defined as confirmed CR or PR or stable disease (SD) for at least 24 weeks (within +/- 7 day visit window).

* Patient still on treatment at time of data cut; DOR, duration of response; PFS, progression free survival; NA, not available

The safety profile observed in neratinib + fulvestrant-treated breast cancer patients in the SUMMIT study was consistent with that observed previously in metastatic patients with HER2 amplified tumors. With anti-diarrheal prophylaxis and management, diarrhea was not a treatment-limiting side effect in SUMMIT. The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 47 patients enrolled in the trial, 11 patients (23%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for those patients was 1.5 days. No patients permanently discontinued neratinib due to diarrhea.

Dr. Lillian Smyth said, "Somatic HER2 mutations represent a distinct class of oncogenic driver mutations that appear to be clinically actionable for metastatic breast cancers. The combination of neratinib plus fulvestrant therapy demonstrates encouraging clinical activity with durable responses in this heavily pretreated metastatic breast cancer patient population with HER2-mutated and hormone receptor-positive disease."

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are very pleased with the updated activity seen with neratinib in combination with fulvestrant in this cohort of patients with HER2-mutated breast cancer. We look forward to the further development of the combination of neratinib and fulvestrant in this patient population."

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 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, 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.

Contact

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

David Schull or Alex Fudukidis, Russo Partners, +1-212-845-4271
david.schull@russopartnersllc.com
alex.fudukidis@russopartnersllc.com

# # # # #