News Release

Puma Biotechnology Presents Results from the Phase II SUMMIT Trial of PB272 for ERBB2 (HER2) Mutant, HER2 Non-Amplified, Metastatic Cancer at the 2017 AACR Annual Meeting

LOS ANGELES, Calif., April 2, 2017 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced that results from an ongoing Phase II clinical trial of Puma's investigational drug PB272 (neratinib) were presented at the 2017 American Association for Cancer Research Annual Meeting (AACR) that is currently taking place in Washington, D.C. The presentation entitled, "Neratinib in HER2 or HER3 mutant solid tumors: SUMMIT, a global, multi-histology, open-label, phase 2 'basket' study," was presented as a plenary session by David Hyman, M.D., Director of Developmental Therapeutics at Memorial Sloan Kettering Cancer Center (MSK), and principal investigator of the trial.

The Phase II SUMMIT basket trial is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating HER2 or HER3 mutations. All patients received loperamide (16 mg per day initially) prophylactically for the first cycle of treatment in order to reduce the neratinib-related diarrhea.

Included in the presentation were data on 141 patients enrolled in the neratinib monotherapy arm of the trial, including 124 patients with HER2 mutations and 17 patients with HER3 mutations. This included patients with 21 unique tumor types, with the most common being breast, lung, bladder and colorectal cancer. There were also 30 distinct HER2 and 12 distinct HER3 mutations observed among these patients, with the most frequent HER2 variants involving S310, L755, A755_G776insYVMA and V777.

In the HER2-mutant cohort, clinical responses were observed in tumors with S310, L755, V777, P780_Y781insGSP and A775_G776insYVMA mutations. When stratified by tumor type, responses were observed in patients with breast, cervical, biliary, salivary and non-small-cell lung cancers, which led to cohort expansions in these tumor types. No activity was observed in the HER3-mutant cohort. A more detailed presentation of the data is presented in Table 1 below and a copy of the full presentation is available on the Puma Biotechnology website.

Table 1: SUMMIT Trial Efficacy Summary

	HER2^{mut} Breast (n=25)	HER2^{mut} Bladder (n=16)	HER2^{mut} Lung (n=26)	HER2^{mut} Colorectal (n=12)	HER2^{mut} Biliary tract (n=9)	HER2^{mut} Cervical (n=5)	HER3^{mut} NOS (n=17)
ORR at week 8, n (%)	8 (32.0)	0 (0.0)	1 (3.8)	0 (0.0)	2 (22.2)	1 (20.0)	0 (0.0)
(95% CI)	(14.9--53.5)	(0.0--20.6)	(0.1--19.6)	(0.0--26.5)	(2.8--60.0)	(0.5--71.6)	(0.0--20.6)
Clinical benefit rate, n (%)	10 (40.0)	3 (18.8)	11 (42.3)	1 (8.3)	3 (33.3)	3 (60.0)	2 (11.8)
(95% CI)	(21.1--61.3)	(4.0--45.6)	(23.4--63.1)	(0.2--38.5)	(7.5--70.1)	(14.7--94.7)	(1.6--38.3)
Median PFS, months	3.5	1.8	5.5	1.8	2.8	20.1	1.7
(95% CI)	(1.9--4.3)	(1.7--3.5)	(2.7--10.9)	(1.4--1.9)	(0.5--3.7)	(0.5--NA)	(1.4--2.0)

The neratinib safety profile observed in the SUMMIT study is 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 141 patients enrolled in the neratinib monotherapy arm with safety data available, 31 patients (22%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for those patients was 2 days. 4 patients (2.8%) permanently discontinued neratinib due to diarrhea and 21 patients (14.9%) temporarily discontinued neratinib due to diarrhea and then restarted after the diarrhea subsided.

Dr. David Hyman stated, "Neratinib showed signs of clinical activity in several of the cohorts in the SUMMIT trial. The safety profile of the drug was manageable and the diarrhea was not treatment-limiting with appropriate prophylaxis and management. We look forward to completing enrollment in the ongoing cohorts in the study and continuing to utilize the basket trial design to explore possible treatment options for these select patient populations."

"The basket-trial design we are utilizing for SUMMIT is enabling us to evaluate the clinical potential of neratinib in patients with specific mutation-types rather than limiting exploration to one tumor type at a time. It is an efficient approach that is generating clinically meaningful information to guide targeted therapy across a broad spectrum of tumor types with HER mutations, including in patients with rare tumors who may not otherwise have access to investigational therapies," said Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology. "We are very pleased with the preliminary activity seen with neratinib in the SUMMIT trial. We look forward to advancing this targeted compound into further clinical development in multiple HER2 mutant tumor types, both as monotherapy and in novel combinations."

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. 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 development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types 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 development of the Company's drug candidates. 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 no product revenue and no products approved for marketing; the Company's dependence on PB272, which is still under development and may never receive regulatory approval; 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; 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 Annual Report on Form 10-K for the year ended December 31, 2016. 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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