News Release

Puma Biotechnology Presents Results of Biomarker Analysis of Phase II Trial of PB272 in Neoadjuvant Treatment of HER2-Positive Locally Advanced Breast Cancer at the 2016 San Antonio Breast Cancer Symposium

LOS ANGELES, Calif., Dec. 7, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that a biomarker analysis of the NSABP FB-7 Phase II clinical trial of Puma's investigational drug PB272 (neratinib) was presented at the 2016 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled "An exploratory correlative biomarker analysis of NSABP FB-7, a phase II randomized trial evaluating neoadjuvant therapy with weekly paclitaxel (P) plus neratinib (N) or trastuzumab (T) or neratinib and trastuzumab (N+T) followed by doxorubicin and cyclophosphamide (AC) with postoperative T in women with locally advanced HER2-positive breast cancer" was presented as a poster presentation. This trial was sponsored by the NSABP Foundation, Inc.

The FB-7 trial is a randomized Phase II clinical trial for women with HER2-positive locally advanced stage IIB-IIIC invasive breast cancer. Patients were randomly assigned to receive trastuzumab (T) or neratinib (N) or the combination (T+N) with weekly paclitaxel (P) followed by standard doxorubicin and cyclophosphamide chemotherapy (AC) administered prior to surgery. 126 U.S., Canadian, and European patients were randomly assigned to Arm 1 (T+P followed by AC), Arm 2 (N+P followed by AC) or Arm 3 (T+N+P followed by AC). The primary endpoint of the trial was pathological complete response rate (pCR) in the breast and lymph nodes. The clinical safety and efficacy data from this trial was presented at the 2015 SABCS.

A key secondary endpoint of the FB-7 trial was to evaluate molecular and genetic markers for correlation with response. Pre-treatment core biopsy samples (n=59) and post treatment surgical samples (n=17) were obtained from a subset of patients treated in the FB-7 trial. pCR data were available for 51 patients from the biomarker cohort. After excluding low tumor content non-evaluable samples, correlative biomarker analysis was performed in 42 patients.

Expression levels and the activation status of EGFR/HER2 signaling proteins were investigated. The results of the phosphorylated HER2 (phosphoHER2) showed that median levels of phosphoHER2 were higher in the patients who achieved a pCR with neratinib (n=7) than in the patients who did not achieve a pCR who received either trastuzumab (n=8, p=0.07) or the combination of trastuzumab plus neratinib (n=4, p=0.035). There was not a significant difference in the median levels of phosphoHER2 in the patients who achieved a pCR with neratinib (n=7), trastuzumab (n=8, p=0.16) or the combination of trastuzumab plus neratinib (n=4, p=0.10).

The truncated form of HER2 known as p95HER2 was measured by the proprietary assay of Pierian Bioscience. p95HER2 represents a truncated form of the HER2 receptor that lacks the

extracellular trastuzumab binding domain. It is believed to represent a mechanism of trastuzumab resistance. Median p95HER2 levels were higher in samples from patients who achieved a pCR with neratinib than in the patients who did not achieve a pCR who received either trastuzumab (p=0.027) or the combination of trastuzumab plus neratinib (p=0.009). There was not a significant difference in the median levels of p95HER2 in the patients who achieved a pCR with neratinib (n=7), trastuzumab (n=8, p=0.16) or the combination of trastuzumab plus neratinib (n=4, p=0.35).

The MammaPrint assay was performed on 59 samples to determine if there was any imbalance between arms. This assay is a genomic test that analyzes the activity of 70 genes and then calculates a recurrence score that is either low risk or high risk. The results of the MammaPrint showed that the patients in all three arms of the FB-7 trial were balanced with the median MammaPrint risk score being similar across arms. There were only three patients with a MammaPrint low score.

Dr. Samuel Jacobs, Emeritus Clinical Professor in the Department of Medicine, University of Pittsburgh School of Medicine, and the Director of Medical Affairs for the NSABP Foundation, Inc., said, "We are pleased to see the results of this exploratory biomarker analysis which suggests that activation of the HER pathway based on p95HER2 and phosphoHER2 may correlate with pCR to neratinib. Further biomarker analysis in additional datasets will be needed to determine which patients may derive the greatest benefit from neratinib."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased to complete this biomarker analysis of neratinib. Further results of the biomarker analysis should help us to determine the best path forward for neratinib in the neoadjuvant treatment of HER2-positive early stage breast cancer."

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, 2015. 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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