News Release

Puma Biotechnology Announces Positive PB272 (Neratinib) Phase II Data at CTRC-AACR San Antonio Breast Cancer Symposium

Phase II Results Demonstrate Efficacy of PB272 in Combination with Temsirolimus in HER2+ Metastatic Breast Cancer

Los Angeles, Calif., Dec. 7, 2012-- Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced that results from an ongoing Phase II clinical trial of Puma's investigational drug PB272 (neratinib) were presented at the 2012 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation is further detailed below.

Tolerability and efficacy of targeting both mTOR and HER2 signaling in trastuzumab-refractory HER2+ metastatic breast cancer

The Phase II clinical trial of PB272 given in combination with the anticancer drug temsirolimus was conducted at Memorial Sloan-Kettering Cancer Center. The trial was supported by the National Comprehensive Cancer Network®, ASCO's Young Investigator Award, Susan G. Komen for the Cure®, and the Terri Brodeur Breast Cancer Foundation. The initial Phase I/II results of this trial were presented last year. The Phase II portion of the study, presented at the SABCS, enrolled patients with HER2+ metastatic breast cancer and disease progression on trastuzumab. Patients in the study received a median of 3 prior cytotoxic regimens (range 1-12 prior regimens) before entering the trial. Of the 27 patients enrolled in the trial, 14 patients (52%) had either estrogen receptor positive disease or progesterone receptor positive disease. In addition, 20 patients (74%) had visceral metastases and 3 patients (11%) had brain metastases. Patients were administered PB272 at a dose of 240 mg per day in combination with temsirolimus given at a dose of 8 mg weekly.

The results of the study presented showed that the combination of PB272 and temsirolimus had acceptable tolerability. The most frequently observed severe adverse events for the 27 patients evaluable for safety were grade 3 diarrhea (22% of patients), grade 3 mucositis (15%), grade 3 hyperglycemia (4%), grade 3 leukopenia (4%), and grade 3 fatigue (4%). The efficacy results from the trial showed that for the 27 evaluable patients, 12 patients (44%) experienced a partial response (PR) and 1 patient (4%) experienced prolonged stable disease (SD) for greater than 6 months, which translates to a clinical benefit rate of 48%. Patients who experienced a partial response to the combination of neratinib plus temsirolimus demonstrated a maximum change in the size of their target lesions of between 33% and 83%. Clinical benefit was seen in patients previously treated with trastuzumab as well as lapatinib, T-DM1 and pertuzumab. The median progression free survival of the 27 evaluable patients was seen to be 18 weeks (4.2 months). Enrollment in this trial is continuing and is anticipated to reach a total of 34 patients.

Tumor biopsies were also taken from patients prior to entry into the trial in order to assess expression or mutational changes in phosphatase and tensin homolog (PTEN) and phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha (PIK3CA) and to correlate them with response to the combination of PB272 and temsirolimus. Of the 9 patients whose tumors were analyzed for PIK3CA mutation status, 2 patients were found to have mutated PIK3CA. Treatment with the combination of PB272 and temsirolimus resulted in clinical benefit (defined as PR or SD) in 2 (100%) of these patients. Of the 17 patients whose tumors were

analyzed for PTEN status, 8 patients were shown to have reduced PTEN expression and 7 patients were shown to have absent PTEN expression. Treatment with the combination of PB272 and temsirolimus resulted in clinical benefit (PR or SD) in 7 (88%) of the 8 patients with reduced PTEN expression and in 6 (86%) of the 7 patients with absent PTEN expression.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased with the data on the combination of PB272 in combination with temsirolimus. The data continues to demonstrate intriguing antitumor activity in a heavily pretreated population and compares favorably to what would typically be seen for other treatment options for patients in this setting. We look forward to continuing to study this combination and to advancing the combination of PB272 and temsirolimus into Phase III trials in 2013."

About Puma Biotechnology

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. The Company is initially focused on the development of PB272 (neratinib), an oral potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2 positive metastatic breast cancer and non-small cell lung cancer.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements that 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 its lead drug candidate, 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 from time to time in the Company's filings with the Securities and Exchange Commission, including the Company's Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2012. 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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