News Release

Puma Biotechnology Announces Positive Interim PB272 (Neratinib) Phase II Data at 2014 CTRC-AACR San Antonio Breast Cancer Symposium

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

LOS ANGELES, **Calif., Dec. 12, 2014** − Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced that interim results from an ongoing Phase II clinical trial of Puma's investigational drug PB272 (neratinib) were presented at the 2014 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. 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 presentation is further detailed below.

The trial was conducted as a Phase I/II trial of PB272 given in combination with the anticancer drug temsirolimus in patients with HER2-positive metastatic breast cancer. The Phase I portion of the trial, which was reported previously, determined that the maximum tolerated dose was 240 mg of neratinib daily with 8 mg of temsirolimus weekly and the dose limiting toxicity was diarrhea. The Phase II portion of the study was conducted in two cohorts. The first cohort, referred to as the Maximum Tolerated Dose (MTD) cohort, received 240 mg of neratinib daily with 8 mg of temsirolimus weekly. This cohort of patients received low dose loperamide (4 mg per day) prophylactically in order to reduce the neratinib related diarrhea. The second cohort of patients, referred to as the Dose Escalation cohort (DE cohort), received 240 mg of neratinib daily and initially received 8 mg of temsirolimus weekly. This cohort of patients received high dose loperamide (16 mg per day initially) prophylactically in order to reduce the neratinib related diarrhea. If patients in the DE cohort had no tolerability issues with the combination of neratinib and temsirolimus given at 8 mg per week during the first cycle of treatment, patients in this DE cohort were allowed to dose escalate the temsirolimus to 15 mg per week for the remainder of the study. Patients in both cohorts in the study received a median of 3 prior regimens in the metastatic setting (range 1-8 prior regimens) before entering the trial. The 37 patients in the MTD cohort were enrolled at 3 centers in the United States and the 45 patients in the DE cohort were enrolled at 8 centers in the United States, Europe and Asia.

The interim safety results of the study showed that the most frequently observed adverse event for the patients who received the combination of neratinib plus temsirolimus was diarrhea. For the 37 patients in the MTD cohort, who received low dose loperamide prophylactically, 12 patients (32%) experienced grade 3 diarrhea. For the 41 patients in the DE cohort, who received high dose loperamide prophylactically and were allowed to dose escalate the temsirolimus dose, 7 patients (17%) reported grade 3 diarrhea. 4 (57%) of the 7 patients in the DE cohort who experienced grade 3 diarrhea were not compliant with the high dose loperamide prophylaxis. There are 4 patients in the DE cohort who did not yet have safety data reported and are therefore not included in the safety population. For the patients in the DE cohort, thus far 47% of the patients have been able to dose escalate from 8 mg per week of temsirolimus to 15 mg per week of temsirolimus.

The interim efficacy results from the trial showed that for the 37 patients in the MTD cohort, 11 patients (30%) experienced a partial response (PR). The median duration of response for this cohort of patients was 3.0 months and the median progression free survival was 4.8 months. For the 37 evaluable patients in the DE cohort, the efficacy results from the trial demonstrated that 11 patients (30%) experienced a partial response (PR). The median duration of response for this cohort of patients was 7.4 months and the median progression free survival is not yet mature. There are a total of 18 patients currently on active treatment in the trial. 8 of

the 17 active patients in the DE cohort have not yet had tumor assessments.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We continue to be pleased with the data on the combination of PB272 with temsirolimus. This interim data continues to demonstrate strong 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 following the remaining patients on study to completion of the trial and advancing the combination of PB272 and temsirolimus into Phase III trials in 2015."

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 (oral neratinib), a potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive breast cancer and patients with non-small cell lung cancer, breast cancer and other solid tumors that have a HER2 mutation.

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 plans with respect to clinical trials. 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 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, 2013. 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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