News Release

Puma Biotechnology Presents Interim Results of Phase II Trial of PB272 for ERBB2 (HER2) Mutant, HER2 Non-Amplified, Metastatic 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 updated interim results from an ongoing Phase II clinical trial of Puma's investigational drug PB272 (neratinib), given as monotherapy and in combination with the anticancer drug fulvestrant, were presented at the 2016 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled "Neratinib plus fulvestrant for ERBB2 mutant, HER2 non-amplified, estrogen receptor-positive, metastatic breast cancer: Preliminary analysis from the Phase II SUMMIT trial" was presented as a poster discussion by Dr. David Hyman, Director, Developmental Therapeutics at Memorial Sloan Kettering Cancer Center.

Interim results from this trial were previously presented at the 2015 SABCS and included patients who were treated with neratinib monotherapy for metastatic breast cancer and whose tumors have a HER2 mutation. The presentation also discussed that a bidirectional cross-talk between hormone receptor and HER2 signaling pathways could lead to endocrine resistance due to activated HER2 signaling and ER-mediated tumor proliferation as a potential resistance mechanism to sustained HER2 inhibition. Preclinical xenograft data has demonstrated that the combination of an anti-estrogen with neratinib results in enhanced anti-tumor activity in preclinical models of estrogen receptor positive/HER2-positive breast tumors. Based on this, the SUMMIT study was amended to allow for the combination of neratinib plus fulvestrant in eligible postmenopausal hormone receptor-positive breast cancer patients. The presentation at SABCS included an update on both the neratinib monotherapy cohort and the neratinib plus fulvestrant cohort.

In the study, patients with HER2 mutant metastatic breast cancer were enrolled and received 240 mg of neratinib daily either as monotherapy or in combination with fulvestrant. All patients received loperamide (16 mg per day initially) prophylactically for the first cycle of treatment in order to reduce the neratinib-related diarrhea. For the 25 patients in the group who received neratinib monotherapy, 23 patients (92%) had HER2-negative disease, 19 patients (76%) were hormone receptor positive (estrogen receptor or progesterone receptor positive), and patients had received a median of 4 prior lines of therapy in the metastatic setting (range 0-8 prior regimens) before entering the trial. For the 17 patients in the trial who received neratinib plus fulvestrant, 15 patients (88%) had HER2-negative disease, 17 patients (100%) were hormone receptor positive (estrogen receptor or progesterone receptor positive), and patients had received a median of 4 prior lines of therapy in the metastatic setting (range 1-7 prior regimens) before entering the trial.

The interim efficacy results from the trial showed that for the 24 efficacy evaluable patients in the neratinib monotherapy cohort, 8 patients (33.3%) experienced an objective response, which included 3 patients with a complete response and 5 patients with partial responses. At week 8, 8 patients (33.3%) achieved an objective response, with 2 patients achieving a complete response and 6 patients achieving a partial response The secondary endpoints of the trial included confirmed objective response (complete response or partial response), clinical benefit rate and progression free survival (PFS). The results of the trial showed that 6 patients (25%) had a confirmed objective response, 10 patients (41.7%) demonstrated clinical benefit and the median progression free survival was 3.5 months.

For the 12 efficacy evaluable patients in the neratinib plus fulvestrant cohort, 7 patients (58.3%) experienced an objective response, which included 2 patients with a complete response and 5 patients with partial responses. At week 8, 5 patients (41.7%) achieved an objective response, with 2 patients achieving a complete response and 3 patients achieving a partial response. The secondary endpoints of the trial included confirmed objective response (complete response or partial response), clinical benefit rate and progression free survival (PFS). The results of the trial showed that 3 patients (25%) had a confirmed objective response, 7 patients (58.3%) demonstrated clinical benefit and the median progression free survival was 3.7 months. The progression free survival data may not be mature in the neratinib plus fulvestrant cohort as 4 of the 12 efficacy evaluable patients are continuing to receive study treatment without disease progression and an additional 5 patients have not yet had an assessment for efficacy.

The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 25 patients enrolled in the neratinib monotherapy arm, 6 patients (24%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for the patients in the neratinib monotherapy cohort was 1 day. No patient in the neratinib monotherapy cohort has permanently discontinued neratinib due to diarrhea and 5 patients (20%) have temporarily discontinued neratinib due to diarrhea and then restarted after the diarrhea subsided. For the 17 patients enrolled in the neratinib plus fulvestrant cohort, 2 of 17 patients (12%) experienced grade 3 diarrhea. The median duration of grade 3 diarrhea was 1 day and typically occurred during the first cycle of treatment. No patient (0%) in the neratinib plus fulvestrant cohort permanently discontinued neratinib due to diarrhea and 2 patients (12%) temporarily discontinued neratinib due to diarrhea and then restarted after the diarrhea subsided.

Dr. David Hyman, Director, Developmental Therapeutics at Memorial Sloan Kettering Cancer Center and principal investigator of the trial, stated, “Neratinib showed promising signs of clinical activity both as a single agent and in the patients treated with the combination of neratinib plus fulvestrant in this preliminary analysis of pre-treated HER2 mutant breast cancer patients. 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 the ongoing neratinib plus fulvestrant cohort and moving this combination forward into future clinical development.”

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, “We are very pleased with the preliminary activity seen with neratinib, both alone and in combination with fulvestrant in this cohort of patients with HER2 mutated breast cancer. We look forward to the completion of the trial and further development of the combination of neratinib and fulvestrant.”

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 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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