Puma Biotechnology Presents Interim Results of Phase II Trial of PB272 for ERBB2 Mutant, HER2 Non-Amplified, Metastatic Breast Cancer at the 2015 San Antonio Breast Cancer Symposium

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that interim results from an ongoing Phase II clinical trial of Puma's investigational drug PB272 (neratinib) were presented at the 2015 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) that is currently taking place in San Antonio, Texas. The presentation entitled “Neratinib for ERBB2 mutant, HER2 non-amplified, metastatic breast cancer: preliminary analysis from SUMMIT – a multicenter, open-label, multi-histology phase II basket trial” will be presented as a poster discussion by Dr. David Hyman, Acting Director, Developmental Therapeutics at Memorial Sloan Kettering Cancer Center.

In May 2014 Puma announced that it expanded the first cohort from the Phase II clinical trial of PB272 (neratinib) in patients with solid tumors who have an activating *ERBB2* (HER2) mutation (SUMMIT basket trial). These interim results are the first presentation of data from this expanded cohort of patients with metastatic breast cancer and whose tumors have a HER2 mutation but are neither HER2 amplified or overexpressed (HER2 negative).

In the cohort, patients with HER2 mutant metastatic breast cancer were enrolled and received 240 mg of neratinib daily. 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 20 patients in the cohort presented, 20 patients (100%) had HER2-negative disease, 17 patients (85%) were hormone receptor positive (estrogen receptor or progesterone receptor positive), and patients had received a median of 4 prior regimens in the metastatic setting (range 0-11 prior regimens) before entering the trial.

The primary endpoint of the trial was objective response at week 8 assessed by anatomic or metabolic imaging. The interim efficacy results from the trial showed that for the 19 efficacy evaluable patients in the breast cancer cohort, 6 patients (32%) experienced a response at week 8. This included one patient with a complete response and five patients with partial responses. 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 (16%) had a confirmed objective response, 8 patients (42%) demonstrated clinical benefit and the median progression free survival was 4.0 months.

The presentation also discussed that a bidirectional cross-talk between hormone receptor and HER2 signaling pathways can lead to endocrine resistance due to activated HER2 signaling and ER-mediated tumor proliferation as a potential resistance mechanism to sustained HER2 inhibition. Preclinical data has demonstrated that the combination of an anti-estrogen with a HER2 inhibitor 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. For the 3 response-evaluable patients who have been enrolled and received the combination of neratinib plus fulvestrant, 3 (100%) of 3 patients have shown a response, including one patient with a complete response and two patients with partial responses. There have also been two patients enrolled on the combination of neratinib plus fulvestrant after progressing on neratinib monotherapy. One (50%) of these two patients has demonstrated a partial response.

The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 130 patients enrolled across all solid tumor cohorts in the SUMMIT study, 25 patients (19%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for the patients in the entire SUMMIT study was 2 days. 2 patients (2%) in the SUMMIT study have permanently discontinued neratinib due to diarrhea and 20 patients (15%) have temporarily discontinued neratinib due to diarrhea and then restarted after the diarrhea subsided. For the breast cancer mutation cohort, 7 of 20 patients (35%) experienced grade 3 diarrhea. The median duration of grade 3 diarrhea was 1 day. No patient (0%) in the breast cancer cohort permanently discontinued neratinib due to diarrhea and 4 patients (20%) temporarily discontinued neratinib due to diarrhea and then restarted after the diarrhea subsided.

Dr. David Hyman, Acting Director, Developmental Therapeutics at Memorial Sloan Kettering Cancer Center and principal investigator of the trial, stated, "Neratinib showed promising signs of clinical activity as a single agent and very encouraging clinical activity in the patients with the combination of neratinib plus fulvestrant in this interim 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 initiating the pivotal trial of the combination that we are currently planning for 2016.”

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 advancing the combination of PB272 and fulvestrant into a pivotal trial in 2016."

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. The Company aims to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. 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, but not limited to, statements regarding the development of our drug candidates and the anticipated timing for the commencement and completion of various 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, 2014 and any subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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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