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Puma Biotechnology Announces Presentation of Phase III Trial of PB272 in Extended Adjuvant Breast Cancer (ExteNET Trial) in Centrally Confirmed HER2-Positive Early Stage Breast Cancer Patients

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced the presentation of positive results from the Phase III clinical trial of Puma's investigational drug PB272 (neratinib) for the extended adjuvant treatment of breast cancer (ExteNET trial) in patients with centrally confirmed HER2-positive early stage breast cancer. The ExteNET trial is a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in women with early stage HER2-positive breast cancer. The data was presented today in an oral presentation at the American Society of Clinical Oncology (ASCO) 2015 Breast Cancer Symposium in San Francisco, California. This data was previously presented in June at the ASCO Annual Meeting in Chicago, Illinois.

The ExteNET trial randomized 2,840 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomized to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of two years after randomization in the trial.

The patient characteristics in the trial were well balanced between the neratinib and placebo arms of the trial. For the 1,420 patients in the neratinib arm of the trial, 1,085 (76.4%) were node positive while for the 1,420 patients in the placebo arm of the trial, 1,084 (76.3%) were node positive. Additionally in the neratinib arm of the trial, 816 (57.5%) patients were hormone receptor positive, and in the placebo arm of the trial, 815 (57.4%) patients were hormone receptor positive. The median time from the last trastuzumab dose to entry into the trial was 4.4 months for the neratinib treated patients and 4.6 months for the placebo-treated patients.

The safety results of the study showed that the most frequently observed adverse event for the neratinib-treated patients was diarrhea, with approximately 39.9% of the neratinib-treated patients experiencing grade 3 or higher diarrhea (1 (0.1%) patient had grade 4 diarrhea). Patients who received neratinib in this trial did not receive any prophylaxis with antidiarrheal agents to prevent the neratinib-related diarrhea. Puma’s recently reported clinical data from several trials have demonstrated that the use of high dose prophylactic loperamide greatly reduces the rate of grade 3 diarrhea with neratinib, with grade 3 diarrhea rates ranging from 0-17% in studies in which high dose loperamide prophylaxis was used. In all of its current ongoing studies Puma is instituting the use of high dose loperamide for the first cycle of treatment in order to continue to reduce the neratinib-related diarrhea.

The primary endpoint of the trial was invasive disease free survival (DFS). The results of the trial demonstrated that treatment with neratinib resulted in a 33% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.67, p = 0.009). The 2-year DFS rate for the neratinib arm was 93.9% and the 2-year DFS rate for the placebo arm was 91.6%. As an inclusion criteria for the ExteNET trial, patients needed to have tumors that were HER2 positive using local assessment. In addition, as a pre-defined subgroup in the trial, patients had centralized HER2 testing performed on their tumor as well. To date, centralized HER2 testing has been performed on 1,705 (60%) of the patients in the ExteNET trial and further central testing on available samples is currently ongoing. For the 1,463 patients whose tumors were HER2 positive by central confirmation, the results of the trial demonstrated that treatment with neratinib resulted in a 49% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.51, p = 0.002). The 2-year DFS rate for the centrally confirmed patients in the neratinib arm was 94.7% and the 2-year DFS rate for the centrally confirmed patients in the placebo arm was 90.6%.

For the pre-defined subgroup of centrally confirmed HER2-positive patients with hormone receptor positive disease, the results of the trial demonstrated that treatment with neratinib resulted in a 75% reduction of risk of invasive disease recurrence or death (hazard ratio = 0.25, p < 0.001). The 2-year DFS rate for the centrally confirmed patients in the neratinib arm was 97.0% and the 2-year DFS rate for centrally confirmed patients in the placebo arm was 88.4%.

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, but not limited to, statements regarding the development of our 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 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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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