News Release

Puma Biotechnology Announces Interim 5-Year Disease Free Survival Data from Phase III Trial of PB272 (Neratinib) in Extended Adjuvant HER2-Positive Early Stage Breast Cancer (ExteNET Trial)

LOS ANGELES, Calif., July 21, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced updated results from the Phase III clinical trial of Puma's investigational drug PB272 (neratinib) for the extended adjuvant treatment of HER2-positive early stage breast cancer (ExteNET trial). 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 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, or death for a period of two years after randomization in the trial. 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 invasive DFS rate for the neratinib arm was 93.9% and the 2-year invasive DFS rate for the placebo arm was 91.6%. These results were previously reported at the 2015 American Society of Clinical Oncology meeting and updated results, including interim 3-year invasive DFS data, were presented at the 2015 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS).

As part of the data analysis for the New Drug Application (NDA) filing in the United States and the Marketing Authorisation Application (MAA) submission in Europe, an updated analysis that included an interim 5-year invasive DFS analysis was performed. This data analysis was performed in order to examine the durability of treatment effect beyond the 2-year data included in the primary analysis. This interim analysis was not a pre-planned analysis in the statistical analysis plan for the trial. For the primary endpoint of the trial, invasive DFS, the 5-year interim results of the trial demonstrated that treatment with neratinib resulted in a 26% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.74, p = 0.017). The 5-year interim invasive DFS rate for the neratinib arm was 90.4% and the 5-year interim invasive DFS rate for the placebo arm was 87.9%. Additional updated results for the 3-year invasive DFS rate and 4-year invasive DFS rate are shown in the table below:

DFS for Intent to Treat (ITT) Population			
	3-Year DFS	4-Year DFS	5-Year Interim DFS
Neratinib	92.5%	91.4%	90.4%
Placebo	90.3%	89.2%	87.9%
Absolute invasive DFS Difference	2.2%	2.2%	2.5%

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 2,140 (75%) of the patients in the ExteNET trial, and further central testing on available samples is currently ongoing. For the 1,777 patients whose tumors were HER2 positive by central confirmation, the interim results of the trial demonstrated that treatment with neratinib resulted in a 30% reduction of risk of invasive disease recurrence

or death versus placebo (hazard ratio = 0.70, p = 0.026). The 5-year interim invasive DFS rate for the centrally confirmed patients in the neratinib arm was 90.8% and the 5-year interim invasive DFS rate for the centrally confirmed patients in the placebo arm was 88.1%.

For the pre-defined subgroup of 1,631 patients with hormone receptor positive disease, the interim results of the trial demonstrated that treatment with neratinib resulted in a 41% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.59, p = 0.002). The 5-year interim invasive DFS rate for the neratinib arm was 91.7% and the 5-year interim invasive DFS rate for the placebo arm was 86.9%. Additional updated results for the 3-year invasive DFS rate and 4-year invasive DFS rate are shown in the table below:

DFS for Hormone Receptor Positive (HR-positive) Population			
	3-Year DFS	4-Year DFS	5-Year Interim DFS
Neratinib	93.8%	92.9%	91.7%
Placebo	89.9%	88.6%	86.9%
Absolute invasive DFS Difference	3.9%	4.3%	4.8%

"We are very pleased with the interim 5-year invasive DFS results from the ExteNET trial with neratinib," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We believe these results support the long term clinical benefit of neratinib in the extended adjuvant treatment of patients with early stage HER2-positive breast cancer who have completed prior trastuzumab-based adjuvant therapy. We look forward to obtaining the full 5-year DFS data, which we anticipate will be available in 2017."

Conference Call and Webcast

The Company will host a conference call to discuss the updated ExteNET trial data at 2:00 p.m. PDT (5:00 p.m. EDT) on July 21. The conference call may be accessed by dialing 1-877-709-8150 for domestic callers and 1-201-689-8354 for international callers. Please specify to the operator that you would like to join the "Puma Biotechnology Update Call." The conference call and presentation slides will be webcast live and accessible through the Investor Relations section of Puma's website at http://www.pumabiotechnology.com/ir_events.html and will be archived there for 30 days following the call. Please visit Puma's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

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 the development of the Company's drug candidates and the announcement of data relative to the Company's 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 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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