News Release

Puma Biotechnology's ExteNET Phase III Study Published Online in *The Lancet Oncology*

LOS ANGELES, Calif., Feb. 11, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that results from the ExteNET Phase III clinical trial of neratinib in patients with early stage HER2 positive breast cancer were published in the journal *The Lancet Oncology*. The article entitled "Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET); a multicentre, randomized, double-blind, placebo-controlled, phase 3 trial" appears in the February 10, 2016 online issue and will be published in a future print issue of the journal.

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 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 primary endpoint of the trial was invasive disease free survival (DFS).

The study demonstrated that the trial hit its primary endpoint and 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%. For the pre-defined subgroup of patients with hormone receptor positive disease, 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 = 0.001). For the patients with hormone receptor positive disease, the 2-year DFS rate for the neratinib arm was 95.4% and the 2-year DFS rate for the placebo arm was 91.2%.

"ExteNET represents the first randomized trial to demonstrate a statistically significant DFS benefit using a HER2 targeted drug in the extended adjuvant treatment of patients with early stage HER2 positive breast cancer who have previously been treated with adjuvant trastuzumab," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We are pleased that *The Lancet Oncology* has chosen to publish these results."

The safety results of the ExteNET 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 the ExteNET trial did not receive any prophylaxis with antidiarrheal agents to prevent the neratinib-related diarrhea. Recently announced interim results of a Phase II study of neratinib monotherapy in patients with HER2 positive early stage breast cancer who have previously been treated with adjuvant trastuzumab where patients received anti-diarrheal prophylaxis with loperamide demonstrated that treatment with prophylactic loperamide reduced the rate of grade 3 or higher diarrhea to between 13.0-18.5%. In addition, the grade 3 diarrhea that was seen in the interim analysis of this Phase II trial was limited to the first 3 weeks of the 12 month treatment period.

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 statements regarding the publication of clinical trial data. 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 Reports on Form 10-Q for the quarters ended June 30, 2015 and September 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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