News Release

Puma Biotechnology Announces European Medicines Agency Validation of Marketing Authorization Application for PB272 (Neratinib) as Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer in Europe

LOS ANGELES, Calif., Aug. 22, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that the Marketing Authorization Application (MAA) for neratinib has been validated by the European Medicines Agency (EMA). Validation of the MAA confirms that the submission is complete and starts the EMA's formal review process. The potential indication for neratinib is for the extended adjuvant treatment of HER2-positive early stage breast cancer that has previously been treated with trastuzumab (Herceptin®)-based adjuvant therapy. The MAA submission is based upon the ExteNET Phase III study, which reached its primary endpoint whereby neratinib demonstrated a statistically significant reduction of risk of invasive disease recurrence or death versus placebo.

"Although the use of trastuzumab in the adjuvant setting has led to a reduction in disease recurrence in patients with early stage HER2-positive breast cancer, there remains an unmet clinical need for further improvement in outcome in order to attempt to further reduce this risk of recurrence following trastuzumab therapy," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "Neratinib may be able to provide this type of improvement to further help the patients with this disease. We look forward to working with the CHMP/EMA during their review of this submission."

In the ExteNET study, 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 disease free survival (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%. Results of the study were published online in *The Lancet Oncology* on February 10, 2016.

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 patient (0.1%) 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. 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% and 18.5%.

About ExteNET

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 DFS.

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 potential benefits of neratinib and the MAA for neratinib in Europe for the potential indication for the extended adjuvant treatment of HER2-positive early stage breast cancer that has previously been treated with trastuzumab (Herceptin®)-based adjuvant therapy. 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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