News Release

Puma Biotechnology Announces U.S. FDA Acceptance of New Drug Application for PB272 (Neratinib) for Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer

LOS ANGELES, Calif., Sept. 20, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for its lead product candidate PB272 (neratinib) for the extended adjuvant treatment of patients with early stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab (Herceptin®)-based therapy.

"The FDA acceptance of our NDA is an important regulatory milestone," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "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 to further reduce the risk of recurrence and improve outcome following trastuzumab therapy. We believe that neratinib may be able to provide this type of improvement to further help patients with this disease. We look forward to working with the FDA during their review of this submission."

The submission is supported by the results of the ExteNET Phase III study, in which 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 invasive 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 invasive DFS rate for the neratinib arm was 95.4% and the 2-year invasive 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. In patients with HER2-positive early stage breast cancer who have previously been treated with adjuvant trastuzumab and received anti-diarrheal prophylaxis with loperamide, interim results of a Phase II study of neratinib monotherapy 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 invasive 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.

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