News Release

Puma Biotechnology Completes Targeted Enrollment in Neratinib Phase III Metastatic Breast Cancer Trial

LOS ANGELES, Calif., July 6, 2017 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that targeted patient enrollment in the Phase III NALA trial of the Company's lead drug candidate PB272 (neratinib) in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments (third-line disease) in the setting of metastatic disease has been completed.

The Phase III NALA trial is a randomized trial of PB272 plus Xeloda versus Tykerb plus Xeloda in patients with third-line HER2-positive metastatic breast cancer. The trial has enrolled approximately 600 patients who are randomized (1:1) to receive either PB272 plus Xeloda or Tykerb plus Xeloda. The trial is being conducted at sites in North America, Europe and Asia-Pacific. The co-primary endpoints of the trial are progression free survival (PFS) and overall survival (OS). The company reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the design of the Phase III clinical trial and the European Medicines Agency (EMA) has also provided follow-on scientific advice (SA) consistent with that of the FDA regarding the Company's Phase III trial design and endpoints used in the trial.

The primary analyses of PFS and OS are event driven. The Company anticipates that primary analysis of PFS will be available during the first half of 2018.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are very pleased to achieve this important milestone for the Phase III NALA trial of neratinib in HER2-positive metastatic breast cancer. We look forward to reporting initial data from the study, which we anticipate will occur during the first half of 2018. We also look forward to the continued development of neratinib in combination with Kadcyla in HER2-positive metastatic breast cancer (FB-10 trial), in patients with HER2-positive breast cancer that has metastasized to the brain (TBCRC-022 trial) and in patients with HER2 non-amplified tumors that have a HER2 mutation (SUMMIT)."

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 Company's clinical trials and the announcement of data relative to these 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, risks pertaining to securities class action, derivative and defamation lawsuits, 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, 2016. 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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