News Release

Puma Biotechnology Initiates Phase II Trial of PB272 (Neratinib) in HER2 Mutation-Positive Solid Tumor Patients

LOS ANGELES, Calif., Oct. 4, 2013 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced that it initiated a Phase II clinical trial of its lead drug candidate PB272 (neratinib) as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial).

The Phase II basket trial is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating HER2 mutations. The study will initially include 6 cohorts (baskets) of patients, each of which will include one of the following cancers: (1) bladder/urinary tract cancer; (2) colorectal cancer; (3) endometrial cancer; (4) gastric/esophageal cancer; (5) ovarian cancer; and (6) all other solid tumors (including prostate, melanoma and pancreatic cancer). Each basket will initially consist of 7 patients. If a certain predetermined objective response rate is seen in the initial cohort of 7 patients, the basket will be expanded to include a larger number of patients.

"It is estimated that approximately 2-10 percent of patients with solid tumors have a HER2 mutation. Preclinical data suggests that neratinib potently inhibits the activity of these cancer-driving mutations, which could translate into clinical benefit for these patients. We are pleased to initiate this basket study in order to further investigate the efficacy of neratinib in these patients with a particular unmet medical need," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We anticipate that we may get an initial indication on the efficacy of neratinib in these mutation-positive patients by late this year or early next year and that we may be able to expand this trial with additional patients and additional cohorts during that same time period."

About Puma Biotechnology

Puma Biotechnology, Inc. is a development stage biopharmaceutical company that acquires and develops innovative products for the treatment of various forms of cancer. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use. 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 metastatic 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 anticipated timing for the commencement and completion of various 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; 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, 2012. 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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