



## News Release

### **Puma Biotechnology Expands Cohort in Phase II Trial of PB272 (Neratinib) in HER2 Mutation-Positive Solid Tumor Patients**

**LOS ANGELES, Calif., May 14, 2014** – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, has expanded the first cohort from its 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 cohort that has been expanded is the cohort that includes patients with metastatic breast cancer that is not HER2 amplified or overexpressed (HER2 negative) and has a HER2 mutation.

The Phase II basket trial, which was initiated in October 2013, 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 (driver) HER2 mutations. The cohorts (baskets) included in the study are: (1) bladder/urinary tract cancer; (2) colorectal cancer; (3) endometrial cancer; (4) gastric/esophageal cancer; (5) ovarian cancer; (6) EGFR mutated and/or amplified primary brain cancer; (7) solid tumors with a HER3 mutation, and (8) all other solid tumors with a HER2 mutation. The breast cancer patients initially entered the study in the “other solid tumors with a HER2 mutation” basket and due to the preliminary activity seen in the trial the Company has expanded the basket, as per the protocol for the trial. The expanded basket will initially enroll a total of 18 patients.

“We are pleased to expand the first cohort in the basket trial. This trial will be the second trial that Puma is running in patients with HER2-negative breast cancer with a HER2 mutation and will be run at many different centers than the investigator-sponsored trial that was initiated in December 2012,” said Alan H. Auerbach, Chief Executive Officer and President of Puma. “We look forward to continuing enrollment into this initially expanded cohort and look forward to expanding additional cohorts from the basket trial, which we anticipate being able to do later this year.”

#### **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 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](http://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, 2013. 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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