News Release

Puma Biotechnology Announces Positive Initial Results from PB272 Phase II Trial in HER2 Mutated Non-Small Cell Lung Cancer

LOS ANGELES, **Calif., Sept. 29, 2014** – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced that positive initial data from the ongoing, open label Phase II clinical trial of its investigational drug PB272 (neratinib) for the treatment of patients with non-small cell lung cancer (NSCLC) with HER2 mutations was presented today as a late-breaking oral presentation at the European Society for Medical Oncology (ESMO) 2014 Congress, taking place in Madrid, Spain. The presentation was entitled "Neratinib with or without temsirolimus in patients with non-small cell lung cancer carrying HER2 somatic mutations: An international randomized Phase II study."

In the trial, patients with confirmed stage IIIB or stage IV NSCLC with documented somatic HER2 mutations were randomized to receive either oral neratinib monotherapy at a dose of 240 mg per day or the combination of oral neratinib (at a dose of 240 mg daily) with intravenous temsirolimus administered at a dose of 8 mg per week. In order to attempt to reduce the neratinib related diarrhea, high-dose loperamide prophylaxis (Imodium) was given to all patients in both arms of the study beginning on day 1 of neratinib dosing. The data presented in the oral presentation involved a total of 27 patients who completed the first stage of the trial; 13 of these patients received neratinib monotherapy and 14 of these patients received the combination of neratinib plus temsirolimus.

The results of the study showed that the combination of PB272 and temsirolimus had acceptable tolerability. Historically the most frequently seen adverse event associated with neratinib has been diarrhea. In the previous Phase I trial of neratinib plus temsirolimus (J Clin Oncol 2014) the diarrhea with neratinib was seen to be dose dependent and its incidence increased with increasing neratinib dosage. In that Phase I trial, grade 3 or higher diarrhea was seen in approximately 30% of the patients treated with doses of neratinib that were 200 mg or higher.

In this Phase II study, all patients received high-dose loperamide in order to attempt to prevent or reduce the neratinib-related diarrhea. For the 13 patients enrolled in the neratinib monotherapy arm, 1 (8%) patient experienced grade 3 diarrhea, and for the 14 patients enrolled in the combination of neratinib plus temsirolimus arm, 2 (14%) patients experienced grade 3 diarrhea. There were no grade 4 diarrhea events seen in the trial. For the 3 patients in the study (1 in the monotherapy arm, 2 in the combination arm) who experienced grade 3 diarrhea, 2 of the 3 patients were not compliant with the loperamide prophylaxis regimen and were not taking loperamide at the onset of grade 3 diarrhea.

The efficacy results from the trial showed that for the 13 patients in the trial who received neratinib monotherapy, no patient experienced a partial response, 7 (54%) patients achieved stable disease and 4 (31%) patients achieved clinical benefit (defined as a partial response or stable disease for 12 or more weeks). For the 14 patients who received the combination of neratinib plus temsirolimus, 3 (21%) patients experienced a partial response, 11 (79%) patients experienced stable disease and 9 (64%) patients achieved clinical benefit. The median progression free survival of the neratinib monotherapy arm was 2.9 months and the median progression free survival of the arm that received neratinib plus temsirolimus was 4.0 months. Patients continue to be enrolled in the arm of the trial that is receiving the combination of neratinib plus temsirolimus.

"We are pleased with the initial results of the Phase II trial with neratinib in patients with HER2 mutated non-small cell lung cancer," said Alan H. Auerbach, Chief Executive Officer and President. "The activity seen to

date in the trial confirms the efficacy signal seen in the prior Phase I trial and supports future study. This represented our first clinical trial to implement the high-dose loperamide prophylaxis from the beginning of the trial in order to reduce the neratinib-related diarrhea, and we are very pleased with the reductions in grade 3 or higher diarrhea seen using this prophylaxis in the trial. These results are consistent with what we are seeing in our other studies that are utilizing the loperamide prophylaxis to reduce grade 3 or higher diarrhea with neratinib, which is resulting in an improvement in the tolerability of the agent."

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.

Forward-Looking Statements:

This press release contains forward-looking statements. 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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