News Release

Puma Biotechnology Announces Presentation of Positive PB272 Phase II Data at the 2014 ASCO Annual Meeting

LOS ANGELES, Calif., June 1, 2014 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced the presentation of positive results from an ongoing Phase II clinical trial of Puma's investigational drug PB272 (neratinib) for the treatment of HER2 positive metastatic breast cancer that has metastasized to the brain. The data was presented today in a poster presentation at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting in Chicago, Illinois.

The multicenter Phase II clinical trial is enrolling patients with HER2 positive metastatic breast cancer who have brain metastases. The trial is being performed by the Translational Breast Cancer Research Consortium (TBCRC) and is enrolling three cohorts of patients. Patients in the first cohort (n=40) represent patients with progressive brain metastases who are administered neratinib monotherapy. Patients in the second cohort (n=5) represent patients with brain metastases who are amenable to surgery and are administered neratinib monotherapy prior to and after surgical resection. The third cohort (n=60) enrolls patients with progressive brain metastases who are administered neratinib in combination with the chemotherapy drug capecitabine. The poster presentation reflects only the patients in the first cohort of patients, which are those with progressive brain metastases who received neratinib monotherapy. Enrollment in the second and third cohorts, patients with brain metastases amenable to surgery receiving neratinib monotherapy and patients with progressive brain metastases receiving the combination of neratinib plus capecitabine, is continuing.

In the first cohort of patients, all patients had received prior radiotherapy with 38% of the patients receiving prior whole brain radiotherapy (WBRT) alone, 23% receiving prior stereotactic radiosurgery (SRS) alone and 40% of patients receiving both prior WBRT and SRS. 85% of patients in the first cohort received prior treatment with lapatinib and 83% of patients in the first cohort received two or more prior lines of chemotherapy in the metastatic setting.

The results for the first cohort of the study presented showed that the most frequently observed severe adverse event for the 40 patients evaluable for safety was diarrhea. In the first 12 patients treated in the study, there was no prophylaxis with antidiarrheal agents (loperamide) given in order to try to reduce the neratinib-related diarrhea. In these 12 patients, 29% of the patients experienced grade 3 or higher diarrhea and 25% experienced grade 2 diarrhea. In the next 28 patients, treatment with low doses of loperamide (2 mg) during the first cycle was given in order to try to reduce the neratinib-related diarrhea. In these 28 patients, the grade 3 or higher diarrhea rate was 21% and the grade 2 diarrhea rate was 12%. In the ongoing second and third cohorts in the study, patients are receiving a prophylactic protocol in which a high dose of loperamide, more specifically 16 mg on day 1, then 12 mg for the next two days, then 8 mg for the first two weeks, is given together with the combination of capecitabine plus neratinib in order to try to further reduce the neratinib related diarrhea.

The efficacy results from the first cohort of the trial showed that for the 40 evaluable patients, 3 (8%) patients experienced a partial response (PR), 4 (10%) patients experienced prolonged stable disease (SD) for greater than or equal to 6 months and 12 (30%) patients experienced stable disease (SD) for less than 6 months. The median progression free survival of the 40 evaluable patients was seen to be 1.9 months and the median overall survival was seen to be 8.7 months.

"We are pleased with the initial signal of activity of neratinib in this heavily pretreated population of patients with HER2 positive metastatic breast cancer that has metastasized to the brain, especially given that most of these patients were previously treated with the HER2 tyrosine kinase inhibitor lapatinib," said Alan H. Auerbach, Chief Executive Officer and President. "We look forward to the continued enrollment in the ongoing cohorts of patients and look forward to the data from the cohort of patients who receive the combination of neratinib plus capecitabine."

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, 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.

Contacts:

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

Andreas Marathovouniotis or David Schull, Russo Partners, +1 212 845 4235

andreas.marathis@russopartnersllc.com

david.schull@russopartnersllc.com

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