



## News Release

### **Puma Biotechnology Announces Positive PB272 Phase II Data from TBCRC 022 Trial in Patients with HER2-Positive Metastatic Breast Cancer with Brain Metastases at the 2017 ASCO Annual Meeting**

**LOS ANGELES, Calif., June 3, 2017** – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced the presentation of positive results from an ongoing Phase II clinical trial (Translational Breast Cancer Research Consortium TBCRC 022) of Puma's investigational drug PB272 (neratinib) for the treatment of HER2-positive metastatic breast cancer that has metastasized to the brain. The data were presented today in an oral presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting in Chicago, Illinois.

The multicenter Phase II clinical trial enrolled patients with HER2-positive metastatic breast cancer who have brain metastases. The trial is being performed by the TBCRC and enrolled three cohorts of patients. Patients in the first cohort (n=40) included those with progressive brain metastases who were administered neratinib monotherapy. Data from this cohort were previously reported at the 2014 ASCO Annual Meeting and published in the *Journal of Clinical Oncology* in 2016. Patients in the second cohort (n=5) represent patients who had brain metastases which were amenable to surgery and who were administered neratinib monotherapy prior to and after surgical resection. The third cohort (target enrollment=60) enrolled two sub-groups of patients (prior lapatinib-treated and no prior lapatinib) with progressive brain metastases who were administered neratinib in combination with the chemotherapy drug capecitabine. The oral presentation reflects only the patients in the third cohort of patients without prior lapatinib exposure (cohort 3A, n=37), who all had progressive brain metastases at the time of enrollment and who received the combination of capecitabine plus neratinib. A full copy of the oral presentation that was presented at the ASCO Annual Meeting is available on the Puma Biotechnology website. Results from the second cohort and cohort 3B (prior lapatinib-treated) will be presented at a forthcoming medical meeting.

In cohort 3A, 30% of the patients had received prior craniotomy, 65% of the patients had received prior whole brain radiotherapy (WBRT), and 35% had received prior stereotactic radiosurgery (SRS) to the brain. No patients had received prior treatment with lapatinib.

The primary endpoint of the trial was central nervous system (CNS) Objective Response Rate according to a composite criteria that included volumetric brain MRI measurements, steroid use, neurological signs and symptoms, and RECIST evaluation for non-CNS sites. The secondary endpoint of the trial was CNS response by Response Assessment in Neuro-Oncology-Brain Metastases (RANO-BM) Criteria. The efficacy results from the trial showed that 49% of patients experienced a CNS Objective Response by the composite criteria. The results also

showed that the CNS response rate using the RANO-BM criteria was 24%. The median time to CNS progression was 5.5 months and the median overall survival was 13.5 months, though 49% of patients remain alive and survival data are immature.

The results for cohort 3A showed that the most frequently observed severe adverse event for the 37 patients evaluable for safety was diarrhea. Patients received antidiarrheal prophylaxis consisting of high dose loperamide, given together with the combination of capecitabine plus neratinib for the first cycle of treatment in order to try to reduce the neratinib-related diarrhea. Among the 37 patients evaluable for safety, 32% of the patients had grade 3 diarrhea and 41% had grade 2 diarrhea.

“Neratinib given in combination with capecitabine showed promising activity in patients with heavily pre-treated HER2-positive disease metastatic to the CNS,” said Rachel A. Freedman, MD, MPH, Breast Oncology Center, Susan F. Smith Center for Women's Cancers, Dana-Farber Cancer Institute. “Despite the introduction of several new treatments for patients with HER2-positive metastatic breast cancer, CNS progression events remain a major source of patient morbidity and mortality. Based on the results from TBCRC-022, we look forward to additional trials with neratinib-based regimens for HER2-positive CNS disease.”

“We are very pleased with the activity seen in this trial with the combination of neratinib plus capecitabine,” said Alan H. Auerbach, CEO and President of Puma Biotechnology. “As a small molecule that can cross the blood brain barrier, neratinib potentially offers patients with HER2-positive metastatic breast cancer that has metastasized to the CNS a novel HER2 targeted treatment option. We look forward to working with TBCRC on future trials of neratinib in patients with HER2-positive disease metastatic to the CNS.”

### **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](http://www.pumabiotechnology.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding the development and potential benefits of the Company's drug candidates, 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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