News Release

Puma Biotechnology Presents Positive Phase II Data at the 2016 ASCO Annual Meeting

LOS ANGELES, Calif., June 5, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, presented positive results from an investigator sponsored Phase II trial of neratinib with HER2-mutated, non-amplified breast cancer. The data were presented today in a poster discussion session at the American Society of Clinical Oncology (ASCO) 2016 Annual Meeting in Chicago, Illinois. The poster (Abstract #516), entitled "*Phase II Trial of Neratinib for HER2 Mutated, Non-Amplified Metastatic Breast Cancer (HER2^{mut}MBC),*" was presented from 8:00-11:30 a.m. CDT today with a poster presentation discussion occurring immediately following the poster session.

In the trial, patients with HER2 mutated breast cancer (either in their primary or metastatic tumor) received 240 mg of neratinib daily. Patients received loperamide (16 mg per day initially) prophylactically for the first cycle of treatment in order to reduce the neratinib-related diarrhea. For the 16 patients enrolled in the trial, 16 patients (100%) had HER2-negative disease, 15 patients (94%) were hormone receptor positive (estrogen receptor or progesterone receptor positive), and for the patients with metastatic disease, patients had received a median of 3 prior regimens (range 2-10 prior regimens) before entering the trial. Among these 16 patients, 14 had activating HER2 mutations and 2 patients had HER2 mutations of unknown significance.

The primary endpoint of the Phase II trial was clinical benefit rate (CBR), defined as complete response (CR), partial response (PR) or stable disease (SD) greater than or equal to 6 months. The trial was designed to detect a CBR of 20%. In the 14 patients with activating HER2 mutations, 5/14 (36%) achieved clinical benefit, including 1 patient (7%) with a CR, 1 patient (7%) with a PR, and 3 patients (21%) with SD for greater than or equal to 6 months. The median duration of response in these 5 patients was 6 (range 6-14+) months. The median progression-free survival for all 14 patients with activating HER2 mutations in the trial was 5.0 months. In the 2 patients with HER2 mutations of unknown significance, there was no clinical benefit seen with neratinib.

Based on the preclinical data that has demonstrated that the combination of an anti-estrogen with a HER2 inhibitor results in enhanced anti-tumor activity in preclinical models of estrogen receptor positive/HER2-mutated breast tumors, the study has been amended to administer the combination of neratinib plus fulvestrant in eligible hormone receptor positive breast cancer patients who have an activating HER2 mutation in the tumor. Enrollment in this cohort is currently ongoing and results from this cohort receiving the combination of fulvestrant plus neratinib will be presented at a future medical meeting.

The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 16 patients enrolled in the study, 4 patients (25%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for the patients in the study was 1.5 days.

Dr. Cynthia Ma, Associate Professor of Medicine, Clinical Director of the Breast Cancer Program, Section of Medical Oncology, Division of Oncology, at Washington University School of Medicine and principal investigator of the trial, stated, "Neratinib showed promising clinical activity as a single agent in this trial in patients with HER2 non-amplified breast cancer that has an activating HER2 mutation. We look forward to continuing to enroll the cohort that is receiving the combination of neratinib plus fulvestrant and to reporting those results at a future medical meeting."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are very pleased with the preliminary activity seen with neratinib in this cohort of patients with HER2 mutated breast

cancer. We look forward to advancing the clinical development of the combination of neratinib and fulvestrant and determining the potential registration path for this combination in 2016."

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.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding the anticipated timing relating to 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 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, 2015. 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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