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Puma Biotechnology Expands Cohort in Phase II SUMMIT Trial of PB272 in HER2 Mutation-Positive Cancer Patients

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, has expanded the fourth cohort from its Phase II SUMMIT 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 cervical cancer and whose tumors have a HER2 mutation.

The Phase II SUMMIT basket trial is an open-label, multicenter, multi-histology, international study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating ERBB mutations including EGFR, HER2 and HER3. The cohorts included in the basket study receiving neratinib monotherapy are hormone receptor-negative breast cancer; biliary tract cancers; endometrial cancer; gastric/esophageal cancer; ovarian cancer; and all other solid tumors with a HER2 mutation. The cohorts receiving combination treatment are hormone receptor-positive breast cancer (neratinib plus fulvestrant) and bladder cancer (neratinib plus paclitaxel). The cervical cancer patients initially entered the study in the "other solid tumors with a HER2 mutation" cohort, and due to the preliminary activity seen in the trial, the Company has expanded a separate cervical cancer cohort pursuant to the protocol for the trial. The expanded HER2-mutant cervical cancer cohort will now enroll a total of 18 patients.

Dr. David Hyman, Director, Developmental Therapeutics at Memorial Sloan Kettering Cancer Center and principal investigator of the trial, stated, "We are pleased to expand our evaluation of neratinib in metastatic cervical cancer, an orphan and deadly disease with few treatment options. We believe this once again demonstrates the value of the basket study approach, in particular for developing targeted therapy for rare diseases with clinically-actionable mutations. We look forward to presenting the full results of the SUMMIT trial at a medical meeting in 2017."

"We are pleased to expand the fourth cohort in the basket trial," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "Although it is early, we are pleased with the initial activity that we are seeing in the patients with HER2 mutated cervical cancer in the trial. We look forward to continuing enrollment into this expanded cohort and look forward to presenting the full results from the SUMMIT study in 2017."

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 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, 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, 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.

Language:

English

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