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

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, has expanded the third cohort from its Phase II 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 biliary duct (bile duct) cancer and whose tumors have a HER2 mutation.

The Phase II basket trial, which was initiated in October 2013, is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating (driver) ERBB mutations including EGFR, HER2 and HER3. The cohorts (baskets) included in the study are: (1) bladder/urinary tract cancer; (2) breast cancers; (3) colorectal cancer; (4) endometrial cancer; (5) gastric/esophageal cancer; (6) ovarian cancer; (7) all other solid tumors with a HER2 mutation; (8) EGFR mutated and/or amplified primary brain cancer; and (9) solid tumors with a HER3 mutation. The biliary duct cancer patients initially entered the study in the "other solid tumors with a HER2 mutation" basket and due to the preliminary activity seen in the trial the Company has expanded the basket, as per the protocol for the trial. The expanded HER2 mutant metastatic biliary duct basket will now enroll a total of 18 patients.

Dr. David Hyman, Acting Director, Developmental Therapeutics at Memorial Sloan Kettering Cancer Center and principal investigator of the trial, stated, "We are pleased to be expanding our evaluation of neratinib in biliary cancers, 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."

"We are pleased to expand the third 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 biliary duct cancer in the trial. We look forward to continuing enrollment into this initially expanded cohort and look forward to expanding additional cohorts from the basket trial, which we anticipate during 2016."

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. The Company aims to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. 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 various clinical 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 Company's Annual Report on Form 10-K for the year ended December 31, 2014 and in subsequent periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time. 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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