News Release

Puma Biotechnology Announces Publication of PB272 in HER2 Non-Amplified Metastatic Breast Cancer with a HER2 mutation

LOS ANGELES, Calif., Sept. 10, 2015 – Puma Biotechnology, Inc. (NYSE: PBYI), today announced a publication in the September 2015 issue of the Journal of the National Comprehensive Cancer Network describes that a patient with HER2 non-amplified (HER2-negative) metastatic breast cancer who also had a HER2 activating mutation was successfully treated with PB272 (neratinib).

The peer-reviewed publication describes a female patient with advanced stage IV invasive ductal carcinoma of the breast. After multiple treatments with chemotherapy and hormonal therapy, a tumor specimen was submitted to Foundation Medicine for comprehensive genomic profiling. This testing identified a HER2 L755S mutation, an activating mutation located in the tyrosine kinase inhibitor binding site of the HER2 kinase domain. The L755S mutation produces resistance to the HER2 tyrosine kinase inhibitor lapatinib, but in preclinical studies has been shown to be highly sensitive to neratinib.

"Prior to treatment, the patient's ECOG performance status deteriorated and she was essentially homebound with massive ascites and profound weakness," said Dr. Noa Efrat Ben-Baruch, Head of the Department of Oncology, Kaplan Medical Center, Rehovot, Israel and a co-author of the publication. "The patient began treatment with neratinib and within two months her performance status improved, she was able to resume normal daily activities and a CT scan performed showed a partial response that persisted for 11 months. Capecitabine was then added to neratinib and the patient's tumor again responded. This clinical response markedly improved the patient's performance status and quality of life. The treatment of this patient is an excellent example of collaboration between basic research, clinical application and biotechnology companies for the benefit of patients. With the advent of molecular profiling of patients with metastatic disease, such collaborations are of utmost importance for the development of new drug candidates outside of formal clinical trials."

Dr. Ron Bose, from the Siteman Cancer Center and Washington University School of Medicine and a co-author of the publication, added "This case is the first published report of a patient with HER2-mutated breast cancer responding to treatment with a single-agent, HER2-targeted drug. This also validates our previously published preclinical data with neratinib that showed potent antitumor activity in HER2 mutations. Additional study of neratinib in patients with HER2 mutations is clearly warranted."

"We are very pleased to see the activity of neratinib in this case report," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We continue to be encouraged by the results of our ongoing studies of neratinib in patients with HER2 mutations, including our ongoing trials in breast cancer, lung cancer and the basket study, and we look forward to sharing more information about these trials later this year."

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 the announcement of data relative to the Company's 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 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, 2014 and Quarterly Report on Form 10-Q for the quarter ended June 30, 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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