



News Release

Puma Biotechnology Updates Timeline for Filing New Drug Application

NDA Filing Currently Anticipated for Q1 2016

LOS ANGELES, Calif., Dec. 2, 2014 – Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, today provided an update on the timeline for filing its New Drug Application (NDA) for the approval of PB272 (neratinib) in the extended adjuvant treatment of HER2-positive early stage breast cancer.

Puma had previously communicated that it anticipated filing the NDA for PB272 in the first half of 2015. This was based on the feedback it had previously received from regulatory agencies, which had been focused on the proposed clinical indication of HER2-positive metastatic breast cancer. Since the Company's initial NDA filing will now be for the extended adjuvant HER2-positive early stage breast cancer indication, based on the company's recent meetings with the U.S. Food and Drug Administration (FDA), Puma will need to submit data from preclinical carcinogenicity studies with its NDA filing in accordance with International Conference on Harmonization (ICH) guidelines. In order to accommodate this requirement, Puma intends to delay its proposed timeline for filing the NDA until the first quarter of 2016.

Conference Call and Webcast

The Company will host a conference call to discuss the NDA filing timeline update at 2:00 p.m. PST (5:00 p.m. EST) on Tuesday, December 2, 2014. The conference call may be accessed by dialing 1-877-709-8150 for domestic callers and 1-201-689-8354 for international callers. Please specify to the operator that you would like to join the "Puma Biotechnology Update Call." The conference call will also be webcast live and accessible through the Investor Relations section of Puma's website at http://www.pumabiotechnology.com/ir_events.html and will be archived there for 30 days following the call. Please visit Puma's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

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 anticipated timing with respect to plans to file for regulatory approval. 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, 2013. 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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