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Puma Biotechnology Announces FDA Advisory Committee to Review Neratinib for the Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer

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LOS ANGELES, Calif.--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has scheduled the New Drug Application (NDA) for neratinib for discussion by the Oncologic Drugs Advisory Committee (ODAC) on May 24, 2017. Neratinib is an investigational therapy for the extended adjuvant treatment of early stage HER2-positive breast cancer that has previously been treated with a trastuzumab containing regimen.

ODAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cancer and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

Puma Biotechnology announced on September 20, 2016 that the FDA had accepted for filing the NDA for neratinib. The NDA for neratinib is based on results from both the Phase III ExteNET trial in extended adjuvant early stage HER2-positive breast cancer and the Phase II CONTROL trial in extended adjuvant early stage HER2-positive breast cancer.

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 ODAC's scheduled review of the NDA for neratinib. 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, 2016. 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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