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# Puma Biotechnology Provides Update from Meeting with European Medicines Agency

## Release Date:

Monday, November 30, 2015 1:11 pm PST

## Terms:

## Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that based on its recent meeting with the European Medicines Agency (EMA), the Company plans to submit a Marketing Authorisation Application (MAA) for the approval of neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in patients who have previously been treated with a trastuzumab-containing regimen in the first half of 2016.

Puma recently conducted an MAA pre-submission meeting with the EMA. The purpose of this meeting was to provide the EMA with data from neratinib's non-clinical and clinical development programs that will form the basis of MAA sections for EMA review and approval. The data discussed with the EMA included non-clinical data (pharmacology, toxicology and carcinogenicity) and clinical trial data including the data from the Phase III trial of neratinib in the extended adjuvant treatment of HER2-positive early stage breast cancer (ExteNET trial). Upon review of this material, the EMA assessed that there were no critical concerns that would prevent Puma from submitting a complete MAA for European centralized review in support of neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in patients who have previously been treated with a trastuzumab-containing regimen.

## Conference Call and Webcast

The Company will host a conference call to discuss this EMA meeting at 2:00 p.m. PST (5:00 p.m. EST) on Monday, November 30, 2015. 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 be webcast live and accessible through the Investor Relations section of Puma's website at [http://www.pumabiotechnology.com/ir\\_events.html](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 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](http://www.pumabiotechnology.com).

## Forward-Looking Statements:

This press release contains forward-looking statements, including, but not limited to, statements regarding the development of our drug candidates and the timing of regulatory filings. 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 any subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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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