News Release

Puma Biotechnology Updates Timeline for Filing New Drug Application

NDA Filing Currently Anticipated Mid-2016

LOS ANGELES, **Calif., March 28, 2016** – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, announced that based on its recent meetings with the U.S. Food and Drug Administration (FDA), the Company now plans to submit its New Drug Application (NDA) for the approval of neratinib for the treatment of extended adjuvant breast cancer that has previously been treated with a trastuzumab-containing regimen in mid-2016.

Puma has recently conducted a series of meetings and communications with the FDA. The purpose of these communications was to provide the FDA with the data from neratinib's non-clinical and clinical development programs that will form the basis of the Company's NDA for neratinib for the treatment of extended adjuvant breast cancer that has previously been treated with a trastuzumab-containing regimen. The data discussed with the FDA included preclinical data (pharmacology, toxicology, reproductive toxicity, 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) and the Phase II trial of neratinib monotherapy in the extended adjuvant treatment of HER2-positive early stage breast cancer where patients received loperamide prophylaxis in order to prevent the neratinib-related diarrhea. Following its review of this material, the FDA requested that Puma amend the current statistical analysis plan for the ExteNET trial to incorporate the FDA's recommendations with regard to rules for censoring the data for recurrent disease events or death.

For the primary endpoint of the ExteNET trial (Invasive Disease Free Survival), the analysis was based on all recurrent disease events and deaths occurring within 2 years and 28 days post randomization. The FDA has requested that events (disease recurrence or deaths) observed after missing 2 or more scheduled disease assessments be censored at the last available disease assessment time prior to the event occurrence. The FDA's requested approach was a sensitivity analysis used in the ExteNET trial's original statistical analysis plan but will now be the primary analysis approach used in the trial's updated statistical analysis plan. In order to accommodate this change, Puma expects to delay filing its NDA for neratinib for the treatment of extended adjuvant breast cancer that has previously been treated with a trastuzumab-containing regimen until mid-2016.

The primary analysis results of the trial do not appear to be altered materially by the updated analysis approach. Provided below are the results of the original and updated analyses of the primary endpoint of invasive disease-free survival (iDFS) for the intent to treat (ITT) population:

1) ITT population applying the original event and censoring rule:
    - 179 iDFS events
    - 33% reduction in risk of iDFS vs. placebo (hazard ratio=0.67 (0.50, 0.91), 1-sided P=0.005)
    - iDFS rates 93.9% (neratinib arm) vs. 91.6% (placebo arm)

2) ITT population applying the revised event and censoring rule per FDA:
    - 173 iDFS events
    - 34% reduction in risk of iDFS vs. placebo (hazard ratio=0.66 (0.49, 0.90), 1-sided P=0.004)
    - iDFS rates 94.2% (neratinib arm) vs. 91.9% (placebo arm)

Conference Call and Webcast

The Company will host a conference call and webcast to discuss this update at 1:30 p.m. PDT (4:30 p.m. EDT) on Monday, March 28, 2016. 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 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 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, but not limited to, statements regarding the anticipated timing for the filing of a new drug application. 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, 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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