News Release

Puma Biotechnology Provides Update on Review of Marketing Authorisation Application for PB272

LOS ANGELES, Calif., March 1, 2017 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that based on its recent meeting with the Rapporteur, Co-Rapporteur and review team members, as well as the European Medicines Agency (EMA), the Company plans to modify the summary of product characteristics (SmPC), sometimes referred to as the European product label, in its Marketing Authorisation Application (MAA) to restrict the intended population to patients initiating neratinib treatment within one year after completion of adjuvant trastuzumab therapy. The proposed SmPC will continue to include both hormone receptor positive and hormone receptor negative patients.

Puma recently conducted a meeting with the Rapporteur, Co-rapporteur and members of the review team as well as EMA to discuss the responses to the 120-day list of questions received in connection with the Company's MAA for neratinib that was submitted in the summer of 2016. The initially proposed indication was for the "extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab based therapy." During this meeting it was discussed that neratinib would likely be sequenced immediately after adjuvant trastuzumab and more benefit was observed in the subgroup of patients who received neratinib within 1 year from prior trastuzumab completion when compared with those patients receiving neratinib after 1 year from the completion of prior trastuzumab treatment. In addition, data from the pivotal adjuvant trastuzumab trials suggest that patients are at higher risk of recurrence closer to completion of adjuvant trastuzumab, and the risk of recurrence may decrease over time.

Based on this meeting, Puma will be revising the proposed SmPC in its MAA for neratinib to restrict the intended population to those patients initiating neratinib treatment within one year after completion of adjuvant trastuzumab therapy. The Committee for Medicinal Products for Human Use (CHMP) is continuing to review Puma's MAA and has not yet made a final decision to recommend approval of the drug for the updated or any other indication and there is no guarantee when, if ever, the MAA will be approved. The tables below, based on the interim 5 year analysis announced in July 2016, show results for the invasive disease free survival (DFS) of the initially proposed intent to treat population and the intent to treat population (both hormone receptor positive and hormone receptor negative) in the subgroup of patients who initiated neratinib treatment within one year after completion of adjuvant trastuzumab therapy.

DFS for Initially Proposed Intent to Treat (ITT) Population				
	2-Year DFS	3-Year DFS	4-Year DFS	5-Year Interim DFS
Neratinib	94.3%	92.5%	91.4%	90.4%
Placebo	91.9%	90.3%	89.2%	87.9%
Absolute invasive DFS Difference	2.4%	2.2%	2.2%	2.5%

DFS for Intent to Treat (ITT) Population in Patients Initiating Neratinib Treatment Less Than One Year After the Completion of Adjuvant Trastuzumab				
	2-Year DFS	3-Year DFS	4-Year DFS	5-Year Interim DFS
Neratinib	93.8%	92.0%	90.8%	89.9%
Placebo	91.0%	89.5%	88.3%	86.8%
Absolute invasive DFS Difference	2.8%	2.5%	2.5%	3.1%

Puma plans to file a Current Report on Form 8-K with the Securities and Exchange Commission containing the updated Kaplan-Meier curves for the subgroup of patients randomized within one year after completion of adjuvant trastuzumab therapy for: (i) the intent to treat population; (ii) the subgroup of patients with centrally confirmed HER2 positive disease; (iii) the hormone receptor positive subgroup of patients and (iv) the hormone receptor negative subgroup of patients.

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 Company's plans to modify the SmPC in its MAA to restrict the intended population to patients initiating neratinib treatment within one year after completion of adjuvant trastuzumab therapy. 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, 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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