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Puma Biotechnology Announces Agreement with FDA on Special Protocol Assessment for Phase III Trial of PB272 (Neratinib) in HER2-Positive Metastatic Breast Cancer Patients

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LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the planned Phase III clinical trial of the Company's lead drug candidate PB272 (neratinib) in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments (third-line disease). The SPA is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints and planned statistical analysis approach of the Phase III trial to be used in support of a New Drug Application (NDA) for PB272. The European Medicines Agency (EMA) has also provided follow-on scientific advice (SA) consistent with that of the FDA regarding the Company's Phase III trial design and endpoints to be used and the ability of such design to support the submission of a European Union (EU) Market Authorization Application (MAA).

Pursuant to the SPA and SA, the Phase III trial will be a randomized trial of PB272 plus Xeloda versus Tykerb plus Xeloda in patients with third-line HER2-positive metastatic breast cancer. The trial is expected to enroll approximately 600 patients who will be randomized (1:1) to receive either PB272 plus Xeloda or Tykerb plus Xeloda. The trial will be conducted at approximately 150 sites in North America, Europe and Asia-Pacific. The agreed upon co-primary endpoints of the trial are progression-free survival and overall survival. The Company plans to use the progression-free survival data from the trial as the basis for submission of an NDA/MAA for Accelerated/Conditional Approval for PB272 from the regulatory agencies. Puma anticipates that it will begin patient enrollment in this Phase III trial in March or April of this year.

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "Obtaining FDA and EMA agreement on the overall Phase III trial design, and more specifically patient population and primary endpoints, represents an important milestone in the global development of PB272 and for Puma as a company. We look forward to initiating patient enrollment in the Phase III trial shortly."

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 (neratinib), an oral potent irreversible tyrosine kinase inhibitor, for the treatment of patients with HER2-positive metastatic breast cancer and non-small cell lung cancer.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements that 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 its lead drug candidate, 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 from time to time in the Company's filings with the Securities and Exchange Commission, including the Company’s Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2012. 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:
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