News Release

Puma Biotechnology Receives FDA Advisory Committee Support for Neratinib

LOS ANGELES, Calif., May 24, 2017 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 12 - 4 to recommend approval of PB272 (neratinib) for the extended adjuvant treatment of HER2-positive early stage breast cancer based on finding that the risk-benefit profile of neratinib is favorable.

The ODAC vote was based on a review of the clinical development program that included 11 trials in breast cancer and represented approximately 2,000 patient years' experience. The focus of the meeting was the Phase III ExteNET study, which provided one year of continuous therapy with neratinib after patients completed one year of therapy with a trastuzumab-based regimen. The study demonstrated a statistically significant 33% relative reduction of risk of invasive disease recurrence within two years after treatment.

"Despite advances in adjuvant therapy for HER2-positive breast cancer, disease recurrence remains a risk. Since there are no effective therapies for patients whose disease recurs, there is an important need for additional options to further reduce the risk of recurrence," said Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology.

ODAC is an independent panel of experts that evaluates data concerning the efficacy and safety of marketed and investigational cancer treatments and makes appropriate recommendations to the FDA. Its vote is not binding, but is considered by the FDA in its decision-making process.

"We appreciate the committee's comments and the support of the many clinicians, patients and advocates who participated in today's meeting," Mr. Auerbach added. "We look forward to further discussion with the FDA."

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. 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, risks pertaining to securities class action, derivative and defamation lawsuits, 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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