



News Release

Puma Biotechnology Announces Meeting of Scientific Advisory Group on Oncology in Europe to Review Neratinib for Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer

LOS ANGELES, Calif., Dec. 13, 2017 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that the European Medicines Agency (EMA) has requested that the Scientific Advisory Group on Oncology provide an opinion on the clinical aspects of the Marketing Authorization Application (MAA) for neratinib at a meeting to be held on January 11, 2018. In Europe, neratinib is an investigational therapy for the extended adjuvant treatment of early stage HER2-positive breast cancer that has previously been treated with a trastuzumab containing regimen.

The Scientific Advisory Group on Oncology is convened at the request of the EMA to provide independent recommendations on scientific or technical matters related to pediatric and adult clinical oncology and hematology, or on any other scientific issue relevant to the work of the EMA that relates to this area.

Puma Biotechnology announced on August 22, 2016 that the MAA for neratinib had been validated by the EMA. The MAA for neratinib is based on results from both the Phase III ExteNET trial in extended adjuvant early stage HER2-positive breast cancer and the Phase II CONTROL trial in extended adjuvant early stage HER2-positive breast cancer. On August 2, 2017, Puma announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the EMA, had issued its Day-180 List of Outstanding Issues in the process of their ongoing regulatory review of Puma's MAA. The Company expects to respond to the Day-180 List of Outstanding Issues by the deadline of December 22, 2017.

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, oral was approved by the U.S. Food and Drug Administration in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

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 only recently commenced commercialization and shipment of its only FDA approved product; the Company's

dependence upon the commercial success of NERLYNX (neratinib); the Company's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company's ability to achieve or sustain profitability; the Company's ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company's operations; the effectiveness of sales and marketing efforts; the Company's ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. 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.

Contacts

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

David Schull or Amiad Finkelthal, Russo Partners, +1 212 845 4200
david.schull@russopartnersllc.com
amiad.finkelthal@russopartnersllc.com

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