



News Release

Puma Biotechnology Launches Expanded Access Program for PB272 (Neratinib) for U.S. Patients with HER2-Positive Breast Cancer or HER2-Mutated Cancers

Caligor Opco LLC to Provide Regulatory and Logistical Management

LOS ANGELES, Calif., April 2, 2017 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, has initiated an expanded access program (EAP) in the United States to provide its investigational therapy, PB272 (neratinib), to patients with HER2-positive breast cancer or HER2-mutated cancers. The program will provide access to neratinib for the treatment of early stage HER2-positive breast cancer (extended adjuvant setting), HER2-positive metastatic breast cancer and HER2-mutated solid tumors. Patients must not be able to participate in any ongoing neratinib clinical trial to qualify for Puma’s expanded access program. Puma announced a Managed Access Program for neratinib outside the United States in the fourth quarter of 2016.

The U.S. Food and Drug Administration (FDA) permits expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions who do not otherwise qualify for participation in a clinical trial and lack satisfactory therapeutic alternatives.

Caligor Opco LLC, which administers the Managed Access Program for neratinib, also will manage the U.S. expanded access program by providing regulatory and logistical support.

“This expanded access program reflects our commitment to make neratinib available to eligible patients who lack therapeutic treatment options,” said Alan H. Auerbach, Chief Executive Officer and President of Puma. “As a specialist firm that focuses on early access to medicines, Caligor will facilitate access to neratinib for patients who may benefit from this therapy.”

About the Neratinib Expanded Access Program

The neratinib EAP is a program for U.S. patients with early stage HER2-positive breast cancer (extended adjuvant setting), HER2-positive metastatic breast cancer and HER2-mutated solid tumors. This EAP is being administered on behalf of Puma by Caligor Opco LLC. U.S. healthcare professionals seeking more information about the neratinib EAP can email neratinibUS@caligorr.com for additional information. Patients who are interested in enrolling in the neratinib EAP should speak with their physician to determine if neratinib is an appropriate option. Neratinib is an investigational agent and, as such, has not been approved by the FDA or any other regulatory agencies in any markets.

About Caligor

Caligor Opco LLC, a portfolio company of Diversis Capital, LLC, is a global company that manages the regulatory, logistics and supply chain needs for global access programs as well as the sourcing, storing and distribution of comparator drugs for clinical trials. Caligor’s global access programs help to meet the medical needs of patients worldwide by providing access to medicines in situations where

the drug has not yet been approved, or is otherwise commercially unavailable. In addition, through its proprietary TrialAssist™ program, Caligor optimizes its services by providing for labeling, QP certification, storage, distribution and destruction of clinical trial and unlicensed medicines managed in the access programs. The company serves pharmaceutical and biotechnology companies from facilities in Secaucus, New Jersey and Dartford, UK, as well as strategically situated depot locations worldwide. More information is available at <http://caligorrx.com>.

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 may be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding the expanded access program for PB272 (neratinib) for the treatment of early stage HER2-positive breast cancer (extended adjuvant setting), HER2-positive metastatic breast cancer and HER2-mutated solid tumors. 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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