



News Release

Puma Biotechnology Initiates a Managed Access Program for PB272 (Neratinib) Outside the United States

Caligor Opco LLC to provide regulatory, logistical and supply chain support

LOS ANGELES, Calif., Dec. 6, 2016 – Puma Biotechnology, Inc. (NYSE: PBYI), a biopharmaceutical company, has initiated a Managed Access Program for PB272 (neratinib). Managed access programs provide physicians and patients access to medicines when there are limited or no other therapeutic options available.

Puma’s Managed Access Program for neratinib will enable participation from countries outside the United States, including European Union Member States, where permitted by applicable rules, procedures and regulatory authorities. 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 managed access program. Patients in the managed access program will be given neratinib and will be instructed to take a prophylaxis during treatment to manage neratinib-related diarrhea, which the Company expects will consist of high dose loperamide and budesonide.

Puma Biotechnology has partnered with Caligor Opco LLC, which specializes in early access to medicines, to implement and oversee the Managed Access Program for neratinib.

“The guiding principle behind our Managed Access Program is to provide neratinib—through physician-requested access—to patients with significant unmet medical needs as soon as practical, in a manner that is safe, ethical, compliant and effective,” said Alan H. Auerbach, Chief Executive Officer and President of Puma. “With Caligor managing the day-to-day operations of the program, we can direct our efforts toward our regulatory filings and implementing our plans for commercialization.”

Questions or inquiries regarding the Neratinib Managed Access Program should be directed to neratinib@caligorr.com.

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 unlicensed / unapproved 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://caligorr.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 can be found at www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding the Managed 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 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, 2015. 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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