News Release

Puma Biotechnology Announces FDA Clearance of IND for Alisertib in Small Cell Lung Cancer

LOS ANGELES, Calif., Aug. 8, 2023 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, has been notified by the U.S. Food and Drug Administration (FDA) that its Investigational New Drug (IND) submission has been reviewed, and Puma can proceed with the clinical development of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer (SCLC). Puma's Phase II trial (Study PUMA-ALI-4201) will enroll up to 60 patients with extensive stage small cell lung cancer who have progressed after first-line platinum-based chemotherapy and immunotherapy. Patients must provide tissue-based biopsies so that biomarkers can be analyzed. Alisertib will be dosed at 50 mg BID on days 1-7 of every 21 day cycle. The Company anticipates initiating the Phase II trial in the second half of 2023.

The primary endpoint of the trial will be objective response rate with secondary endpoints of duration of response, disease control rate, progression free survival and overall survival. The Company will also be looking at each of these endpoints within selected pre-specified biomarker subgroups as well as to assess whether there is enhanced efficacy in any biomarker subgroup. Puma will be performing its biomarker analysis of the ALI-4201 trial in parallel with the execution of the clinical trial. Puma plans to perform an initial interim analysis for the evaluation of the biomarkers as well as an evaluation of the efficacy. Based upon the outcomes of the study, the Company anticipates meeting with the FDA to explore the potential for an accelerated approval pathway for alisertib in small cell lung cancer.

"Treatment options for patients with small cell lung cancer that has progressed on or after platinum-based chemotherapy are limited, and there is an urgent need for new drugs to treat this patient population," said Taofeek K. Owonikoko, MD, PhD, Chief of the Division of Hematology/Oncology and Associate Director for Translational Research and Co-Leader of the Cancer Therapeutics Program at the UPMC Hillman Cancer Center. "The results from the previous clinical trials of alisertib in small cell lung cancer suggest that the drug may represent a potentially promising treatment option for these patients and, more specifically, for patient subsets whose tumors harbor potential molecular markers that are likely associated with the clinical activity of an aurora kinase A inhibitor such as alisertib," said Dr. Owonikoko.

Alan H. Auerbach, Chief Executive Officer, President and Founder of Puma, stated, "We are pleased to move forward with the clinical development of alisertib in small cell lung cancer. We are eagerly awaiting the start of this Phase II trial, and we hope that the study will provide much needed insight into the clinical activity of alisertib in small cell lung cancer and, more specifically, in patients with molecularly defined tumors that may be targetable with an aurora kinase A inhibitor like alisertib."

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. Puma in-licensed the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in 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. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. NERLYNX was granted marketing authorization by the European Commission in 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

In September 2022, Puma entered into an exclusive license agreement for the development and commercialization of the anti-cancer drug alisertib, a selective, small molecule, orally administered inhibitor of aurora kinase A. Initially, Puma intends to focus the development of alisertib on the treatment of small cell lung cancer and breast cancer.

Further information about Puma Biotechnology may be found at https://www.pumabiotechnology.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Puma's anticipated milestones and the development of alisertib. All forward-looking statements involve risks and uncertainties that could cause Puma'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 risk factors disclosed in the periodic and current reports filed by Puma with the Securities and Exchange Commission from time to time, including Puma's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent reports. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Puma assumes no obligation to update these forward-looking statements, except as required by law.

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