News Release

Puma Biotechnology Receives FDA Orphan Drug Designation for Alisertib for the Treatment of Small Cell Lung Cancer

LOS ANGELES, Calif., Sept. 21, 2023 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to alisertib, a selective, small-molecule, orally administered inhibitor of aurora kinase A, for the treatment of patients with small cell lung cancer (SCLC). SCLC is an aggressive form of lung cancer with a poor prognosis, and with limited treatment options for patients whose cancer has progressed on or after platinum-based chemotherapy.

"Obtaining Orphan Drug Designation from the FDA signifies our continued progress and commitment to the development of alisertib for the treatment of small cell lung cancer," said Alan H. Auerbach, Chief Executive Officer, President and Founder of Puma. "There is an urgent need for new treatments for patients with small cell lung cancer, and we look forward to the initiation of our Phase II trial (Study PUMA-ALI-4201) of alisertib in small cell lung cancer."

The FDA grants Orphan Drug Designation to investigational therapies being developed to treat, diagnose or prevent a rare disease or condition affecting fewer than 200,000 people in the United States. Further, Orphan Drug Designation provides benefits to drug developers, including assistance in the drug development process, tax credits for qualified trials, waiver of certain FDA fees, and the potential for seven years of post-approval marketing exclusivity.

Puma received FDA clearance of its Investigational New Drug application for the clinical development of alisertib monotherapy for the treatment of patients with extensive stage SCLC in August 2023 and anticipates initiating the Phase II trial in the second half of 2023.

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 the development and commercialization 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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