News Release

Puma Biotechnology Announces Exclusive License Agreement with Takeda for the Development and Commercialization of Alisertib, an Investigational Aurora Kinase A Inhibitor

LOS ANGELES, Calif., Sept. 20, 2022 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, today announced an agreement with Takeda to license the worldwide research and development and commercial rights to alisertib, a selective, small-molecule, orally administered inhibitor of aurora kinase A. Alisertib is an adenosine triphosphate–competitive and reversible inhibitor of aurora kinase A and results in disruption of mitosis leading to apoptosis of rapidly proliferating tumor cells that are dependent on aurora kinase A. Alisertib has been tested in clinical trials in patients with metastatic cancers including breast cancer, small cell lung cancer, head and neck cancer, ovarian cancer, peripheral T cell lymphoma and acute myeloid leukemia.

Under the terms of the agreement, Puma will assume sole responsibility for the global development and commercialization of alisertib. Takeda will receive an upfront license fee of $7 million and is eligible to receive potential future milestone payments of up to $287.3 million upon Puma's achievement of certain regulatory and commercial milestones over the course of the agreement, as well as tiered royalty payments for any net sales of alisertib.

Puma initially intends to focus the development of alisertib on the treatment of patients with metastatic estrogen receptor-positive (ER-positive) HER2-negative breast cancer, triple-negative breast cancer and small cell lung cancer. In ER-positive HER2-negative breast cancer, alisertib has previously been tested in a Phase II clinical trial as a single agent (Lancet Oncology 2015), in a Phase II randomized clinical trial as a single agent compared to a combination with fulvestrant (SABCS 2020) and in a Phase II randomized clinical trial in combination with paclitaxel compared to paclitaxel monotherapy (JAMA Network Open 2021). In triple-negative breast cancer, alisertib has previously been tested in a Phase II clinical trial as a single agent (Lancet Oncology 2015) and in a randomized clinical trial in combination with paclitaxel compared to paclitaxel monotherapy (JAMA Network Open 2021). Alisertib has demonstrated meaningful clinical activity in these populations and most notably in ER-positive breast cancer patients who have been previously treated with a CDK4/6 inhibitor (JAMA Network Open 2021). Alisertib has also been previously tested in small cell lung cancer in a Phase II clinical trial as a single agent (Lancet Oncology 2015) and in a Phase II randomized clinical trial in combination with paclitaxel compared to paclitaxel monotherapy (Journal of Thoracic Oncology 2020).

"There continues to be a need for new drugs for the treatment of metastatic ER- positive, HER2-negative breast cancer and triple negative breast cancer," said Joyce A. O'Shaughnessy, M.D., the Celebrating Women Chair in Breast Cancer Research at Baylor University Medical Center, Texas Oncology, and Chair of Breast Cancer Research for the US Oncology Network in Dallas, Texas. "The results from the clinical trials of alisertib in these two indications are encouraging and suggest that the drug may be able to provide a clinical benefit to these patient populations, and, due to its novel mechanism, alisertib may be able to provide a benefit in patients who have developed resistance to other treatments modalities," said Dr. O'Shaughnessy.

"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 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 patients with molecularly defined tumors that are likely to respond to 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 be able to complete this licensing agreement with Takeda for alisertib. To date, alisertib has demonstrated strong evidence of antitumor activity, both as a single agent and in combination with other anticancer drugs, in patients with metastatic ER-positive and triple negative breast cancer, as well as in small cell lung cancer. We look forward to the continued development of alisertib."

Puma will host a conference call today at 2:00 p.m. PDT/5:00 p.m. EDT to discuss the alisertib licensing agreement. The call may be accessed by dialing (877) 709-8150 (domestic) or (201) 689-8354 (international). Please dial in at least 10 minutes in advance and inform the operator that you would like to join the "Puma Biotechnology Conference Call." A live webcast of the conference call and presentation slides may be accessed on the Investors section of the Puma Biotechnology website at https://www.pumabiotechnology.com. A replay of the call will be available shortly after completion of the call and will be archived on Puma's website for 90 days.

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-licenses 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.

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, 2021 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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