News Release

Puma Biotechnology Announces Phase II Clinical Trial Design for Alisertib in HER2-Negative, Hormone Receptor-Positive Metastatic Breast Cancer

LOS ANGELES, Calif., Dec. 11, 2023 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company (the Company), announced the design of the Phase II trial of alisertib for the treatment of patients with HER2-negative, hormone receptor-positive metastatic breast cancer (PUMA-ALI-1201). Based on the Company's interactions with the U.S. Food and Drug Administration (FDA), the Company will be initiating a Phase II trial of alisertib in combination with endocrine treatment (consisting of either anastrozole, exemestane, letrozole, fulvestrant or tamoxifen) in patients with chemotherapy-naïve HER2-negative, hormone receptor-positive metastatic breast cancer. Patients must have been previously treated with CDK 4/6 inhibitors and received at least two prior lines of endocrine therapy in the recurrent or metastatic setting to be eligible for the trial. The Company has updated the presentation on its website to include a slide that describes the PUMA-ALI-1201 trial. The Company plans to initiate this trial in the second half of 2024.

Patients will be dosed with alisertib given at either 30 mg, 40 mg or 50 mg twice daily (BID) on days 1-3, 8-10 and 15-17 on a 28-day cycle in combination with the endocrine therapy of the investigator's choice. Patients must not have been previously treated with the endocrine treatment that will be given in combination with alisertib in the trial. Each dose level will enroll up to 50 patients. Patients must provide blood samples and tissue-based biopsies so that biomarkers can be evaluated. The primary efficacy end points will include objective response rate (ORR), duration of response (DOR), disease control rate (DCR) and progression-free survival (PFS). As a secondary objective, the Company will be evaluating each of these efficacy endpoints within biomarker subgroups in order to determine whether any biomarker subgroup correlates with better efficacy as has been seen in preclinical and clinical studies in other cancers including breast cancer and small cell lung cancer. The Company will then look to focus the future clinical development of alisertib in combination with endocrine therapy for patients with HER2-negative hormone receptor-positive breast cancer in patients with these biomarkers.

Based on its interactions with the FDA, the Company believes that this trial design will satisfy the FDA's Project Optimus intended to find the optimal dose of alisertib in combination with endocrine therapy in patients with HER2-negative, hormone receptor-positive metastatic breast cancer to move into a pivotal Phase III trial. Once the optimal alisertib dose is identified, the Company plans to engage with global regulatory agencies regarding the design of a pivotal Phase III trial, which it anticipates will be a randomized trial of alisertib plus investigator's choice endocrine therapy versus placebo plus investigator's choice endocrine therapy in patients with chemotherapy naïve HER2-negative, hormone receptor-positive metastatic breast cancer.

"There continues to be a need for new drugs for the treatment of metastatic HER2-negative, hormone receptor-positive breast cancer," said Alvin Wong, PharmD, Chief Scientific Officer of Puma Biotechnology. "The clinical trials of alisertib to date in HER2-negative, hormone receptor-positive metastatic breast cancer have demonstrated alisertib's potential clinical benefit in this patient population, and we look forward to initiating the PUMA-ALI-1201 trial in 2024."

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are excited to move forward with the development of alisertib in HER2-negative hormone receptor-positive metastatic breast cancer. We believe that the data from TBCRC 041, which tested alisertib alone and with fulvestrant and the randomized trial of alisertib plus paclitaxel versus paclitaxel alone, have demonstrated that alisertib is active in patients with HER2-negative hormone receptor-positive metastatic breast cancer and in biomarker focused subgroups. We also recognize our fiscal responsibility to the shareholders of the Company and will be carefully managing the development expenses for alisertib in order to protect the Company's future profitability."

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 Company's expectations regarding the development of alisertib and clinical trials involving 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.

Contacts

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

David Schull or Olipriya Das, +1 212 845 4200
david.schull@russopartnersllc.com
olipriya.das@russopartnersllc.com

# # # # #