Puma Biotechnology Initiates ALISCA®-Lung2, a Phase II Trial of Alisertib in Combination with Paclitaxel for the Treatment of Patients with Advanced Small Cell Lung Cancer

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LOS ANGELES--(BUSINESS WIRE)--Sep. 17, 2026--

Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced the initiation of its ALISertib in CAncer (ALISCA®-Lung2) Phase II trial (PUMA-ALI-4202; NCT07465757) of alisertib in combination with paclitaxel for the treatment of patients with advanced small cell lung cancer. The ALISCA®-Lung2 trial is a sequential dose escalation study that will enroll approximately 50 patients with small cell lung cancer who have progressed on or after treatment with platinum-based chemotherapy and immunotherapy.

The primary endpoint of the trial is the safety and tolerability of alisertib when administered with paclitaxel. Secondary endpoints include objective response rate, duration of response, disease control rate, progression-free survival and overall survival. Puma will also evaluate clinical biomarkers to help identify which patients have the greatest benefit to guide the future development of alisertib.

Taofeek K. Owonikoko, MD, PhD and Chair of the trial's Steering Committee, said, "Treatment options for patients with small cell lung cancer that has progressed following platinum-based chemotherapy and immunotherapy remain limited, and there is an urgent need for new treatment approaches for these patients. I am pleased to see further evaluation of alisertib in these patients." Dr. Owonikoko is the Executive Director of the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center, and the Kevin J. Cullen, MD Distinguished Professor of Oncology at the University of Maryland School of Medicine. He added, "The results from previous clinical trials of alisertib in small cell lung cancer, including those in combination with paclitaxel, 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."

Alan H. Auerbach, Chief Executive Officer, President and Founder of Puma, stated, "We are pleased to initiate this Phase II trial, and we hope that the study will provide important insight into the safety and clinical activity of alisertib in combination with paclitaxel in patients with small cell lung cancer. We are continuing to advance alisertib monotherapy in the ALISCA®-Lung1 trial as well, and we view the ALISCA®-Lung2 trial as additive to the clinical development of alisertib in small cell lung cancer. We look forward to the progress of both the ALISCA®-Lung1 and ALISCA®-Lung2 trials, as well as our other ongoing clinical programs, in the months ahead."

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) in 2011. 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. In February 2024, Puma initiated ALISCA®-Lung1, a Phase II clinical trial of alisertib monotherapy for the treatment of patients with extensive stage small cell lung cancer. In November 2024, Puma initiated ALISCA®-Breast1, a Phase II clinical trial of alisertib in combination with endocrine therapy for the treatment of patients with HER2-negative, HR-positive metastatic breast cancer. In September 2026, Puma initiated ALISCA®-Lung2, a Phase II clinical trial of alisertib in combination with paclitaxel for the treatment of patients with advanced small cell lung cancer. ALISCA® 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 Puma'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, any adverse impact on Puma's business or the global economy and financial markets, any changes in Puma's product candidates' regulatory approvals, results from Puma's clinical trials, any litigation involving Puma, any changes to Puma's in-licensed intellectual property and 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, 2025 and subsequent filings. 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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