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Puma Biotechnology Expands Cohorts in Phase II SUMMIT Trial of Neratinib in Cancer Patients with Tumors with Activating EGFR or HER2 Mutations

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LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, has expanded two additional cohorts from the Phase II SUMMIT clinical trial investigating its lead drug candidate neratinib in patients with solid tumors who have an activating EGFR or HER2 mutation. The cohorts that have been expanded are (i) HER2 mutant patients with metastatic salivary gland cancer and (ii) patients with EGFR exon 18 mutation-positive lung cancer.

The Phase II SUMMIT basket trial is an open-label, multi-center, multi-histology, international study to evaluate the safety and efficacy of neratinib administered daily to patients who have solid tumors with activating EGFR, HER2 or HER4 mutations. The salivary gland cancer patients initially entered the study in the “other solid tumors with a HER2 mutation” cohort, and due to the preliminary activity seen in the trial, the Company has expanded a separate salivary gland cancer cohort pursuant to the protocol for the trial. The expanded HER2-mutant salivary gland cancer cohort and the expanded EGFR exon 18 mutant lung cancer cohort will each now enroll approximately 18 patients.

“We are pleased to expand our evaluation of neratinib in metastatic HER2 mutant salivary gland cancer and exon 18 mutated lung cancer from SUMMIT, as they both represent orphan and deadly diseases with few treatment options,” said Alan H. Auerbach, Chief Executive Officer and President of Puma. “We believe this once again demonstrates the value of the basket study approach, in particular for developing targeted therapy for rare diseases with clinically-actionable mutations. We look forward to continuing enrollment into these expanded cohorts and presenting updated trial results.”

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. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in July 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. NERLYNX was granted marketing authorization by the European Commission in September 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 www.pumabiotechnology.com.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding the expected timing for presentation of clinical trial results. 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, 2018. 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.

Language:

English

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