Published on *Puma Biotechnology Investor Center* (https://investor.pumabiotechnology.com) on 3/18/19 12:45 pm PDT

Puma Biotechnology Presents Interim Results from the Phase II SUMMIT Trial of Neratinib for HER2 (ERBB2) Mutant, Metastatic Cervical Cancer at the Society of Gynecologic Oncology (SGO) 2019 Annual Meeting

Release Date:
Monday, March 18, 2019 12:45 pm PDT

Terms:

Dateline City:
LOS ANGELES

Oral Plenary Presentation Receives SGO Presidential Award

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced today that updated results from the cervical cancer cohort of SUMMIT, an ongoing Phase II basket trial examining the efficacy of neratinib in HER2-mutated cancers, were reported at the Society of Gynecologic Oncology (SGO) 2019 Annual Meeting in Honolulu, Hawaii. “Neratinib in patients with HER2-mutant, metastatic cervical cancer: findings from the phase II SUMMIT ‘basket’ trial,” was presented during the Scientific Plenary Session by Anishka D’Souza, M.D., Assistant Professor of Clinical Medicine, Keck School of Medicine of University of Southern California (USC). SGO selected this abstract as the recipient of the 2019 SGO Presidential Award. Slides from the presentation are available on the Puma Biotechnology website.

The Phase II SUMMIT ‘basket’ trial is an open-label, multicenter, multinational study to evaluate the safety and efficacy of neratinib administered daily to patients who have solid tumors with activating, somatic HER2 mutations. The cervical cancer cohort was comprised of 11 patients with advanced and/or metastatic disease treated with neratinib monotherapy. Patients received a median of 2 (range 1–4) prior regimens in the recurrent or metastatic setting before entering this trial. Six patients (54.5%) had been previously treated with bevacizumab prior to entering the study; 7 patients (63.6%) had received prior surgery; and 9 patients (81.8%) received prior radiation therapy. The objective response rate was 27.3% (95% CI: 6.0%–61.0%). The clinical benefit rate was 54.5% (95% CI: 23.4%–83.3%) and included 3 patients with confirmed partial responses and 3 patients with stable disease that lasted greater than 16 weeks. The median progression free survival was 7.0 months (95% CI: 0.7–20.1 months).

The safety profile observed in neratinib-treated cervical cancer patients in SUMMIT was consistent with that reported for HER2-amplified metastatic breast cancer. The most frequently observed adverse event was diarrhea, any grade (n=9, 81.8%) including 1 (9%) grade 3 diarrhea event. The duration of grade 3 diarrhea was 1 day. None of the diarrhea events resulted in dose reduction, dose discontinuation or hospitalization.

“Somatic HER2 mutations represent a distinct class of oncogenic driver mutations that appear to be clinically actionable for metastatic cervical cancers. Treatment with neratinib led to durable responses and disease control in metastatic patients with HER2-mutant cervical cancer,” said Dr. D’Souza, who practices oncology at the USC Norris Comprehensive Cancer Center.

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, “We are very pleased with the activity seen with neratinib in this cohort of patients with HER2-mutated cervical cancer. We look forward to the further development of neratinib in this patient population.”

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 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 for the extended adjuvant treatment of hormone receptor-positive HER2-positive early stage breast cancer in September 2018. 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 development of Puma’s product candidates. 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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ISIN:
US74587V1070
