News Release

Puma Biotechnology Presents Interim Results from the Biliary Tract Cohort of its Phase II SUMMIT Basket Trial of Neratinib at the ESMO World Congress on Gastrointestinal Cancer 2019

LOS ANGELES, Calif., July 3, 2019 – Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, presented updated interim results from the biliary cancer cohort of SUMMIT, an ongoing Phase II basket trial examining the efficacy of neratinib in HER2-mutated cancers, at the European Society for Medical Oncology (ESMO) 21st World Congress on Gastrointestinal Cancer 2019, currently taking place in Barcelona, Spain. "Treating *HER2*-mutant Biliary Tract Cancer with Neratinib: Benefits of HER2-directed Targeted Therapy in the Phase 2 SUMMIT 'Basket' Trial" was an oral presentation by James J. Harding, MD, Assistant Attending, Gastrointestinal Oncology and Early Drug Development Service, Memorial Sloan Kettering Cancer Center on July 3rd at 6:10 p.m. CEST. In addition, a poster presentation summarizing the trial results will be presented on July 4 beginning at 11:05 a.m. CEST. The slides and poster presentation will be available on the Puma 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 biliary cancer cohort comprised 20 patients with advanced and/or metastatic disease treated with neratinib monotherapy. More specifically, 9 patients had cholangiocarcinoma, 9 had gallbladder cancer and 2 had cancer of the Ampulla of Vater. Patients received a median of 2 (range 0-7) prior systemic regimens before entering this trial. Most patients had received a gemcitabine-based regimen (n=18, 90%), 11 patients (55%) had undergone prior surgery, and 4 patients (20%) received prior radiation therapy. The confirmed objective response rate was 10% (95% CI: 1.2–31.7). The clinical benefit rate was 30% (95% CI: 11.9–54.3) and included 2 patients with confirmed partial responses and 4 patients with stable disease that lasted ≥ 16 weeks. The median progression-free survival was 1.8 months (95% CI: 0.9–3.7).

The safety profile observed in the neratinib-treated biliary tract cancer cohort is consistent with that previously reported for all *HER2*-mutated cancer patients in the SUMMIT trial. The most frequently observed adverse event was diarrhea, any grade (n=10, 50%) including 4 (20%) patients with grade 3 diarrhea. None of the diarrhea events resulted in dose discontinuation within the biliary tract cancer cohort; 2 patients reduced study drug due to diarrhea events.

"Somatic HER2 mutations represent a distinct class of oncogenic driver mutations that appear to be clinically actionable for a subset of metastatic biliary tract cancers. A subset of cholangiocarcinoma and gallbladder cancer patients had tumor shrinkage or extended disease control suggesting anti-tumor activity in this rare population. These early findings in targeting HER2 in advanced bile duct cancers warrant further clinical and translational investigation." said Dr. Harding.

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are very pleased with the initial activity seen with neratinib in this cohort of patients with biliary tract cancer. We look forward to the further enrollment of patients in the SUMMIT trial and further development of neratinib in this *HER2*-mutated 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. 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 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.

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