News Release

Puma Biotechnology Announces Publication of Results from Phase II SUMMIT Trial Evaluating Neratinib in *HER2*-Mutant, Metastatic Cervical Cancers

Data published online in Gynecologic Oncology

LOS ANGELES, Calif., July 27, 2020 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that data from the cervical cancer cohort of SUMMIT, an ongoing Phase II basket trial examining the safety and efficacy of neratinib in *HER2*-mutated cancers, were published in the journal *Gynecologic Oncology*. The paper, "Neratinib in patients with *HER2*-mutant, metastatic cervical cancer: Findings from the phase 2 SUMMIT basket trial," appears in the July 25, 2020 online issue at https://www.gynecologiconcology-online.net/article/S0090-8258(20)33660-X/pdf and will be published in a future print issue of the journal.

The Phase II SUMMIT 'basket' trial is an open-label, international multi-histology study to evaluate the safety and efficacy of neratinib, administered daily to patients, across a broad spectrum of cancer types in patients whose tumors harbor activating *HER2* somatic mutations. The primary endpoint was confirmed objective response rate. Secondary endpoints included response duration, clinical benefit rate, progression-free survival, overall survival, and safety.

Sixteen patients with *HER2*-mutant, persistent, metastatic or recurrent cervical cancer with disease progression after platinum-based treatment for advanced or recurrent disease were enrolled in the cohort and received oral neratinib daily with mandatory loperamide prophylaxis during the first cycle.

Three of 12 RECIST-measurable patients had confirmed partial responses (overall response rate of 25%; 95% CI 5.5–57.2%); three had stable disease more than 16 weeks (clinical benefit rate of 50%; 95% CI 21.1–78.9%). Response duration for responders were 5.6, 5.9, and 12.3 months. Median progression-free survival was 7.0 months (95% CI 1.0–18.3 months) and the median overall survival was 16.8 months (95% CI 4.1–months not evaluable).

The safety profile observed in neratinib-treated cervical cancer patients in SUMMIT was consistent with that reported for *HER2*-positive metastatic breast cancer. Diarrhea (75%), nausea (44%), and decreased appetite (38%) were the most common of all grade adverse events. One patient (6%) reported grade 3 diarrhea. The rate of grade 3 diarrhea was considerably lower than reported for metastatic breast cancer patients. While this is a limited dataset, more remains to be revealed as more patients are enrolled. There were no grade 4 events, and no diarrhea-related treatment discontinuations.

Dr. Bradley J. Monk, Professor in the Division of Gynecologic Oncology, University of Arizona College of Medicine and Medical Director of the US Oncology Research Network Gynecological Program, said, "Neratinib demonstrates encouraging clinical activity in metastatic cervical cancer patients with tumors harboring an activating *HER2* mutation. Given the limited options for the treatment of cervical cancer after platinum-based therapy failure, neratinib warrants further investigation in this molecular-defined patient population."

The data was initially presented by Anishka D'Souza, M.D., Assistant Professor of Clinical Medicine, Keck School of Medicine of University of Southern California (USC), during the scientific plenary session at the Society of Gynecologic Oncology (SGO) 2019 Annual Meeting in March 2019.

Alan H. Auerbach, Chief Executive Officer and President of Puma, 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 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.

Further information about Puma Biotechnology may be found at www.pumabiotechnology.com.

IMPORTANT SAFETY INFORMATION

NERLYNX® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated:

- As a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
- 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.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea. If diarrhea occurs despite recommended prophylaxis, treat with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.
- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue NERLYNX in patients experiencing Grade 4 liver abnormalities.
- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS:

The most common adverse reactions (reported in ≥ 5% of patients) were as follows:

- NERLYNX as a single agent: Diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increased, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased, and urinary tract infection.

- NERLYNX in combination with capecitabine: Diarrhea, nausea, vomiting, decreased appetite, constipation, fatigue/asthenia, weight decreased, dizziness, back pain, arthralgia, urinary tract infection, upper respiratory tract infection, abdominal distention, renal impairment, and muscle spasms.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and www.NERLYNX.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors. When patients require gastric acid reducing agents, use an H_2-receptor antagonist or antacid. Separate NERLYNX by at least 3 hours with antacids. Separate NERLYNX by at least 2 hours before or 10 hours after H_2-receptor antagonists.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- Moderate CYP3A4 and P-glycoprotein (P-gp) dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

• **Lactation:** Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

To help ensure patients have access to NERLYNX, Puma has implemented the Puma Patient Lynx support program to assist patients and healthcare providers with reimbursement support and referrals to resources that can help with financial assistance. More information on the Puma Patient Lynx program can be found at www.NERLYNX.com or 1-855-816-5421.

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