News Release

Puma Biotechnology Presents Interim Results from the Phase II SUMMIT Trial of Neratinib for EGFR Exon 18-Mutated, Metastatic Non-Small Cell Lung Cancer at WCLC 2020

LOS ANGELES, Calif., Jan. 29, 2021 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, presented interim results from the ongoing SUMMIT trial of neratinib in the cohort of metastatic non-small cell lung cancer (NSCLC) patients with epidermal growth factor (EGFR) exon 18 mutations who have been previously treated with an EGFR targeted tyrosine kinase inhibitor (TKI). The data were presented in an oral discussion at the 2020 World Conference on Lung Cancer (WCLC 2020) presented by the International Association for the Study of Lung Cancer (IASLC) that is currently taking place in Singapore. The presentation, entitled, "Neratinib in Pretreated EGFR Exon 18-Mutated Non-Small Cell Lung Cancer (NSCLC): Initial Findings from the SUMMIT Basket Trial," is being presented at an Oral Session by Valentina Boni, MD, PhD, START Madrid-CIOCC, Centro Oncologico Clara Campal, HM Sanchinarro.

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 EGFR exon 18 or HER2 mutations. In the EGFR exon 18 mutation cohort, patients with lung cancer with single or complex EGFR exon 18 mutations, who were EGFR TKI naïve or were previously exposed to EGFR TKI, were enrolled into this study and received 240 mg of neratinib daily as a single agent.

In this cohort of 11, patients had received a median of 2 prior lines of therapy in the metastatic setting (range 1-3 prior regimens) before entering the trial. 10 patients had been previously treated with an EGFR targeted tyrosine kinase inhibitor (gefitinib, erlotinib, osimertinib and/or afatinib).

The interim efficacy results from the trial showed that for the 10 evaluable patients who had previously been treated with an EGFR tyrosine kinase inhibitor, 6 patients (60%) experienced a partial response, which included 4 patients (40%) with a confirmed partial response. 8 patients (80%) experienced clinical benefit (clinical benefit is defined as confirmed complete response or partial response or stable disease for at least 16 weeks). The median duration of response was 7.5 months and the median progression-free survival was 9.1 months. The success criteria for both the 1st stage and the 2nd stage of the Simon's 2-stage design were met and enrollment in the 2nd stage of this cohort continues.

The safety profile observed in the subgroup of patients with EGFR exon 18--mutated NSCLC showed that for the 11 patients who received neratinib in the trial, there were no reports of grade 3 or higher diarrhea. 4 patients (36%) reported grade 1 and 1 patient (9%) reported grade 2 diarrhea. No patients required a dose hold, dose reduction, hospitalization or permanently discontinued neratinib due to diarrhea.

Dr. Boni, an investigator of the trial, said, "We are very excited about these early study results in EGFR exon 18 mutant lung cancer, for whom very few effective treatment options are available once they fail first-line FDA approved EGFR TKI therapy."

Jonathan Goldman, MD, Associate Professor of Hematology & Oncology, Associate Director of Drug Development, and Director of Clinical Trials in Thoracic Oncology at UCLA, said "These early study

results open up a potentially effective option for EGFR exon 18 mutation-positive NSCLC patients once they fail first-line FDA approved TKI therapy."

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are pleased to present this data at the World Conference on Lung Cancer and increase the awareness of neratinib's activity in this patient population within the lung cancer community. We are continuing to enroll this cohort of patients in the SUMMIT trial and we continue to believe that there is a need for new treatments for patients with EGFR exon 18-mutated NSCLC who have previously been treated with EGFR targeted tyrosine kinase inhibitors."

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) 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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