News Release

Puma Biotechnology Presents Data from the EGFR Exon 18-mutant NSCLC Cohort of the Phase II SUMMIT Trial at the 2021 ASCO Annual Meeting

Neratinib efficacy evidenced in patients with EGFR exon 18-mutant non-small cell lung cancer and CNS involvement

LOS ANGELES, Calif., June 4, 2021 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, presented interim results from the Phase II SUMMIT basket trial, assessing the efficacy of neratinib in patients with EGFR exon 18-mutant non-small cell lung cancer (NSCLC), including patients with central nervous system (CNS) involvement, at the virtual 2021 ASCO Annual Meeting. The presentation, entitled "Neratinib efficacy in a subgroup of patients with EGFR exon 18-mutant non-small cell lung cancer and central nervous system involvement: findings from the SUMMIT basket trial," is included in the **Lung Cancer—Non-Small Cell Metastatic** Poster Session (#9068).

The Phase II SUMMIT basket trial is an open-label, multicenter, multinational study that includes a cohort evaluating the safety and efficacy of neratinib administered daily to patients with EGFR exon 18-mutant non-small cell lung cancer (NSCLC). Patients received 240 mg of neratinib daily as a single agent with mandatory loperamide prophylaxis.

A cohort of 11 patients with EGFR exon 18-mutant NSCLC from the Phase II SUMMIT basket trial, including patients with central nervous system involvement, were evaluated for safety and efficacy. Prior lines of therapies included EGFR tyrosine kinase inhibitors (TKIs) (91%), chemotherapy (55%) and checkpoint inhibitors (IOs) (27%). Patients with stable, asymptomatic CNS metastasis were enrolled. Of the 11 patients, 3 patients had baseline CNS metastasis.

Of the 10 evaluable patients who had previously been treated with an EGFR tyrosine kinase inhibitor, 6 patients (60%) experienced a partial response (PR), and 4 patients (40%) demonstrated a confirmed partial response. Four additional patients showed stable disease (SD) lasting ≥16 weeks – bringing the experienced clinical benefit that includes confirmed complete response or partial response or stable disease for at least 16 weeks to 80%. The median duration of response (DOR) was 7.5 months, and the median progression-free survival (PFS) was 9.1 months with some patients remaining on treatment. Of the 3 patients who had CNS metastases, best responses were 2 PR and 1 SD and individual PFS times were 1.9 to 9.1 months. These results suggest that neratinib can be a potential treatment option for patients with NSCLC and hard-to-treat CNS metastases.

Neratinib was well tolerated in this study, with no occurrences of grade 3 diarrhea reported and there was no incident of any patient requiring a dose hold, dose reduction, hospitalization, or discontinuation of treatment due to diarrhea.

Jonathan W. Goldman, MD, Associate Professor of Hematology & Oncology, Associate Director of Drug Development and Director of Clinical Trials in Thoracic Oncology at UCLA, an investigator on the trial, said, "EGFR exon 18-mutant lung cancer patients have no effective targeted options after first-line FDA-approved EGFR TKI therapy. This study shows that neratinib has the potential to be an efficacious and safe option to treat their disease, possibly with CNS activity as well."

Alan H. Auerbach, Chief Executive Officer and President of Puma, added, "The descriptive findings from this study indicate that neratinib may have a role as a treatment option for rare cancers. We are excited to explore the full potential of neratinib and help patients with difficult to treat conditions."

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 $\geq$ 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.

Forward-Looking Statements

This press release contains forward-looking statements, that 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, any adverse impact on Puma's business or the global economy and financial markets, generally, from the global COVID-19 pandemic, and 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, 2020. 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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