News Release

Puma Biotechnology Presents Updated Findings from the TBCRC-022 Trial at the 2022 San Antonio Breast Cancer Symposium

LOS ANGELES, Calif., Dec. 7, 2022 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, presented updated findings from the Translational Breast Cancer Research Consortium (TBCRC) Trial 022 at the ongoing 2022 San Antonio Breast Cancer Symposium in San Antonio, Texas. The poster (PD7-03), entitled "Neratinib and ado-Trastuzumab-Emtansine (T-DM1) for HER2+ Breast Cancer Brain Metastases (BCBM): Translational Breast Cancer Research Consortium (TBCRC) Trial 022," was presented by Rachel A Freedman, MD, MPH, Breast Oncology Center, Susan F. Smith Center for Women's Cancers, Dana Farber Cancer Institute, at Spotlight Poster Session 7 on December 7 from 5:00 p.m. – 6:15 p.m. CT.

TBCRC-022 is a prospective, multicenter, Phase II study to evaluate the effect of neratinib plus T-DM1 in patients with HER2-positive breast cancer brain metastases. This presentation outlined updates from three cohorts: 4A – patients with previously untreated BCBM; 4B – patients with BCBM progressing after prior local CNS-directed therapy without prior T-DM1 exposure; and 4C – patients with BCBM progressing after prior local CNS-directed therapy with previous T-DM1 exposure. Data from previous cohorts from this study were reported at the 2017 ASCO Annual Meeting. Patients with measurable HER2-positive BCBM received neratinib 160 mg orally once daily plus T-DM1 3.6 mg/kg intravenously every 21 days in the three parallel-enrolling cohorts. Diarrhea prophylaxis with colestipol and loperamide was required during cycle 1. All enrolled patients underwent a brain MRI plus CT scan of the chest/abdomen/pelvis every 6 weeks for 18 weeks, followed by every 9 weeks thereafter.

The primary endpoint, Response Assessment in Neuro-Oncology-Brain Metastases (RANO-BM), was evaluated in each cohort separately. The efficacy results from the trial showed that CNS Objective Response Rate by RANO-BM was 33.3% of patients in cohort 4A, 29.4% in cohort 4B, and 28.6% in cohort 4C. Rates of response + stable disease greater than or equal to 6 months were 50% in cohort 4A, 35.3% in cohort 4B, and 33.3% in cohort 4C.

Intracranial activity was observed for the combination of neratinib plus T-DM1 in all three cohorts, including in patients with prior T-DM1 exposure, suggesting a reversal of resistance to T-DM1. Overall, the most frequently observed adverse event was diarrhea, grade 2 (32%) and grade 3 (23%). These data provide additional evidence for the consideration of neratinib-based combinations in patients with HER2-positive BCBM.

"Neratinib given in combination with T-DM1 showed promising activity in patients with heavily pre-treated HER2-positive disease metastatic to the CNS including patients with prior T-DM1 exposure, which may suggest that neratinib is playing a role in reversing resistance to T-DM1," said Rachel A. Freedman, MD, MPH, Breast Oncology Center, Susan F. Smith Center for Women's Cancers, Dana-Farber Cancer Institute. "Despite the introduction of several new treatments for patients with HER2-

positive metastatic breast cancer, CNS progression events remain a major source of patient morbidity and mortality. The data from this study provide additional evidence for consideration of neratinib-based combinations in patients with HER2-positive breast cancer brain metastases."

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are pleased with the results from the TBCRC-022 trial on the combination of neratinib and T-DM1. As a small molecule that can cross the blood brain barrier, neratinib potentially offers patients with HER2-positive metastatic breast cancer that has metastasized to the CNS a novel HER2 targeted treatment option. This data adds to the existing body of data that we have from the other previously presented arms from the TBCRC-022 trial that continue to demonstrate that neratinib is active in patients with HER2-positive breast cancer brain metastases."

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.

In September 2022, Puma entered into an exclusive license agreement for the development and commercialization of the anti-cancer drug alisertib, a selective, small molecule, orally administered inhibitor of aurora kinase A. Initially, Puma intends to focus the development of alisertib on the treatment of small cell lung cancer and breast cancer.

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 https://www.NERLYNX.com or by dialing 1-855-816-5421.

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

INDICATIONS

- NERLYNX® (neratinib) tablets, for oral use, 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.

Important Safety Information Regarding NERLYNX® (neratinib) U.S. Indication

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- Diarrhea: Manage diarrhea through either NERLYNX dose escalation or loperamide prophylaxis. 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. Separate NERLYNX by at least 2 hours before or 10 hours after H2-receptor antagonists. Or separate NERLYNX by at least 3 hours with antacids.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- P-gp and moderate CYP3A4 dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- Certain P-gp substrates: Monitor for adverse reactions of P-gp substrates for which minimal concentration change may lead to serious adverse reactions when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- Lactation: Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Puma's anticipated milestones and 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, 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, 2021 and subsequent filings. 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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