News Release

Puma Biotechnology Presents Updated Results from the Phase II SUMMIT Trial of Neratinib for HER2-Mutant, HR-Positive Metastatic Breast Cancer at SABCS 2020

LOS ANGELES, Calif., Dec. 9, 2020 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, presented updated results from the ongoing Phase II SUMMIT trial of neratinib at the 2020 Virtual San Antonio Breast Cancer Symposium (SABCS) that is currently taking place. The presentation entitled, "Latest findings from the breast cancer cohort in SUMMIT – a phase 2 'basket' trial of neratinib + trastuzumab + fulvestrant for HER2-mutant, hormone receptor-positive, metastatic breast cancer," is being presented at a Spotlight Poster Discussion Session by Komal Jhaveri, M.D., FACP, Memorial Sloan Kettering Cancer Center, an investigator of the trial. A copy of this poster presentation is 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 HER2 (ERBB2) or lung cancers with EGFR exon 18 mutations (NCT01953926). In the HER2-mutant, hormone receptor (HR)-positive breast cancer cohort, 51 patients received 240 mg of neratinib daily in combination with trastuzumab and fulvestrant. In this cohort, patients had received a median of 4 prior lines of therapy in the metastatic setting (range 1-10 prior regimens) before entering the trial. 36 patients (70.6%) had received prior fulvestrant, 35 patients (68.6%) had received prior aromatase inhibitor and 4 patients (7.8%) had received prior tamoxifen. Further, 30 patients (58.8%) received prior cyclin-dependent kinase 4/6-inhibitor (CDK4/6i) therapy. Thirty-five patients (68.6%) had received prior chemotherapy.

The interim efficacy summary of the breast cohort that received neratinib in combination with trastuzumab and fulvestrant showed that for the 37 RECIST efficacy evaluable patients, 17 patients (45.9%) experienced a confirmed objective response, including one complete response (2.7%) and 16 (43.2%) partial responses, and 20 patients (54.1%) experienced clinical benefit (clinical benefit is defined as confirmed complete response or partial response or stable disease for at least 24 weeks). The median duration of response was 10.9 months and the median progression-free survival was 8.3 months.

The safety profile observed in patients treated with the combination of neratinib plus trastuzumab plus fulvestrant in the SUMMIT study was consistent with that observed previously in metastatic patients with HER2 amplified tumors. All patients received anti-diarrheal prophylaxis with loperamide alone. The interim safety results of the study showed that the most frequently observed adverse event was diarrhea. For the 51 safety evaluable patients enrolled in this cohort, 20 patients (39.2%) reported grade 3 diarrhea. The median duration of grade 3 diarrhea for those patients was 6 days. No patient permanently discontinued neratinib due to diarrhea.

Komal Jhaveri, M.D., FACP, Memorial Sloan Kettering Cancer Center, Clinical Director of the Early Drug Development Service and Assistant Professor of Medicine, Weill Cornell Medical College, said "HER2 mutations appear to be oncogenic drivers in a subset of metastatic breast cancers and are clinically actionable. The combination of neratinib + trastuzumab + fulvestrant therapy demonstrates encouraging clinical activity with durable responses in this molecular-defined patient population with clinical benefit

observed in patients who have previously been treated after standard of care CDK4/6i and endocrine therapies."

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, "We are pleased to see that the combination of neratinib + fulvestrant + trastuzumab continues to demonstrate encouraging clinical activity in this heavily pre-treated cohort. We are continuing to enroll the randomized cohorts in the SUMMIT trial of neratinib in hormone receptor positive breast cancer patients with HER2 mutations and we anticipate the completion of this enrollment in the first half of 2021."

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, including statements regarding the development of combinations involving neratinib. 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, 2019,

Puma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and subsequent reports. 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.

Contacts

Alan H. Auerbach or Mariann Ohanesian, Puma Biotechnology, Inc., +1 424 248 6500

info@pumabiotechnology.com

ir@pumabiotechnology.com

David Schull or Maggie Beller, Russo Partners, +1 212 845 4200

david.schull@russopartnersllc.com

maggie.beller@russopartnersllc.com

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