News Release

FDA Approves Labeling Supplement for Puma Biotechnology's NERLYNX® (neratinib) for the Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer

Interim data from the Phase II CONTROL Trial showed that the addition of prophylactic treatment with loperamide plus budesomide reduced the rate of discontinuation due to neratinib-associated diarrhea to 11% versus a discontinuation rate of 18% with loperamide alone.

LOS ANGELES, Calif., Oct. 2, 2019 – Puma Biotechnology, Inc. (NASDAQ: PBYI) announced that the U.S. Food and Drug Administration (FDA) has approved a labeling supplement for NERLYNX® (neratinib) for the extended adjuvant treatment of HER2-positive early stage breast cancer. With the approval of the labeling supplement, the label now includes safety information based on interim results from Puma's Phase II CONTROL Trial, a study evaluating antidiarrheal prophylaxis or dose escalation in the reduction of neratinib-associated diarrhea that has a primary endpoint of the incidence of grade 3 or higher diarrhea. Interim data from the trial showed that the addition of prophylactic treatment with loperamide plus budesomide reduced the discontinuation rate due to neratinib-associated diarrhea to 11% versus a discontinuation rate of 18% with loperamide alone.

In the ongoing CONTROL Trial, patients with HER2-positive early stage breast cancer who have completed trastuzumab-based adjuvant therapy receive neratinib daily for a period of one year. The trial initially tested high dose loperamide prophylaxis given for the first 2 cycles (56 days) of treatment (12 mg on days 1-14, 8 mg on days 15-56 and as needed thereafter). The CONTROL Trial (NCT02400476) was then expanded to include four additional cohorts. One cohort received the combination of loperamide and budesonide. For the 64 patients who received the combination of loperamide plus budesonide, the incidence of grade 3 diarrhea was 28% compared to 32% in patients treated with loperamide alone. Diarrhea leading to treatment discontinuation declined to 11% in the loperamide plus budesonide cohort, compared to 18% in the loperamide alone cohort.

"We are pleased to be able to update the label for NERLYNX to include the data on the use of prophylactic loperamide plus budesonide," said Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology. "We believe FDA approval of the labeling supplement will help us to ensure that physicians and patients are better informed in selecting prophylactic therapy that may improve the tolerability of the drug."

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed in the United States as NERLYNX® (neratinib) tablets.

About HER2-Positive Breast Cancer

Approximately 20 to 25 percent of breast cancer tumors over-express the HER2 protein. HER2-positive breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early stage

HER2-positive breast cancer returning after surgery, up to 25% of patients treated with trastuzumab experience recurrence.

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 three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in July 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. NERLYNX was granted marketing authorization by the European Commission in September 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 Regarding NERLYNX® (neratinib) U.S. Indication

NERLYNX® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis 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 (≥ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, weight decreased and urinary tract infection.

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 H2-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 H2-receptor antagonists.
- Strong or moderate CYP3A4 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.

The recommended dose of NERLYNX is 240 mg (six 40 mg tablets) given orally once daily with food, continuously for one year. Antidiarrheal prophylaxis should be initiated with the first dose of NERLYNX and continued during the first 2 months (56 days) of treatment and as needed thereafter.

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

To the extent this press release contains forward-looking statements, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995. All forward-looking statements involve risks and uncertainties that could cause 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, 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, 2018. 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.

Contact

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@russopartnersllp.com