News Release

U.S. Food and Drug Administration Approves Puma's NERLYNX™ (neratinib) for Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer

- *Neratinib becomes the first anti-HER2 treatment to be FDA-approved as extended adjuvant therapy for early-stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy.*
- *Treatment with neratinib resulted in a 34% reduction in the risk of invasive disease recurrence or death versus placebo after patients completed one year of therapy following a trastuzumab-based regimen.*
- *Neratinib addresses an unmet medical need, as up to 25% of HER2-positive early-stage breast cancer patients treated with trastuzumab-based adjuvant treatment experience a recurrence.*

LOS ANGELES, Calif., July 17, 2017 – Puma Biotechnology, Inc. (Nasdaq: PBYI) today announced that the U.S. Food and Drug Administration (FDA) has approved NERLYNX™ (neratinib), formerly known as PB272, a once-daily oral tyrosine kinase inhibitor for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy. Puma expects neratinib to become commercially available in September 2017 and to be marketed as NERLYNX.

FDA approval was based on the Phase III ExteNET trial, a multicenter, randomized, double-blind, placebo-controlled trial of neratinib following adjuvant trastuzumab treatment. Women (n=2,840) with early-stage HER2-positive breast cancer and within two years of completing adjuvant trastuzumab were randomized to receive either neratinib (n=1420) or placebo (n=1420) for one year.

The results of the ExteNET trial demonstrated that after two years of follow-up, invasive disease-free survival (iDFS) was 94.2% in patients treated with neratinib compared with 91.9% in those receiving placebo (HR 0.66; 95% CI: 0.49, 0.90, p=0.008).

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 loss, and urinary tract infection. The most common adverse reaction leading to discontinuation was diarrhea, which was observed in 16.8% of neratinib-treated patients. Hepatotoxicity or increases in liver transaminases led to drug discontinuation in 1.7% of neratinib-treated patients.

"The fear of recurrence is ever present in the minds of most women with breast cancer, from the moment they are diagnosed to long after they finish adjuvant treatment," said Marisa C. Weiss, M.D., Chief Medical Officer and Founder of Breastcancer.org. "New and effective innovative therapeutic options provide huge hope to patients and their families, giving them a better chance of overcoming breast cancer with a chance for a full life."

"Despite advances in the treatment of early stage HER2-positive breast cancer, there remains a need for further therapeutic improvements in order to attempt to further reduce the risk of disease recurrence," said Puma Biotechnology CEO and President Alan H. Auerbach. "We are pleased to be able to bring this new medicine to patients with breast cancer. We would like to express our appreciation to the patients, caregivers

and physicians who contributed to the neratinib clinical development program and, more specifically, the ExteNET trial."

The full prescribing information for NERLYNX will be made available at WWW.NERLYNX.COM. 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 NERLYNX dose and continued during the first 2 cycles (56 days) of treatment and as needed thereafter. A Marketing Authorisation Application for neratinib is under review by the European Medicines Agency (EMA).

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.

Indication

NERLYNX™ is a tyrosine kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

Patient Support

Puma has developed the Puma Patient Lynx support program to provide patients and healthcare providers with assistance related to questions on accessing neratinib and referrals to resources that can help with reimbursement and financial assistance. More information on the Puma Patient Lynx program can be found at www.NERLYNX.com or (1-855-816-5421).

Important Safety Information

There are possible side effects of NERLYNX. Patients must contact their doctor right away if they experience any of these symptoms. NERLYNX treatment may be stopped or the dose may be lowered if the patient experiences any of these side effects.

Diarrhea

Diarrhea is a common side effect of NERLYNX. The diarrhea may be severe, and you may get dehydrated. Your healthcare provider should prescribe the medicine loperamide for you during your first 2 cycles (56 days) of NERLYNX and then as needed. To help prevent or reduce diarrhea:

- You should start taking loperamide with your first dose of NERLYNX.
- Keep taking loperamide during the first 2 cycles (56 days) of NERLYNX treatment and then as needed. Your healthcare provider will tell you exactly how much and how often to take loperamide.
- While taking loperamide, you and your healthcare provider should try to keep the number of bowel movements that you have at 1 or 2 bowel movements each day.
- Tell your healthcare provider if you have more than 2 bowel movements in 1 day, or you have diarrhea that does not go away.

Contact your healthcare provider right away if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever.

Liver Problems

Changes in liver function tests are common with NERLYNX. The patient's doctor will do tests before starting treatment, monthly during the first 3 months, and then every 3 months as needed during treatment with NERLYNX. NERLYNX treatment may be stopped or the dose may be lowered if your liver tests show severe problems. Symptoms of liver problems may include tiredness, nausea, vomiting, pain in the right upper stomach-area (abdomen), fever, rash, itching, yellowing of your skin or whites of your eyes.

Pregnancy

Patients should tell their doctor if they are planning to become pregnant, are pregnant, plan to breastfeed, or are breastfeeding. NERLYNX can harm your unborn baby. Birth control should be used while a patient is receiving NERLYNX and for at least 1 month after the last dose. If patients are exposed to NERLYNX during pregnancy, they must contact their healthcare provider right away.

Common side effects in patients treated with NERLYNX

In clinical studies, the most common side effects seen in patients taking NERLYNX were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis (dry or inflamed mouth, or mouth sores), decreased appetite, muscle spasms, dyspepsia, changes in liver blood tests results, nail problems, dry skin, abdominal distention, weight loss, and urinary tract infection.

Patients should tell their doctor right away if they are experiencing any side effects. Report side effects to the FDA at 1-800-FDA-1088 or http://www.FDA.gov/medwatch. Patients and caregivers may also report side effects to Puma Biotechnology at 1-844-NERLYNX (1-844-637-5969).

Please see Full Prescribing Information, available at www.NERLYNX.com.

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. The Company in-licenses the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the development of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2. Further information about Puma Biotechnology can be found at www.pumabiotechnology.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the Company's expectation that neratinib will become commercially available in September 2017. All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company'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, the fact that the Company has no product revenue and no products approved

for marketing, the Company's dependence on PB272, which is still under development and may never receive regulatory approval, the challenges associated with conducting and enrolling clinical trials, the risk that the results of clinical trials may not support the Company's drug candidate claims, even if approved, the risk that physicians and patients may not accept or use the Company's products, the Company's reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates, risks pertaining to securities class action, derivative and defamation lawsuits, the Company's dependence on licensed intellectual property, and the other risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K for the year ended December 31, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

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