News Release

Puma Biotechnology Receives Day-180 List of Outstanding Issues from Committee for Medicinal Products for Human Use (CHMP)

LOS ANGELES, Calif., Aug. 2, 2017 – Puma Biotechnology, Inc. (Nasdaq: PBYI) announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has issued its Day-180 List of Outstanding Issues in the process of their ongoing regulatory review of Puma's Marketing Authorisation Application (MAA) for neratinib for the extended adjuvant treatment of HER2-positive early stage breast cancer in patients who have previously been treated with trastuzumab (Herceptin®)-based adjuvant therapy.

The CHMP has requested additional data analyses related to the safety and efficacy of neratinib and has instituted a clock stop in order to allow Puma time to respond to this List of Outstanding Issues. The CHMP has set a deadline of December 22, 2017 for Puma to respond to the list. Puma expects the CHMP to issue an opinion regarding the MAA for neratinib in the first quarter of 2018.

U.S. Approval of Neratinib (NERLYNX™)

Neratinib 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.

About HER2-Positive Breast Cancer

Approximately 20% to 25% 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.

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.

The full prescribing information for NERLYNX is 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 dose of NERLYNX and continued during the first 2 months (56 days) of treatment and as needed thereafter.

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 if 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 or 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 test 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 approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX™. NERLYNX 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 NERLYNX, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX 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 expected timing with respect to CHMP's opinion regarding the MAA for neratinib. 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 currently has no product revenue, the Company's dependence upon the commercial success of NERLYNX™ (neratinib), the Company's history of operating losses and its expectation that it will continue to incur losses for the foreseeable future, risks and uncertainties related to the Company's ability to achieve or sustain profitability, the Company's ability to predict its future prospects and forecast its financial performance and growth, failure to obtain sufficient capital to fund the Company's operations, the effectiveness of sales and marketing efforts, the Company's ability to obtain FDA approval or other regulatory approvals for others product candidates, 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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