



Published on *Puma Biotechnology Investor Center* (<https://investor.pumabiotechnology.com>) on 6/26/18 5:51 am PDT

Puma Biotechnology Announces Results of CHMP Reexamination of MAA for Neratinib for Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer

Release Date:

Tuesday, June 26, 2018 5:51 am PDT

Terms:

Dateline City:

LOS ANGELES

LOS ANGELES--([BUSINESS WIRE](#))--Puma Biotechnology, Inc. (Nasdaq: PBYI) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive trend vote recommending the approval of the Marketing Authorisation Application (MAA) for neratinib for the extended adjuvant treatment of early stage HER2-positive hormone receptor positive breast cancer. Today's decision follows a reexamination of the negative opinion announced by the CHMP at its formal meeting with the Company to discuss the MAA on February 23, 2018. The CHMP communicated its intention to hold a final vote at its next meeting.

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.

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, 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 is a registered trademark of Puma Biotechnology, Inc.

IMPORTANT SAFETY INFORMATION

NERLYNX® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a 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.

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 \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 (\geq 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, epistaxis, 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 (PPI) and H2-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- 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.

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 CHMP opinion, the basis for its opinion regarding the Company's MAA, and steps Puma may take in the future to gain marketing approval in Europe. All statements other than historical facts are forward-looking statements and are based on our current expectations, forecasts and assumptions. Forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These risk and uncertainties are identified in our Annual Report on Form 10-K for the year ended December 31, 2017, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and any subsequent documents we file with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We assume no obligation to update these forward-looking statements except as required by law.

Language:

English

Contact:

Puma Biotechnology, Inc.
Alan H. Auerbach or Mariann Ohanesian, +1 424 248 6500
info@pumabiotechnology.com
ir@pumabiotechnology.com

or

Russo Partners
David Schull or Amiad Finkelthal, +1 212 845 4200
david.schull@russopartnersllc.com
amiad.finkelthal@russopartnersllc.com

Ticker Slug:

Ticker: PBYI

Exchange: NASDAQ

ISIN:

US74587V1070

Source URL: <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-announces-results-chmp-reexamination-maa-neratinib-extended-adjuvan>