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# NCCN Guidelines for Central Nervous System Cancers Include NERLYNX® (neratinib) in Combination With Capecitabine or Paclitaxel as Treatment Options for Patients With Breast Cancer Brain Metastases

## Release Date:

Monday, April 2, 2018 5:45 am PDT

## Terms:

## Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (Nasdaq: PBYI), a biopharmaceutical company, announced today that NERLYNX® (neratinib) has been included as a recommended treatment option in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology Central Nervous System Cancers for Breast Cancer patients with brain metastases. The NCCN designated NERLYNX in combination with capecitabine as a category 2A treatment option and NERLYNX in combination with paclitaxel as a category 2B treatment option. Use, as designated for breast cancer patients with brain metastases, is outside the FDA approved indication for NERLYNX and considered investigational.

“Physicians use the NCCN Guidelines as the standard resource for determining the best course of treatment for patients,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “We believe the updated NCCN guidelines will increase awareness, which will help assist patients, their caregivers and their healthcare providers in making informed decisions while treating this significant unmet need in advanced breast cancer.”

## About Brain Metastases in Breast Cancer

Breast cancer is one of three types of cancers that are most likely to metastasize to the brain. Across all sub-types, approximately 10-15% of women with metastatic breast cancer develop brain metastases. This rate is as high as 30% for women with advanced HER2+ disease.

## About National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 27 of the world’s leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers.

Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

## 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 a trastuzumab-based regimen experience recurrence.

## 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](http://www.NERLYNX.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

#### **DRUG INTERACTIONS:**

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H<sub>2</sub>-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](http://www.NERLYNX.com) or 1-855-816-5421.

#### **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. NERLYNX® (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. 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 commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

Further information about Puma Biotechnology can be found at [www.pumabiotechnology.com](http://www.pumabiotechnology.com).

#### **Language:**

English

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