



Published on *Puma Biotechnology Investor Center* (<https://investor.pumabiotechnology.com>) on 7/31/18 5:30 am PDT

# Puma Biotechnology Files New Drug Submission for NERLYNX® in Canada

## Release Date:

Tuesday, July 31, 2018 5:30 am PDT

## Terms:

## Dateline City:

LOS ANGELES

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that Health Canada has accepted for review the Company's New Drug Submission (NDS) for the medicinal product NERLYNX® (neratinib) for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. The NDS recently passed the mandatory validation period by Health Canada, the country's federal regulator for drugs and health products, and has now entered the review period.

"Health Canada's acceptance of our NDS represents another important regulatory milestone in our commitment to increasing access to NERLYNX around the world to reduce disease recurrence following trastuzumab therapy in patients with early stage HER2-positive breast cancer," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We look forward to working with Health Canada during their review of our submission."

Neratinib, an oral irreversible pan-HER kinase inhibitor, was approved by the 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®. The drug also received a recommendation for marketing authorization from the Committee for Medicinal Products for Human Use (CHMP) in June 2018 and is being reviewed by the European Commission, which has the authority to approve medicines for the European Union.

## 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. 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 is a registered trademark of Puma Biotechnology, Inc.

## Important Safety Information (ISI)

### 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 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](http://www.NERLYNX.com) or 1-855-816-5421.

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

#### **Language:**

English

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#### **Ticker Slug:**

*Ticker:* PBYI

*Exchange:* NASDAQ

*ISIN:*

US74587V1070

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**Source URL:** <https://investor.pumabiotechnology.com/press-release/puma-biotechnology-files-new-drug-submission-nerlynx-canada>