# Protect HER Future with NERLYNX: Defend Against Recurrence in HER2+ Early-Stage Breast Cancer<sup>1,2\*</sup>





#### PROGRAM FEATURING

- Efficacy and safety results from the pivotal ExteNET Trial
- Descriptive analyses of the ExteNET trial: iDFS and CNS subgroup data and final OS results
- Option for a two-week dose escalation

PRESENTED BY:

VIJAYAKRISHNA GADI, MD, PHD

**PROGRAM HOST:** 

ROBIN GINGOLD

**PROGRAM INFORMATION:** 

WEDNESDAY, OCTOBER 20, 2021 at 6:00 PM

UNIVERSITY OF ILLINOIS IN CHICAGO MEDICAL

CENTER, WINNETKA, IL

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VINA ENOTECA

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PLEASE REGISTER ONLINE AT: <a href="http://pumareg.tsgmeded.com">http://pumareg.tsgmeded.com</a>

**Enter Event Code: 52599** 

Please register by October 14, 2021 as space is limited.

Registration assures your spot and assists Puma Biotechnology with holding efficient and compliant programs.

#### INDICATIONS AND USAGE:

**NERLYNX®** (neratinib) tablets, for oral use, is a kinase inhibitor indicated:

 As a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.

## **SELECT IMPORTANT SAFETY INFORMATION**

**ADVERSE REACTIONS:** The most common adverse reactions (reported in ≥ 5% of patients) were:

• NERLYNX as a single agent: diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increased, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased, and urinary tract infection.

New Jersey, Minnesota, Vermont, the Department of Defense, and the Department of Veterans Affairs have restrictions on receiving in-kind benefits (e.g., meals, paid parking) at company-sponsored events. For all attendees, please be advised that information such as your name and the value and purpose of any educational item, meal, or other items of value you receive may be publicly disclosed. You are accountable for understanding such restrictions and complying with them. If you are licensed in or affiliated with any of these states or federal agencies, Puma Biotechnology policies may restrict you from consuming any portion of the Puma Biotechnology-sponsored meal at this program or from receiving any other in-kind benefit from Puma Biotechnology (e.g., paid parking) in connection with the program.

This program is sponsored by Puma Biotechnology, Inc. This is not an independent educational program, and no CME credits will be provided.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; HER2 = human epidermal growth factor receptor 2, iDFS = invasive disease-free survival; CNS = central nervous system

Please see additional Important Safety Information on next page and accompanying Full Prescribing Information including Patient Information.

NERLYNX® (neratinib) tablets, for oral use

#### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS: None** 

# **WARNINGS AND PRECAUTIONS:**

- Diarrhea: Manage diarrhea through either NERLYNX dose escalation or loperamide prophylaxis. If diarrhea occurs despite recommended
  prophylaxis, treat 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 ≥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.

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To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) 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. Separate NERLYNX by at least 2 hours before or 10 hours after H<sub>2</sub>-receptor antagonists. Or separate NERLYNX by at least 3 hours after antacids.
- Strong CYP3A4 inhibitors: Avoid concomitant use.
- P-gp and moderate CYP3A4 dual inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- Certain P-gp substrates: Monitor for adverse reactions of P-gp substrates for which minimal concentration change may lead to serious adverse
  reactions when used concomitantly with NERLYNX.

## **USE IN SPECIFIC POPULATIONS:**

• Lactation: Advise women not to breastfeed.

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Please see accompanying Full Prescribing Information including Patient Information.

#### References:

1. Chan A, et al. Clin Breast Cancer. 2021;21(1):80-91.e7. 2. Martin M, et al. Lancet Oncol. 2017;18(12):1688–1700.