

### **AGAINST HER2+ BREAST CANCER RECURRENCE**

### What is NERLYNX tablets?

- NERLYNX is a prescription medicine used alone to treat adults with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer **and** who have previously been treated with trastuzumab-based therapy.
- NERLYNX is also used with a medicine called capecitabine to treat adults with HER2-positive breast cancer that has spread to other parts of the body (metastatic) **and** who have received 2 or more anti-HER2 therapy medicines for metastatic breast cancer.

It is not known if NERLYNX is safe and effective in children.

### SELECT IMPORTANT SAFETY INFORMATION

The most serious risks of NERLYNX are diarrhea and liver problems. NERLYNX can also harm your unborn baby. You should use effective birth control during treatment and for at least one month after your last dose of NERLYNX.



### What do I need to know about HER2+ breast cancer?

Having HER2+ breast cancer can bring with it a range of emotions. Some days you may feel irritable, angry, or hopeless. And there are days where you almost forget your diagnosis and feel like yourself again. But no matter how you're feeling, it's important to know the facts about what's going on with your condition.

### You're not in this alone.

About Simple Sim

people with breast cancer have HER2+ breast cancer.

### What is HER2+ breast cancer?

You may already know this, but people with HER2+ breast cancer have a gene mutation that causes their cells to make too much of the HER2 protein. HER2 protein tells cells to grow and divide. If you have too much, your cells may grow faster than normal and behave aggressively—this causes HER2+ breast cancer.

HER2+ breast cancer is different from other breast cancers. It grows quicker, tends to be more aggressive, and is more likely to come back or spread, even after other treatments. But there are medicines out there that are made to specifically target the HER2 protein.

### WHERE COULD NERLYNX (NERATINIB) TABLETS FIT INTO MY TREATMENT PLAN?



Treatment prior to surgery to reduce tumor size. This includes treatments like chemotherapy, chemotherapy plus trastuzumab, endocrine therapy, and/or radiation therapy.

Surgery such as a lumpectomy or mastectomy.

Please see Important Safety Information at the end of this brochure and Product Information on the NERLYNX website.

Treatment given after surgery, with the goal of destroying any cancer cells that might remain in the body.

Medication given after adjuvant therapy with the goal of reducing the chance of the cancer coming back.

In early-stage breast cancer, NERLYNX is an extended adjuvant anti-HER2 targeted medication following trastuzumab-based therapy.

## What's the difference between early-stage and metastatic HER2+ breast cancer?

**Early-stage HER2+** breast cancer is cancer that has not spread beyond the breast and the nearby lymph nodes.

Metastatic HER2+ breast cancer, also called Stage IV or advanced breast cancer, is cancer that has spread beyond the breast and nearby lymph nodes to other parts of the body.

### What can I do to reduce the risk of recurrence?

With breast cancer, there is always some level of risk of the cancer returning. That's why no matter if your diagnosis was a month ago or years ago, it's important to know what's ahead so you and your healthcare team can make plans. Taking NERLYNX after adjuvant trastuzumab-based treatment may help reduce that risk.

In early-stage HER2+ breast cancer the risk of recurrence can be as high as

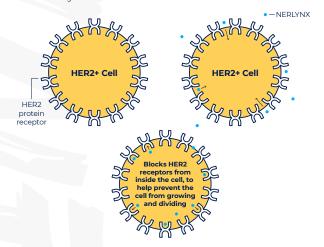




### What's NERLYNX?

NERLYNX is a once a day, oral treatment for adults with HER2+ breast cancer. NERLYNX is taken after adjuvant (after surgery) trastuzumab-based therapy when used by people with early-stage HER2+ breast cancer. NERLYNX is a small molecule targeted therapy that works inside your cells and helps stop HER2 protein signals.

With NERLYNX, you may help further reduce the risk that your HER2+ breast cancer will return.



Learn more about how NERLYNX works here.

### What are the most serious side effects of NERLYNX?

The most serious risks of NERLYNX are diarrhea and liver problems. NERLYNX can also harm your unborn baby. You should use effective birth control during treatment and for at least one month after your last dose of NERLYNX.

Please see <u>Important Safety Information</u> at the end of this brochure and <u>Product Information</u> on the NERLYNX website.

# What should I know about how NERLYNX was studied in early-stage HER2+ breast cancer?

NERLYNX was studied in a phase 3 trial examining the safety and effectiveness of NERLYNX vs placebo. The clinical trial included 2,840 people who had early-stage HER2+ breast cancer.



In a clinical study, NERLYNX reduced the risk of recurrence by 34% at 2 years. This was the primary endpoint of the trial.

In absolute numbers, 94.2% of all people studied who were HER2+ and took NERLYNX had no return of cancer after 2 years, compared to the 91.9% of people on placebo: a difference of 2.3%.

With NERLYNX, you may help further reduce the risk that your HER2+ breast cancer will return.

Please see <u>Important Safety Information</u> at the end of this brochure and <u>Product Information</u> on the NERLYNX website.



### What is the effect of NERLYNX in people who are HER2+ and HR+?

NERLYNX was also studied in people with early-stage HER2+ breast cancer who were HR+ as well. In an additional analysis conducted after the clinical trial was completed, 75% of patients enrolled in the clinical trial (2,117 out of 2,840) agreed to remain in the study beyond the initial 2 years. Of the HER2+ and HR+ population, 95% were also treated with endocrine therapy.



In this analysis, patients who received NERLYNX had a 42% lower risk of recurrence at 5 years.

After 5 years, 90.8% of all people studied who were HER2+ and HR+ and took NERLYNX had no return of cancer, compared to the 85.7% of people taking placebo: a difference of 5.1%.

Talk to your doctor for more information on NERLYNX data. Your doctor will help you manage expectations.

#### SELECT IMPORTANT SAFETY INFORMATION

Diarrhea is a common side effect of NERLYNX, but it can also be severe. Diarrhea may lead to loss of too much body salts and fluid, which can cause dehydration. Call your healthcare provider right away if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever. You may be prescribed antidiarrheals as needed. Always take antidiarrheals exactly as your healthcare provider tells you.

# Does NERLYNX impact the development of HER2+ breast cancer recurrence in the CNS?

In an additional analysis conducted after the clinical trial was completed, NERLYNX was shown to have an effect on CNS (central nervous system: brain and spinal cord) metastases in people with early-stage HER2+ breast cancer.

In absolute numbers, 98.4% of people given NERLYNX (n=670) did not experience a CNS recurrence, or death from any cause, compared to 95.7% of those given placebo (n=664): a benefit of 2.7%.



Reduction for HER2+ and HR+

This translates to a 59% reduction in the risk of CNS recurrence or death in people with HER2+ and HR+ breast cancer given NERLYNX.

### SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of NERLYNX when used alone include: diarrhea; nausea; stomach-area (abdomen) pain; tiredness; vomiting; rash; dry or inflamed mouth, or mouth sores; decreased appetite; muscle spasms; upset stomach; nail problems including color change; dry skin; swelling of your stomach-area; nosebleed; weight loss; urinary tract infection.



### What support is available to me and my family?

### **Mentor Program\***

If you are considering or already being treated with NERLYNX, our mentor program connects you with someone who currently takes or has taken NERLYNX.<sup>†</sup>

While every experience with NERLYNX is unique, and your doctor should always be your primary source of information for treatment decisions, hearing from someone who has taken NERLYNX helps you:

- Learn about another person's real life experiences
- Understand why they felt NERLYNX was the right step for them
- Gain confidence to take this next step toward reducing the risk that breast cancer will return



- Learn about the resources available as you take NFRI YNX
- \*The mentor program is here for you with support and resources. Your healthcare team should always be your primary source of information for treatment decisions.
- †Puma mentors are compensated for their time.

It's important to see your treatment through. Learn how our mentor program can help <u>here</u>.

Please see <u>Important Safety Information</u> at the end of this brochure and <u>Product Information</u> on the NERLYNX website.

### IMPORTANT SAFETY INFORMATION

What is the most important information I should know about NERLYNX (ner links)?

### NERLYNX may cause serious side effects, including:

 Diarrhea. Diarrhea is a common side effect of NERLYNX, but it can also be severe. Diarrhea may lead to loss of too much body salts and fluid, which can cause dehydration. Your healthcare provider will prescribe NERLYNX in one of two ways to help manage diarrhea:

#### Full dose of NERLYNX:

- Your healthcare provider will prescribe the antidiarrheal medicine loperamide for you during your first 2 months (56 days) of treatment with NERLYNX and then as needed. Your healthcare provider will tell you exactly how much and how often to take this medicine.
- If you are prescribed the full dose of NERLYNX from the start of your treatment, be sure that your healthcare provider also prescribes antidiarrheals with NERLYNX. You should start taking loperamide with your first dose of NERLYNX.
- After 2 months (56 days) of treatment with NERLYNX, follow your healthcare provider's instructions about taking loperamide as needed to control diarrhea.

#### A lower starting dose of NERLYNX:

 Your healthcare provider will start you on a lower dose of NERLYNX for the first 2 weeks of treatment and then increase you to a full dose NERLYNX regimen. Tell your healthcare provider right away if you develop diarrhea; you may be prescribed loperamide as needed.

#### To help prevent or reduce diarrhea during treatment with NERLYNX:

- Your healthcare provider may also need to give you additional antidiarrheals, fluids, and electrolytes to manage diarrhea when you start treatment with NERLYNX. Follow your healthcare provider's instructions on how to take antidiarrheal medicines.
- Always take antidiarrheals exactly as your healthcare provider tells you.
- While taking antidiarrheals, 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 you have diarrhea that does not go away.
- Call your healthcare provider right away if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever.

Your healthcare provider may change your dose of NERLYNX, temporarily stop, or completely stop NERLYNX if needed to manage your diarrhea.

See "What are the possible side effects of NERLYNX?" for more information about side effects.

### Before taking NERLYNX, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems. You may need a lower dose of NERLYNX.
- are pregnant or plan to become pregnant. NERLYNX can harm your unborn baby. If you are a female who can become pregnant:
  - Your healthcare provider should do a pregnancy test before you start taking NERLYNX.
  - You should use effective birth control (contraception) during treatment and for at least 1 month after your last dose of NERLYNX.
  - Talk with your healthcare provider about forms of birth control that you can use during this time.
- Tell your healthcare provider right away if you become pregnant during treatment with NERLYNX.



- Males with female partners who can become pregnant should use effective birth control during treatment and for 3 months after the last dose of NERLYNX.
- are breastfeeding or plan to breastfeed. It is not known if NERLYNX passes into your breast milk. Do not breastfeed during treatment and for at least 1 month after your last dose of NERLYNX.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Especially tell your healthcare provider if** you take medicines used to decrease stomach acid, called proton pump inhibitors or PPIs. You should avoid taking these medicines during treatment with NERLYNX.

### What should I avoid while taking NERLYNX?

You should avoid eating products that contain grapefruit during treatment with NERLYNX.

#### What are the possible side effects of NERLYNX?

#### NERLYNX may cause serious side effects, including:

### See "What is the most important information I should know about NERLYNX?"

- Liver problems. Changes in liver function tests are common with NERLYNX. Your healthcare provider should do blood tests before you begin treatment, monthly during the first 3 months, and then every 3 months as needed during treatment with NERLYNX. Your healthcare provider will stop your treatment with NERLYNX if your liver tests show severe problems. Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:
- tiredness
- nauseavomiting
- vomiting
   pain in the right upper stomacharea (abdomen)
- fever - rash - itchina
- ach- yellowing of your skin or whites of your eyes

### The most common side effects of NERLYNX when used alone include:

- · diarrhea
- nausea
- stomach-area (abdomen) pain
- tiredness
- vomitingrash
- dry or inflamed mouth, or mouth sores
- decreased appetite

capecitabine include:

- muscle spasms
- upset stomach
- nail problems including color change
- · dry skin
- swelling of your stomach-area
- nosebleed
- weight lossurinary tract infection
- The most common side effects of NERLYNX when used with
- diarrhea
- nausea
- vomiting
- decreased appetite
- constipation
- tiredness/weakness
- weight loss
- dizziness
- back pain

- joint pain
- · urinary tract infection
- upper respiratory tract infection
- swelling of your stomach-area
- kidney problems
- · muscle spasms

These are not all of the possible side effects of NERLYNX. For more information, ask your Healthcare Provider.

Tell your healthcare provider if you have any side effects that bother you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Product Information on the NERLYNX website.



### Take a stand against the risk of recurrence with NERLYNX at NERLYNX.com





Follow below to join our community!







Please see Important Safety Information within and Product Information on the NERLYNX website.

