NERLYNX® Appropriate Use

NERLYNX® (neratinib) is indicated for the extended adjuvant treatment of women with early-stage hormone receptor positive, HER2-overexpressed/amplified breast cancer within one year after completion of trastuzumab-based adjuvant therapy.

Dear Healthcare Professional,

Please take careful note of this important safety information regarding NERLYNX® (neratinib). This information is being provided to assist you in the appropriate use of NERLYNX® and to facilitate the discussion with your patient pertaining to the specific important risks listed below:

- Diarrhea
- Stomatitis
- Hepatotoxicity

The accompanying **NERLYNX® PRESCRIBER CHECKLIST** includes detailed information and actions on managing these risks in clinical practice.

You should discuss the risks associated with NERLYNX® therapy with patients or their caregivers. Additionally, please provide the patient or caregiver with the **NERLYNX® PATIENT CHECKLIST.**

REPORTING ADVERSE EVENTS: Please report to Knight Therapeutics any medication errors and/or adverse events suspected to be associated with the use of NERLYNX® by telephone at 1-844-483-5636 or by email at medinfo@gudknight.com.

Refer to the NERLYNX® Product Monograph for complete prescribing information.

The Product Monograph is available online at www.gud-knight.com, by telephone at 1-844-483-5636, or by email at medinfo@gudknight.com.

This material was developed by Knight Therapeutics as part of the Risk Management Plan for NERLYNX®.
It is not intended for promotional use.

NERLYNX® Prescriber Checklist

Please take careful note of this important safety information regarding NERLYNX® (neratinib). This information is being provided to assist you in the appropriate use of NERLYNX® and to facilitate the discussion with your patient pertaining to the specific important risks listed below.

Diarrhea

In the clinical trial, 95% of patients receiving NERLYNX® reported diarrhea (40% Grade 3, 0.1% Grade 4). Severe diarrhea and sequelae, such as dehydration, hypotension and renal failure have been reported.

- ☐ **Antidiarrheal prophylaxis with loperamide is recommended,** as per the Product Monograph.
- ☐ **Manage diarrhea proactively** with adequate oral hydration, avoiding aggravating foods, and treating with additional antidiarrheal therapy.
- ☐ **Dose modifications are recommended for patients with diarrhea,** as per the Product Monograph.
- ☐ Advise patients of the risk of diarrhea, and instruct them to watch for signs and symptoms accordingly.

Stomatitis

In the clinical trial, 14% of patients receiving NERLYNX® reported stomatitis (0.6% Grade 3+).

- ☐ **Recommend dental examination prior to and during NERLYNX® therapy.** Regular dental prophylaxis and treatment should also be considered if indicated.
- ☐ Educate patients on oral hygiene, including regular brushing, flossing and mouth rinsing.
- ☐ Advise patients of the risk of stomatitis, and instruct them to avoid irritants such as tobacco, alcohol, spicy, acidic or very hot food.

Hepatotoxicity

NERLYNX® has been associated with hepatotoxicity, characterized by increased liver enzymes. In the clinical trial, 12% of patients receiving NERLYNX® reported hepatotoxicity (1.7% Grade 3+).

- ☐ **Conduct liver function tests prior to and during NERLYNX® therapy.** Patients who experience Grade >3 diarrhea, requiring IV fluid treatment, or any signs or symptoms of hepatotoxicity should be evaluated for changes in liver function tests.
- ☐ **Dose modifications or treatment discontinuation are recommended for patients with treatment-emergent hepatotoxicity,** as per the Product Monograph.
- ☐ **Avoid concomitant use of NERLYNX® with strong or moderate CYP3A4 inhibitors.**
- ☐ Advise patients of the risk of hepatotoxicity, and instruct them to watch for signs and symptoms accordingly.

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