CLINICAL UPDATE

Brand Name	Trazimera™
Generic Name	trastuzumab-qyyp
Drug Manufacturer	Pfizer, Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Strength (150 mg single-dose vial)

FDA APPROVAL DATE

November 30, 2020

LAUNCH DATE

March 10, 2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

N/A; Biologic License Application (BLA): 761081

DISPENSING RESTRICTIONS

Specialty

Overview

INDICATION(S) FOR USE

Trazimera™ is a HER2/neu receptor antagonist indicated for:

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

MECHANISMS OF ACTION

The HER2 (or c-erbB2) proto-oncogene encodes a transmembrane receptor protein of 185 kDa, which is structurally related to the epidermal growth factor receptor. Trastuzumab products have been shown, in both in vitro assays and in animals, to inhibit the proliferation of human tumor cells that overexpress HER2.

Trastuzumab products are mediators of antibody-dependent cellular cytotoxicity (ADCC). In vitro, trastuzumab product mediated ADCC has been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2.

DOSAGE FORM(S) AND STRENGTH(S)

For Injection: 150 mg lyophilized powder in a single-dose vial for reconstitution.
For Injection: 420 mg lyophilized powder in a multiple-dose vial for reconstitution.

DOSE & ADMINISTRATION

For intravenous (IV) infusion only. Do not administer as an intravenous push or bolus.

CLINICAL UPDATE

Do not substitute Trazimera™ (trastuzumab-qyyp) for or with ado-trastuzumab emtansine.
Perform HER2 testing using FDA-approved tests by laboratories with demonstrated proficiency.

Adjuvant Treatment of HER2-Overexpressing Breast Cancer
Administer at either:

- Initial dose of 4 mg/kg over 90-minute intravenous infusion, then 2 mg/kg over 30-minute intravenous infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose of Trazimera™, administer 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy, or
- Initial dose of 8 mg/kg over 90 minutes intravenous infusion, then 6 mg/kg over 30 to 90 minutes intravenous infusion every three weeks for 52 weeks.

Metastatic HER2-Overexpressing Breast Cancer
Initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent weekly doses of 2 mg/kg as 30-minute intravenous infusions.

Metastatic HER2-Overexpressing Gastric Cancer
Initial dose of 8 mg/kg over 90 minutes intravenous infusion, followed by 6 mg/kg over 30 to 90 minutes intravenous infusion every 3 weeks.

EFFICACY

Efficacy data consistent with original approved strength of 420 mg in multi-dose vial.