Herzuma® (trastuzumab-pkrb) – New and expanded indications

- On May 16, 2019, the FDA approved Teva and Celltrion's Herzuma (trastuzumab-pkrb), in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease, and for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as a single agent following multi-modality anthracycline based therapy.
    - Previously Herzuma was approved for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, or as part of a treatment regimen with docetaxel and carboplatin.
    - Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.
- Herzuma is also indicated in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer and as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.
- Herzuma is a biosimilar to Genentech's Herceptin (trastuzumab).
    - With the approval of the new and expanded indications, Herzuma now has all of the same indications as Herceptin.
- Like Herceptin, Herzuma also carries boxed warnings for cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity.
- In addition, a single-dose vial containing 150 mg of Herzuma in a lyophilized powder has also been approved.
    - Previously, Herzuma was only available in a multiple-dose vial containing 420 mg of Herzuma in a lyophilized powder.
- The recommended dosage of Herzuma varies by indication as follows:

Indication	Recommended Dosage
Adjuvant breast cancer (during and following paclitaxel, docetaxel, or docetaxel/carboplatin)	• Initial dose of 4 mg/kg as an intravenous (IV) infusion, then 2 mg/kg IV weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin). • One week following the last weekly dose of Herzuma, administer Herzuma 6 mg/kg IV every three weeks to complete a total of 52 weeks of therapy.
Adjuvant breast cancer (as a single agent within 3 weeks following completion of multi-modality, anthracycline based chemotherapy regimens)	• Initial dose of 8 mg/kg by IV, then subsequent doses at 6 mg/kg IV every three weeks. • Extending adjuvant treatment beyond one year is not recommended.

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Metastatic breast cancer	Alone or in combination with paclitaxel, at an initial dose of 4 mg/kg IV followed by subsequent once weekly doses of 2 mg/kg IV until disease progression.
Metastatic gastric cancer	Initial dose of 8 mg/kg IV followed by subsequent doses of 6 mg/kg IV every three weeks until disease progression.

  - — Do not substitute Herzuma with Kadcyla® (ado-trastuzumab emtansine).
  - — For additional dosing information, refer to the Herzuma drug label.

- Teva/Celltrion's launch plans for Herzuma are pending