Kanjinti™ (trastuzumab-anns) – New biosimilar approval

- On June 13, 2019, Amgen and Allergan announced the FDA approval of Kanjinti (trastuzumab-anns), a biosimilar to Genentech's Herceptin® (trastuzumab).
    - Kanjinti is the fifth FDA-approved biosimilar to Herceptin.
    - Mylan's Ogivri® (trastuzumab-dkst) was the first biosimilar to Herceptin and was approved in December 2017. In December 2018, Teva and Celltrion's Herceptin biosimilar, Herzuma® (trastuzumab-pkrb), was approved. Samsung Bioepis and Merck's Ontruzant® (trastuzumab-dttb) was approved in January 2019. Pfizer's Trazimera™ (trastuzumab-qyyp) was approved in March 2019.
    - Mylan, Teva/Celltrion, Samsung Bioepis/Merck, and Pfizer's launch plans for Ogivri, Herzuma, Ontruzant, and Trazimera are pending.

- Kanjinti, Trazimera, Ontruzant, Herzuma, Ogivri, and Herceptin share the following indications:
    - **Adjuvant breast cancer:** 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; or as a single agent following multi-modality anthracycline based therapy.
    - **Metastatic breast cancer:** in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer; or as a single agent for treatment of HER2 overexpressing breast cancer in patients who have received ≥ 1 chemotherapy regimens for metastatic disease.
    - **Metastatic gastric cancer:** 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.
    - Patients should be selected for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
    - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
    - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.

- Kanjinti has been approved as a biosimilar, ***not*** as an interchangeable product.

- Like Herceptin, Kanjinti carries a boxed warning regarding the risk of cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity.

- Another warning and precaution of Kanjinti is exacerbation of chemotherapy-induced neutropenia.

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- The most common adverse reactions vary by indication.
    - In adjuvant breast cancer, the most common adverse reactions (≥ 5%) with trastuzumab use were headache, diarrhea, nausea, and chills.
    - In metastatic breast cancer, the most common adverse reactions (≥ 10%) with trastuzumab use were fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.
    - In metastatic gastric cancer, the most common adverse reactions (≥ 10%) with trastuzumab use were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

- The recommended dosage of Kanjinti 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 Kanjinti, administer Kanjinti 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.
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 Kanjinti with Kadcyla® (ado-trastuzumab emtansine).
    - For additional dosing information, refer to the Kanjinti drug label.

- Amgen's launch plans are pending. Kanjinti will be available as a 420 mg lyophilized powder in a multiple-dose vial for reconstitution.