Kanjinti™ (trastuzumab-anns) – First-time biosimilar launch

- On July 19, 2019, Allergan and Amgen announced the launch of Kanjinti (trastuzumab-anns), a biosimilar to Genentech's Herceptin (trastuzumab).
    - 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 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.

- Similar to Herceptin, Kanjinti carries a boxed warning for cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity.

- The wholesale acquisition cost (WAC) of Kanjinti is $3,697.26 per 420 mg multi-dose vial. This is 15% lower than the WAC for Herceptin.