Kadcyla® (ado-trastuzumab emtansine) – New indication

- On May 3, 2019, Genentech announced the FDA approval of Kadcyla (ado-trastuzumab emtansine), as a single agent, for the adjuvant treatment of patients with HER2-positive early breast cancer (EBC) who have residual invasive disease after neoadjuvant taxane and Herceptin® (trastuzumab)-based treatment.
    - Select patients for therapy based on an FDA-approved companion diagnostic for Kadcyla.
- Kadcyla is also approved as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer (MBC) who previously received Herceptin and a taxane, separately or in combination. Patients should have either:
    - Received prior therapy for metastatic disease, or
    - Developed disease recurrence during or within six months of completing adjuvant therapy.
- The efficacy of Kadcyla for HER2-positive, EBC was demonstrated in an open-label study (KATHERINE) of 1,486 patients. Patients received Kadcyla or Herceptin. The major efficacy outcome of the study was invasive disease-free survival (IDFS).
    - After a median follow-up of 40 months, a statistically significant improvement in IDFS was observed in patients who received Kadcyla vs. Herceptin. A total of 12.2% of Kadcyla patients experienced an event vs. 22.2% of Herceptin treated patients (Hazard ratio = 0.50 [95% CI: 0.39, 0.64]; $p < 0.0001$)
- Kadcyla carries a boxed warning for hepatotoxicity, cardiac toxicity, and embryo-fetal toxicity.
- The recommended dose of Kadcyla is 3.6 mg/kg given as an intravenous infusion every 3 weeks (21-day cycle). Kadcyla should not be administered at doses greater than 3.6 mg/kg.
    - Herceptin should not be substituted for or with Kadcyla.
    - Patients with EBC should receive treatment for a total of 14 cycles unless there is disease recurrence or unmanageable toxicity.
    - Patients with MBC should receive treatment until disease progression or unmanageable toxicity.