Enhertu® (fam-trastuzumab deruxtecan-nxki) – New indication

- On August 11, 2022, Daiichi Sankyo and AstraZeneca announced the FDA approval of Enhertu (fam-trastuzumab deruxtecan-nxki), for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
    - This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Enhertu is also approved for HER2-positive metastatic breast cancer, HER2-low metastatic breast cancer, and locally advanced or metastatic gastric cancer.
- The approval of Enhertu for the new indication was based on DESTINY-Lung02, a multi-cohort, randomized, blinded, dose-optimization study in unresectable or metastatic HER2-mutant non-squamous NSCLC with disease progression after one prior systemic therapy. Patients received Enhertu 5.4 mg/kg by intravenous (IV) infusion every 3 weeks until disease progression or unacceptable toxicity. The major efficacy outcomes were confirmed ORR and DOR.
    - The confirmed ORR was 57.7% (95% CI: 43.2, 71.3).
    - The median DOR was 8.7 months (95% CI: 7.1, not estimable).
- Enhertu carries a boxed warning for interstitial lung disease and embryo-fetal toxicity.
- The recommended dosage of Enhertu for the treatment of NSCLC is 5.4 mg/kg given as an IV infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.
    - Refer to the Enhertu drug label for dosing for all its other indications.