Datroway® (datopotamab deruxtecan-dlnk) – New drug approval

- On January 17, 2025, Daiichi Sankyo and AstraZeneca announced the FDA approval of Datroway (datopotamab deruxtecan-dlnk), for the treatment of adult patients with unresectable or metastatic, hormone receptor **(HR) positive**, human epidermal growth factor receptor 2 **(HER2) negative** (IHC 0, IHC 1+ or IHC 2+/ISH-) **breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease**.

- In the U.S., more than 300,000 cases of breast cancer are diagnosed annually. Approximately 70% of diagnosed cases are considered what has been historically called HR positive, HER2 negative breast cancer (measured as HER2 score of IHC 0, IHC 1+ or IHC 2+/ISH-).

- Datroway is a Trop-2-directed antibody and topoisomerase inhibitor conjugate.

- The efficacy of Datroway was established in TROPION-Breast01, an open-label, randomized study in 732 patients with unresectable or metastatic HR positive, HER2 negative breast cancer. Patients were randomized to Datroway or investigator's choice of chemotherapy until unacceptable toxicity or disease progression. The major efficacy outcomes were progression-free survival (PFS) and overall survival (OS).

    - **Median PFS was 6.9 months and 4.9 months in the Datroway and chemotherapy arms, respectively** (hazard ratio 0.63, 95% CI: 0.52, 0.76; p < 0.0001).
    - **Median OS was 18.6 months and 18.3 months in the Datroway and chemotherapy arms, respectively** (hazard ratio 1.01, 95% CI: 0.83, 1.22; **not statistically significant).**

- Warnings and precautions for Datroway include **interstitial lung disease/pneumonitis, ocular adverse reactions, stomatitis, and embryo-fetal toxicity.**

- The most common adverse reactions (≥ 20%), including laboratory abnormalities, with Datroway use were stomatitis, nausea, fatigue, decreased leukocytes, decreased calcium, alopecia, decreased lymphocytes, decreased hemoglobin, constipation, decreased neutrophils, dry eye, vomiting, increased ALT, keratitis, increased alanine transaminase, and increased alkaline phosphatase.

- The recommended dose of Datroway is **6 mg/kg (up to a maximum of 540 mg for patients ≥ 90 kg) administered as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.**

- Daiichi Sankyo and AstraZeneca plan to launch Datroway in approximately two weeks from approval. Datroway will be available as a 100 mg lyophilized powder in a single-dose vial.