Trodelvy® (sacituzumab govitecan-hziy) – New indication

- On February 3, 2023, Gilead announced the FDA approval of Trodelvy (sacituzumab govitecan-hziy), for the treatment of adult patients with unresectable locally advanced 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 endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

- Trodelvy is also approved for the treatment of adult patients with:

    — Unresectable locally advanced or metastatic triple-negative breast cancer who have received two or more prior systemic therapies, at least one of them for metastatic disease
    — Locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

- HR-positive/HER2-negative breast cancer is the most common type of breast cancer and accounts for approximately 70% of all new cases. Almost one in three cases of early-stage breast cancer eventually become metastatic, and among patients with HR+/HER2- metastatic disease, the five-year relative survival rate is 30%.

- The approval of Trodelvy for the new indication was based on TROPiCS-02, an open-label, randomized study in in 543 patients with unresectable locally advanced or metastatic HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer. Patients were randomized to receive Trodelvy or single agent chemotherapy. The primary outcome measure was progression-free survival (PFS). Additional efficacy measures included overall survival (OS), objective response rate (ORR) and duration of response (DOR).

    — Median PFS was 5.5 months for Trodelvy vs. 4.0 months for chemotherapy (hazard ratio [HR] 0.661, 95% CI: 0.529, 0.826; p = 0.0003).
    — Median OS was 14.4 months for Trodelvy vs. 11.2 months for chemotherapy (HR 0.789, 95% CI: 0.646, 0.964; p = 0.0200).
    — The ORR was 21.0% for Trodelvy vs. 14.0% for chemotherapy (odds ratio 1.625, 95% CI: 1.034, 2.555; p = 0.0348).
    — Median DOR was 8.1 months (95% CI: 6.7, 9.1) for Trodelvy vs. 5.6 months (95% CI: 3.8, 7.9) for chemotherapy.

- Trodelvy carries a boxed warning for neutropenia and diarrhea.

- The recommended dosage of Trodelvy for all its uses is 10 mg/kg administered as an intravenous infusion once weekly on days 1 and 8 of 21-day treatment cycles. Treatment should be continued until disease progression or unacceptable toxicity.