Trodelvy® (sacituzumab govitecan-hziy) – Expanded indication

- On April 7, 2021, Gilead announced the FDA approval of Trodelvy (sacituzumab govitecan-hziy), for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
    - Trodelvy was previously approved for the treatment of adult patients with mTNBC who have received at least two prior therapies for metastatic disease.
- In addition to the expanded indication, the FDA also granted Trodelvy full approval. The FDA had previously granted accelerated approval to Trodelvy in April 2020 based on objective response rate and duration of response results in a Phase 1/2 study.
- The full approval and expanded indication for Trodelvy was based on the ASCENT trial, a open-label, randomized study in 529 patients with unresectable locally advanced or mTNBC who had relapsed after at least two prior chemotherapies. Patients were randomized to receive Trodelvy or physician's choice of single agent chemotherapy. Efficacy measures included progression-free survival (PFS) and overall survival (OS).
    - Median PFS was 4.8 months vs. 1.7 months for Trodelvy and chemotherapy, respectfully (hazard ratio [HR] 0.43, 95% CI: 0.35, 0.54; $p < 0.0001$).
    - Median OS was 11.8 months vs. 6.9 months for Trodelvy and chemotherapy, respectfully (HR 0.51, 95% CI: 0.41, 0.62; $p < 0.0001$).
- Trodelvy carries a boxed warning for neutropenia and diarrhea.
- The recommended dose of Trodelvy is 10 mg/kg administered as an intravenous infusion once weekly on days 1 and 8 of 21-day treatment cycles. Treatment should continue until disease progression or unacceptable toxicity.
    - Trodelvy should not be administered at doses greater than 10 mg/kg.
    - Premedication is recommended for prevention of infusion reactions and prevention of chemotherapy-induced nausea and vomiting.