Trodelvy™ (sacituzumab govitecan-hziy) – Indication withdrawal

- On October 18, 2024, Gilead announced plans to voluntarily withdraw the accelerated approval for Trodelvy (sacituzumab govitecan-hziy) for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
    - This decision was made in consultation with the FDA.
- This decision does not affect the other approved Trodelvy indications. Trodelvy is also approved for 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
    - 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 was granted accelerated approval for mUC in 2021 based on tumor response rate and duration of response data from the single-arm TROPHY-U-01 study. Continued approval for this indication was contingent on verification and description of clinical benefit in the confirmatory TROPiCS-04 study.
    - As previously announced, the TROPiCS-04 study did not meet the primary endpoint of overall survival in the intention-to-treat population.
- Gilead will be notifying healthcare providers of this update. People receiving Trodelvy for mUC should discuss their care with their healthcare provider.