Trodelvy™ (sacituzumab govitecan-hziy) – New drug approval

- On April 22, 2020, the FDA announced the approval of Immunomedics' Trodelvy (sacituzumab govitecan-hziy), for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.
    - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- TNBC is an aggressive breast cancer that accounts for up to 20% of all breast cancer cases. TNBC is a type of breast cancer that tests negative for estrogen receptors, progesterone receptors and human epidermal growth factor receptor 2 (HER2) protein. Therefore, triple-negative breast cancer does not respond to hormonal therapy medicines or medicines that target HER2.
- Trodelvy is a Trop-2-directed antibody and topoisomerase inhibitor drug conjugate, meaning that the drug targets the Trop-2 receptor that helps the cancer grow, divide and spread, and is linked to topoisomerase inhibitor, which is a chemical compound that is toxic to cancer cells.
- The efficacy of Trodelvy was established in a single-arm study in 108 patients with mTNBC who had received at least two prior treatments for metastatic disease. Patients received Trodelvy until disease progression or intolerance to the therapy. Major efficacy outcome measures were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 33.3% (95% CI: 24.6, 43.1).
    - The median DOR was 7.7 months (95% CI: 4.9, 10.8). The percentage of patients with a response of at least 6 months or 12 months was 55.6% and 16.7%, respectively.
- Trodelvy carries a boxed warning for neutropenia and diarrhea.
- Additional warnings and precautions for Trodelvy include hypersensitivity, nausea and vomiting, use in patients with reduced UGT1A1 activity, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 25%) with Trodelvy use were nausea, neutropenia, diarrhea, fatigue, anemia, vomiting, alopecia, constipation, rash, decreased appetite, and abdominal pain.
- The recommended dose of Trodelvy is 10 mg/kg administered as an intravenous (IV) infusion once weekly on days 1 and 8 of 21-day treatment cycles. Treatment should be continued until disease progression or unacceptable toxicity.
    - Trodelvy should not be administered at doses greater than 10 mg/kg.
    - Premedication for prevention of infusion reactions and prevention of chemotherapy-induced nausea and vomiting is recommended.
    - Patients should be monitored during the infusion and for at least 30 minutes after completion of infusion.
    - Trodelvy should not be substituted for or used with other drugs containing irinotecan or its active metabolite SN-38.

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- Immunomedics plans to launch Trodelvy as soon as possible. Trodelvy will be available as a 180 mg lyophilized powder in single-dose vials for reconstitution.