Tivdak™ (tisotumab vedotin-tftv) – New drug approval

- On September 20, 2021, Seagen and Genmab announced the FDA approval of Tivdak (tisotumab vedotin-tftv), for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
    - This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- It is estimated that in 2021, more than 14,480 new cases of invasive cervical cancer will be diagnosed in the U.S., and 4,290 women will die from the disease.
- Tivdak is a first-in-class antibody-drug conjugate directed to tissue factor; a protein expressed on cervical cancer cells.
- The efficacy of Tivdak was established in innovaTV 204, an open-label, single-arm study in 101 patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens in the recurrent or metastatic setting, including at least one prior platinum-based chemotherapy regimen. Patients received Tivdak until disease progression or unacceptable toxicity. The major efficacy outcome measures were confirmed objective response rate (ORR) and duration of response (DOR).
    - The confirmed ORR was 24% (95% CI: 15.9, 33.3).
    - The median DOR was 8.3 months (95% CI: 4.2, not reached).
- Tivdak carries a boxed warning for ocular toxicity.
- Additional warnings and precautions for Tivdak include peripheral neuropathy, hemorrhage, pneumonitis, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 25%) with Tivdak use, including laboratory abnormalities, were decreased hemoglobin, fatigue, decreased lymphocytes, nausea, peripheral neuropathy, alopecia, epistaxis, conjunctival adverse reactions, hemorrhage, decreased leukocytes, increased creatinine, dry eye, increased prothrombin international normalized ratio, prolonged activated partial thromboplastin time, diarrhea, and rash.
- The recommended dose of Tivdak is 2 mg/kg (up to a maximum of 200 mg for patients ≥ 100 kg) administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.
    - Refer to the Tivdak drug label for additional information regarding premedication and required eye care.

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- Seagen and Genmab's launch plans for Tivdak are pending. Tivdak will be available as a 40 mg lyophilized cake or powder in a single-dose vial for reconstitution

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