Jemperli™ (dostarlimab) – New drug approval

- On April 22, 2021, the FDA announced the approval of GlaxoSmithKline's Jemperli (dostarlimab-gxly), for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatments with a platinum-containing regimen.
    - 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 a confirmatory trial(s).
- EC is the most common gynecologic malignancy in the U.S, with approximately 60,000 new cases expected in 2021. Currently, patients with advanced and recurrent EC have limited therapeutic options following front-line standard treatment. It is estimated that 25 to 30% of patients with advanced EC have dMMR tumors.
- Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody.
- The safety and efficacy of Jemperli was established in the GARNET study, a single-arm, open-label, multi-cohort trial in 71 patients with dMMR recurrent or advanced EC who had progressed on or after treatment with a platinum-containing therapy. Major efficacy outcome measures were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 42.3% (95% CI: 30.6, 54.6).
    - A DOR ≥ 6 months was found in 93.3% of responders.
- Warnings and precautions for Jemperli include immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic hematopoietic stem-cell transplantation after PD-1/PD-L1–blocking antibody, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Jemperli use were fatigue/asthenia, nausea, diarrhea, anemia, and constipation.
- The recommended dose of Jemperli is 500 mg every 3 weeks for the first 4 doses. Subsequent dosing should begin 3 weeks after Dose 4 and is 1,000 mg every 6 weeks (Dose 5 onwards). Jemperli should be administered as an intravenous infusion over 30 minutes.
    - Refer to the Jemperli drug label for complete dosing and administration recommendations.
- GlaxoSmithKline's launch plans for Jemperli are pending. Jemperli is available as a 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.