Jemperli (dostarlimab-gxly) – New indication

- On August 17, 2021, GlaxoSmithKline announced the FDA approval of Jemperli (dostarlimab-gxly), for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

- Jemperli is also approved for the for the treatment of adult patients with dMMR recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.

- Both of Jemperli's indications are approved under accelerated approval based on tumor response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

- The approval of Jemperli for the new indication was based on GARNET, a non-randomized, open-label, multicohort study. The efficacy population consisted of a cohort of 209 patients with dMMR recurrent or advanced solid tumors who progressed following systemic therapy and had no satisfactory alternative treatment options. The major efficacy outcome measures were overall response rate (ORR) and duration of response (DOR).

    — The ORR was 41.6% (95% CI: 34.9, 48.6).
    — The median DOR was 34.7 months (range: 2.6, 35.8+).

- The recommended dose of Jemperli for both of its indications is:

    — Dose 1 through Dose 4: 500 mg every 3 weeks
    — Subsequent dosing beginning 3 weeks after Dose 4 (Dose 5 onwards): 1,000 mg every 6 week
    — Jemperli should be administered as an intravenous infusion over 30 minutes. Patients should be treated until disease progression or unacceptable toxicity.

- Patients should be selected for treatment with Jemperli based on the presence of dMMR in tumor specimens. Information on FDA-approved tests for the detection of dMMR status is available at https://www.fda.gov/companiondiagnostics.