## Jemperli (dostarlimab-gxly) – Updated indication

- On February 10, 2023, GSK announced that the FDA granted **full approval** to Jemperli (dostarlimab-gxly), for the treatment of adult patients with mismatch repair deficient (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 in any setting and are not candidates for curative surgery or radiation.
    - Jemperli previously received accelerated approval for the treatment of adult patients with dMMR recurrent or advanced endometrial cancer that had progressed on or following prior treatment with a platinum-containing regimen.
- Jemperli is also approved for the treatment of adult patients with 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.
    - This indication remains an accelerated approval.
- The full approval for Jemperli is based on additional data collected from the A1 expansion cohort of the ongoing GARNET trial, a phase 1, open-label, single-arm study in 141 patients with dMMR advanced or recurrent endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen. The major outcome measures were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 45.4% (95% CI: 37.0, 54.0).
    - The median DOR was not reached (range: 1.2+, 52.8+ months).
- The recommended dosage of Jemperli 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 weeks
    - Jemperli is administered as an intravenous infusion over 30 minutes. Patients are treated until disease progression or unacceptable toxicity.