Jemperli (dostarlimab-gxly) – Expanded indication

- On August 1, 2024, GSK announced the FDA approval of Jemperli (dostarlimab-gxly), in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC).
    - Jemperli was previously approved for this indication in patients with EC that is mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H).
    - This approval broadens the previous indication for Jemperli plus chemotherapy to include patients with mismatch repair proficient (MMRp)/microsatellite stable (MSS) tumors.
- Jemperli is also approved as a single agent for the treatment of:
    - Adult patients with dMMR recurrent or advanced EC, 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.
    - 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.
- The approval of Jemperli for the expanded indication was based on RUBY, a randomized, double-blind, placebo-controlled study in 494 patients with primary advanced or recurrent EC. Patients were randomized to Jemperli plus carboplatin-paclitaxel followed by Jemperli or carboplatin-paclitaxel plus placebo followed by placebo. The major efficacy outcomes were overall survival (OS) and progression-free survival (PFS).
    - In the overall population, median OS was 44.6 months in the Jemperli arm vs. 28.2 months in the placebo arm (hazard ratio [HR] 0.69, 95% CI: 0.54, 0.89; $p = 0.002$). Median PFS was 11.8 months and 7.9 months, respectively (HR 0.64, 95% CI: 0.51, 0.80; $p < 0.0001$).
    - In patients with MMRp/MSS EC (n = 372), the OS HR was 0.82 (95% CI: 0.62, 1.08) with a median OS of 32.5 months in the Jemperli arm vs. 28.2 months in the placebo arm. The PFS HR was 0.78 (95% CI: 0.60, 1.00) with a median PFS of 9.8 months vs. 7.9 months, respectively.
- The recommended dose of Jemperli for the treatment of adults with primary advanced or recurrent EC is 500 mg every 3 weeks for 6 cycles in combination with carboplatin and paclitaxel followed by 1,000 mg Jemperli as monotherapy every 6 weeks for all cycles thereafter. Treatment should be continued until disease progression, unacceptable toxicity, or up to 3 years.
    - Refer to the Jemperli drug label for dosing for its other indications.