Jemperli® (dostarlimab-gxly) – New indication

- On July 31, 2023, the FDA announced the approval of GSK's 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 that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).

- Jemperli is also approved:

    - As a single agent 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 in any setting and are not candidates for curative surgery or radiation
    - As a single agent 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.

- The approval of Jemperli for the new indication was based on RUBY, a randomized, double-blind, placebo-controlled study in a pre-specified subgroup of 122 patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer. Patients were randomized to receive (1) Jemperli, carboplatin and paclitaxel followed by Jemperli, or (2) placebo, carboplatin and paclitaxel followed by placebo. Treatment with Jemperli continued until disease progression, unacceptable toxicity, or a maximum of 3 years. In the dMMR/MSI-H subgroup, the major efficacy outcome was progression-free survival (PFS). Additional efficacy outcome measures included overall survival (OS), objective response rate (ORR), and duration of response (DOR).

    - The PFS in the Jemperli-treated group was 30.3 months vs. 7.7 months in the placebo-treated group (Hazard ratio 0.29; 95% CI: 0.17, 0.50; $p < 0.0001$).
    - The ORR was 73.8% in the Jemperli-treated group vs. 62.2% in the placebo-treated group.
    - The median DOR was not reached (range: 3.4, 28.3+) in the Jemperli-treated group vs. 5.4 months (range: 2.7, 27.2+) in the placebo-treated group.
    - Overall survival data in the subpopulation were immature with 27% deaths.

- The most common adverse reactions (≥ 20%) with Jemperli use in combination with carboplatin and paclitaxel in patients with dMMR/MSI-H endometrial cancer were rash, diarrhea, hypothyroidism, and hypertension. The most common grade 3 or 4 laboratory abnormalities (≥ 10%) were decreased neutrophils, decreased hemoglobin, decreased white blood cell count, decreased lymphocytes, increased glucose, decreased sodium, and decreased platelets.

- The recommended dose of Jemperli for the treatment of the new indication is 500 mg every 3 weeks for 6 doses (the first 6 doses are administered in combination with carboplatin and paclitaxel) followed by 1,000 mg monotherapy every 6 weeks.

    - Jemperli should be administered prior to carboplatin and paclitaxel when given on the same day.
    - Jemperli should be administered until disease progression, unacceptable toxicity, or up to 3 years.

Continued . . .

- Refer to the carboplatin and paclitaxel drug labels for dosing and administration information.
- Refer to the Jemperli drug label for dosing for all its other indications.