Jemperli (dostarlimab) Injection 500 mg

GSK

JEMPERLI is supported by efficacy and safety data in the largest single-agent anti-PD-1 immunotherapy trial in dMMR/MSI-H EC to date[1-3]

Proven efficacy in dMMR/MSI-H EC patients[2]*

- Objective Response Rate (ORR) 45.5% (95% CI: 37.1-54.0)
- Disease Control Rate (DCR) 60.1% (95% CI: 51.6-68.2)

Sustained Benefit[2]*

- Durable response - mDOR not reached at 27.6 months follow up

Manageable safety profile[1,2]

- 8.5% discontinuation rate due to TRAEs[2]*

JEMPERLI is indicated as monotherapy for the treatment of adult patients with recurrent or advanced mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.[1]

JEMPERLI Succinct Safety Information

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings & Precautions: Immune related adverse events can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI. These immune-mediated adverse reactions can be severe or fatal, can occur in any organ system or tissue or may affect more than one body system simultaneously and may include the following: Immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies (hypothyroidism, hyperthyroidism and adrenal insufficiency), immune-mediated nephritis with renal dysfunction, immune-related rash and solid organ transplant rejection. For suspected immune-related adverse reactions, adequate evaluation including specialty consultation should be ensured. Withhold or permanently discontinue JEMPERLI and administer corticosteroids or other appropriate therapy administered based on the severity of reaction. Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation before or after being treated with a PD-1/PD-L1–blocking antibody.

Pregnancy: Not recommended for use during pregnancy and in women of childbearing potential not using contraception. **Lactation:** Not recommended during breast-feeding and breastfeeding should be avoided for at least 4 months after the last dose of dostarlimab.

Adverse Reactions: Very common adverse reactions occurring in > 10% of patients were anaemia, nausea, diarrhoea, vomiting, arthralgia, pruritus, rash, pyrexia, hypothyroidism and transaminases increased.

Please refer to full prescribing information for more details.

Abbreviations:
dMMR=mismatch repair deficient; CI=confidence interval; EC=endometrial cancer; mDOR=median duration of response; MSI-H= microsatellite instability-high; TRAEs=treatment-related adverse events

*GARNET was a multicentre, uncontrolled, open-label study. Patients received doses of 500 mg every 3 weeks for 4 cycles followed by 1,000 mg every 6 weeks for all cycles thereafter. ORR, DOR, and DCR analysis included 143 patients with dMMR/MSI-H EC and 27.6 months median follow up. The safety of JEMPERLI for recurent/advanced dMMR-MSI-H endometrial cancer has been evaluated in 153 patients who received JEMPERLI monotherapy in the GARNET study.[2]

References:
1. JEMPERLI (dostarlimab) Singapore Prescribing Information.
2. Oaknin A, et al. Dostarlimab in advanced/recurrent mismatch repair deficient/microsatellite instability-high or proficient/stable endometrial cancer: the GARNET study. Presented at:2022 ASCO Annual Meeting; 3-7 June 2022; Chicago, IL, USA.
3. Oaknin A, Tinker AV, Gilbert L, et al. Clinical activity and safety of the anti-programmed death 1 monoclonal antibody dostarlimab for patients with recurrent or advanced mismatch repair-deficient endometrial cancer: a nonrandomized Phase 1 clinical trial. JAMA Oncol. 2020;13(16):1766-1772.

Scan for full Prescribing Information

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Veeva Vault

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Document Name: SG JEMPERLI Pull Up Banner (2)

Country: Singapore

Product: JEMPERLI

Type: Promotional Material

Role	Signature
Octavia Chong - Medical (octavia.x.chong@gsk.com)	It is approved that this material has been examined and is believed to be in accordance with the relevant Code of Practice and any other relevant regulations, policies and SOPs. Date: 14-Apr-2023 04:30:39 GMT+0000
Clara Chia Xin Ying (clara.x.chiaxinying@gsk.com), cc952884, on behalf of Juli Teng - Final Form Inspection (juli.p.teng@gsk.com)	I hereby certify that the final form of this digital or hard copy material has been inspected and is approved for use Date: 17-Apr-2023 01:29:43 GMT+0000