Jemperli (dostarlimab-gxly) Injection 500 mg

Let their light *Shine* with JEMPERLI

The first immunotherapy approved in combination with carboplatin and paclitaxel to treat dMMR/MSI-H primary advanced or recurrent endometrial cancer.[1]

Not an actual patient.

dMMR=mismatch repair deficient; MSI-H=microsatellite instability-high.

INDICATIONS

- JEMPERLI, in combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).
- JEMPERLI, as a single agent, is indicated 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.

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see additional Important Safety Information throughout, as well as full Prescribing Information, also available at JEMPERLIHCP.com.

The RUBY Trial Had a Major Efficacy Outcome of PFS* With Additional Efficacy Outcomes of OS, ORR, and DOR[1,2]

Randomization was stratified by MMR/MSI status, prior external pelvic radiotherapy, and disease status (recurrent, primary Stage III, or primary Stage IV).[1]

*Assessed by the investigator according to RECIST v 1.1.[1]

†In RUBY, 494 patients underwent randomization to each treatment arm. The safety profile was evaluated in the 241 patients who were randomized to JEMPERLI + CP with primary advanced or recurrent endometrial cancer (EC). The safety data presented on page 6 reflects exposure to JEMPERLI in 52 patients with dMMR/MSI-H primary advanced or recurrent EC.[1,2]

‡JEMPERLI was administered prior to chemotherapy on Day 1 of each 21-Day cycle. Treatment with JEMPERLI continued until disease progression, unacceptable toxicity, or a maximum of 3 years.[1,2]

AUC=area under the curve; CP=carboplatin-paclitaxel; DOR=duration of response; IV=intravenous; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; Q3W=every 3 weeks; Q6W=every 6 weeks; RECIST=Response Evaluation Criteria in Solid Tumors.

IMPORTANT SAFETY INFORMATION (CONT'D)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

- Based on the severity of the adverse reaction, withhold or permanently discontinue JEMPERLI. In general, if JEMPERLI requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

- JEMPERLI can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Pneumonitis occurred in 2.3% (14/605) of patients, including Grade 2 (1.3%), Grade 3 (0.8%), and Grade 4 (0.2%) pneumonitis.

Immune-Mediated Colitis

- Colitis occurred in 1.3% (8/605) of patients, including Grade 2 (0.7%) and Grade 3 (0.7%) adverse reactions. Cytomegalovirus infection/reactivation have occurred in patients with corticosteroid-refractory immune-mediated colitis. In such cases, consider repeating infectious workup to exclude alternative etiologies.

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Groundbreaking 71% Reduction in the Risk of Progression or Death vs CP Alone[1]

Superior PFS With JEMPERLI + CP vs CP Alone in the dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer Patient Population (n=122)[1]

# at Risk																	
JEMPERLI + CP	60	55	52	43	38	34	32	31	30	28	26	20	14	10	10	5	1	0
Placebo + CP	62	54	51	34	25	13	11	11	9	6	6	5	3	2	2	1	0	

30.3 Months Median PFS† with JEMPERLI + CP

(95% CI: 11.8, NR) vs 7.7 months with CP alone (95% CI: 5.6, 9.7)

Overall Survival Data in the dMMR/MSI-H Subgroup Were Immature With 27% Deaths[1‡]

- HR=0.29 (95% CI: 0.13, 0.64)[3]*
- OS was a prespecified exploratory analysis in the dMMR/MSI-H subgroup with no planned hypothesis testing, and no conclusions can be drawn from this analysis[1]
- OS continues to be evaluated in the dMMR/MSI-H subgroup[1]

*Based on stratified Cox regression model.[1]
†One-sided *P*-value based on stratified log-rank test was statistically significant.[1]
‡OS in the dMMR/MSI-H subgroup was not powered to demonstrate statistically significant differences.[1,3]
Median follow-up time was 25 months.[2]
CI=confidence interval; CP=carboplatin-paclitaxel; HR=hazard ratio; NR=not reached.

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Hepatitis

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.5% (3/605) of patients.

Immune-Mediated Endocrinopathies

- Adrenal Insufficiency
  - Adrenal insufficiency occurred in 1.2% (7/605) of patients, including Grade 2 (0.5%) and Grade 3 (0.7%). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

Immune-Mediated Endocrinopathies (cont'd)

- Hypophysitis
  - JEMPERLI can cause immune-mediated hypophysitis. Grade 3 hypophysitis occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypophysitis occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

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73.8% Objective Response Rate With JEMPERLI + CP After >2 Years of Follow-up[1,2]

Objective Response Rate (ORR)*

~1 Out of 3

Patients Who Responded Achieved a Complete Response With JEMPERLI + CP (n=11/31)[1]

CP Alone:
Patients on CP alone achieved a 62.2% ORR (n=28/45, 95% CI: 46.5, 76.2) with 11.1% CR (n=5/45) and 51.1% PR (n=23/45).[1]

*Confirmed responses as assessed by investigator according to RECIST v1.1.[1]
Median follow-up time was 25 months.[2]
CP=carboplatin-paclitaxel; CR=complete response; PR=partial response.

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Endocrinopathies (cont'd)

- Thyroid Disorders
  - Grade 2 thyroiditis occurred in 0.5% (3/605) of patients. Grade 2 hypothyroidism occurred in 12% (28/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypothyroidism occurred in 8% (46/605) of patients receiving JEMPERLI as a single agent. Hyperthyroidism occurred in 3.3% (8/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel, including Grade 2 (2.9%) and Grade 3 (0.4%). Hyperthyroidism occurred in 2.3% (14/605) of patients receiving JEMPERLI as a single agent, including Grade 2 (2.1%) and Grade 3 (0.2%). Initiate thyroid hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

Immune-Mediated Endocrinopathies (cont'd)

- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis
  - JEMPERLI can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Grade 3 type 1 diabetes mellitus occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 3 type 1 diabetes mellitus occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

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Duration of Response With JEMPERLI + CP After >2 Years of Follow-up[2*†]

61.3% (n=19/31) of Responders Had a DOR >1 Year[1]

Over half of responders on JEMPERLI + CP had a DOR greater than 1 year compared with 14.3% (n=4/28) of patients on CP alone; 25 months median follow-up time.[1,2]

Median DOR Was Not Reached at 2 Years[1,2]

(95% CI: 3.4, 28.3+) after 25 months median follow-up with JEMPERLI + CP compared with median DOR of 5.4 months (95% CI: 2.7, 27.2+) with CP alone.[1,2]

*Confirmed responses as assessed by investigator according to RECIST v1.1.
† For patients with a partial or complete response.[1]

Estimated Probability of Patients Remaining in Response at 2 Years[3‡]

# at Risk (# of Events)																
JEMPERLI + CP	31 (0)	31 (0)	30 (1)	24 (7)	22 (8)	21 (9)	19 (11)	19 (11)	17 (12)	16 (12)	12 (12)	9 (12)	9 (12)	2 (12)	1 (12)	0 (12)
Placebo + CP	28 (0)	28 (0)	18 (10)	13 (15)	8 (19)	6 (21)	4 (23)	2 (25)	1 (26)	1 (26)	1 (26)	1 (26)	1 (26)	1 (26)	0 (26)	

‡Probability of response estimated from Kaplan-Meier curves with a median follow-up of 25 months.[2,3]
CP=carboplatin-paclitaxel; NR=not reached.

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Nephritis with Renal Dysfunction

- JEMPERLI can cause immune-mediated nephritis, which can be fatal. Grade 2 nephritis, including tubulointerstitial nephritis, occurred in 0.5% (3/605) of patients.

Immune-Mediated Dermatologic Adverse Reactions

- JEMPERLI can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies.

Immune-Mediated Dermatologic Adverse Reactions (cont'd)

Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue JEMPERLI depending on severity.

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Established Safety Profile With Over 2 Years of Efficacy Follow-up[1,2]

Adverse Reactions (≥10%) in Patients With dMMR/MSI-H Endometrial Cancer Who Received JEMPERLI + CP in RUBY[1]

Adverse Reaction	JEMPERLI + CP (N=52)		Placebo + CP (N=65)	
	All Grades %	Grade 3 or 4 %	All Grades %	Grade 3 or 4 %
Skin & Subcutaneous Tissue				
Rash*	42	8	20	0
Dry skin	12	0	8	0
Gastrointestinal Disorders				
Diarrhea	40	1.9	31	0
Endocrine Disorders				
Hypothyroidism†	23	0	6	0
Vascular Disorders				
Hypertension	21	10	11	6
General & Administration Site				
Pyrexia	14	0	1.5	0

Graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03.
*Includes rash, rash maculo-papular, palmar-plantar erythrodysesthesia syndrome, rash pustular, skin exfoliation, vulvovaginal rash, and dermatitis bullous.
†Includes hypothyroidism and immune-mediated hypothyroidism.

- Adverse reactions leading to discontinuation of JEMPERLI included rash maculo-papular, fatigue, general physical health deterioration, acute kidney injury, infusion-related reaction, keratitis, muscular weakness, and myelosuppression (8 patients total)[1]
- The most common adverse reactions, including laboratory abnormalities (≥20%), were decreased hemoglobin, decreased white blood cell count, decreased platelets, decreased lymphocytes, increased glucose, increased alkaline phosphatase, decreased neutrophils, rash, diarrhea, increased aspartate aminotransferase, increased alanine aminotransferase, decreased sodium, hypothyroidism, and hypertension[1]
- Serious adverse reactions occurred in 13% of patients receiving JEMPERLI + CP; the most common serious adverse reaction was sepsis, including urosepsis (6%)[1]
- Fatal adverse reactions occurred in 6% of patients receiving JEMPERLI including septic shock (3.8%) and myelosuppression (1.9%)[1]

In patients receiving JEMPERLI + CP
15% (n=8) of Patients
permanently discontinued JEMPERLI due to adverse reactions[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 605 patients treated with JEMPERLI or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Other Immune-Mediated Adverse Reactions (cont'd)

- *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy

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JEMPERLI + CP Dosing Established in the RUBY Trial

Deliver a Proven Combination Up Front, Then Continue With Single-Agent Immunotherapy[1]

- The Q3W dosing schedule allows for more frequent patient monitoring during the 6-cycle treatment initiation phase
- The number of infusion visits is reduced after transitioning to the Q6W monotherapy phase
  - Additional monitoring may be required per clinical discretion
- JEMPERLI provides sustained target engagement as measured by direct PD-1 binding and stimulation of IL-2 production throughout the dosing interval at the recommended dose

Recommended Dosage of JEMPERLI in dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer[1]

*30-minute intravenous infusion.
†First 6 doses are administered in combination with carboplatin and paclitaxel. Refer to the Prescribing Information for the agents administered in combination with JEMPERLI, as appropriate.
‡Administer JEMPERLI prior to carboplatin and paclitaxel when given on the same day.
CP=carboplatin-paclitaxel; IL-2=interleukin 2; IV=intravenous; PD-1=programmed death receptor 1.

IMPORTANT SAFETY INFORMATION (CONT'D)

Other Immune-Mediated Adverse Reactions (cont'd)

- *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis
- *Ocular*: Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur
- *Gastrointestinal*: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis
- *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

Other Immune-Mediated Adverse Reactions (cont'd)

- *Endocrine*: Hypoparathyroidism
- *Other (Hematologic/Immune)*: Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection

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See Patient Types With dMMR/MSI-H Status Who May Benefit From JEMPERLI + CP

For dMMR/MSI-H Primary Advanced Endometrial Cancer, JEMPERLI + CP May Help From the Start[1,2]

"I was so scared when I was diagnosed with stage III advanced endometrial cancer. *But my doctor let me know that I could start treatment with JEMPERLI plus carboplatin and paclitaxel that has been proven to work in people with biomarker status like mine."**

– Penny, 66

Preoperative Diagnosis on Endometrial Biopsy
Grade 3 endometrial cancer

Preoperative Imaging
PET/CT consistent with pelvic node metastasis

Prior Interventions
Minimal invasive total hysterectomy with bilateral salpingo-oophorectomy and surgical staging

FIGO Staging/Histology After Surgical Pathological Evaluation
Stage IIIC1 carcinosarcoma

Biomarkers
dMMR/MSI-H status confirmed following hysterectomy

Performance Status
ECOG 1 at baseline

Initial Systemic Therapy Recommendation
JEMPERLI (dostarlimab-gxly) + CP

***Not an actual patient.**
Based on patients treated in the RUBY trial.

CP=carboplatin-paclitaxel; CT=computed tomography; ECOG=Eastern Cooperative Oncology Group; FIGO=International Federation of Gynecology and Obstetrics; PET=positron emission tomography.

IMPORTANT SAFETY INFORMATION (CONT'D)

Infusion-Related Reactions

- Severe or life-threatening infusion-related reactions have been reported with PD-1/PD-L1–blocking antibodies. Severe infusion-related reactions (Grade 3) occurred in 0.2% (1/605) of patients receiving JEMPERLI. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue JEMPERLI based on severity of reaction.

Complications of Allogeneic HSCT

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after treatment with a PD-1/PD-L1–blocking antibody, which may occur despite intervening therapy. Monitor patients closely for transplant-related complications and intervene promptly.

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See Patient Types With dMMR/MSI-H Status Who May Benefit From JEMPERLI + CP

JEMPERLI + CP May Help When dMMR/MSI-H Endometrial Cancer Comes Back[1]

*"**After chemoradiation, I thought I was in the clear.** When my cancer came back more aggressively, my doctor knew it was time to try a different approach."**

– Rebecca, 61

Preoperative Diagnosis on Endometrial Biopsy
Grade 3 endometrioid cancer

Prior Interventions
Total hysterectomy bilateral salpingo-oophorectomy and surgical staging (at initial diagnosis)

FIGO Staging/Histology After Surgical Pathological Evaluation
Stage II endometrial cancer, grade 3 endometrioid with lymphatic space involvement and outer third tumor spread

Adjuvant Treatment
Cisplatin with external beam radiotherapy followed by carboplatin and paclitaxel

Follow-Up Imaging (7 Months Following Completion of Treatment)
CT at 7 months confirmed recurrent disease with metastases to lung and liver indicating low potential for cure by surgery and/or radiation

Biomarkers
MSI-H status confirmed at 7 months, following biopsy of recurrent tumor

Performance Status
ECOG 1 at baseline

Systemic Therapy Recommendation
JEMPERLI (dostarlimab-gxly) + CP

CP=carboplatin-paclitaxel.

***Not an actual patient. Based on patients treated in the RUBY trial.**

IMPORTANT SAFETY INFORMATION (CONT'D)

Embryo-Fetal Toxicity and Lactation

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in breastfed child, advise women not to breastfeed during treatment with JEMPERLI and for 4 months after their last dose.

Common Adverse Reactions

The most common adverse reactions (≥20%) in patients with dMMR/MSI-H EC who received JEMPERLI in combination with carboplatin and paclitaxel were rash, diarrhea, hypothyroidism, and hypertension.

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Treatment for Patients With dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

Groundbreaking PFS and Established Safety Profile With JEMPERLI + CP[1]

Robust Trial Design

- Major efficacy outcome measure was PFS and additional efficacy outcome measures included OS, ORR, and DOR in the dMMR/MSI-H endometrial cancer subgroup[1]
- Trial included patients with broad disease characteristics and those with aggressive histologies[1]

>2 Years of Follow-Up

- 25 months median efficacy follow-up in the RUBY trial[2]

Durable PFS

- 71% reduction in the risk of progression or death (HR=0.29; 95% CI: 0.17, 0.50*; *P*<0.0001†)[1]
- 30.3 months median PFS† with JEMPERLI + CP (95% CI: 11.8, NR) vs 7.7 months with CP alone (95% CI: 5.6, 9.7)[1]

Established Safety Profile

- The safety profile of JEMPERLI + CP was established with over 2 years of efficacy follow-up in the RUBY trial[1,2]
- Most common adverse reactions (≥20%) with JEMPERLI + CP in patients with dMMR/MSI-H EC are rash, diarrhea, hypothyroidism, and hypertension[1]

*Based on stratified Cox regression model.
†One-sided *P*-value based on stratified log-rank test was statistically significant.
CP=carboplatin-paclitaxel.

IMPORTANT SAFETY INFORMATION (CONT'D)

Common Adverse Reactions (cont'd)

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 most common adverse reactions (≥20%) in patients with dMMR EC who received JEMPERLI as a single agent were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash.

Common Adverse Reactions (cont'd)

The most common Grade 3 or 4 laboratory abnormalities (>2%) were decreased lymphocytes, decreased sodium, increased alanine aminotransferase, increased creatinine, decreased neutrophils, decreased albumin, and increased alkaline phosphatase.

Please see full Prescribing Information, also available at JEMPERLIHCP.com.

References:
1. JEMPERLI. Prescribing information. GSK; 2023.
2. Mirza MR, et al. *N Engl J Med.* 2023;388(23):2145-2158.
3. Data on file, GSK.

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