Jemperli
(dostarlimab-gxly) Injection 500 mg

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, or
  - 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 is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

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, including Medication Guide.

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dMMR=mismatch repair deficient; MSI-H=microsatellite instability-high; NCCN=National Comprehensive Cancer Network.

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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

For Dostarlimab-gxly (JEMPERLI) + CP[2]

Dostarlimab-gxly (JEMPERLI) in combination with carboplatin-paclitaxel is included in the NCCN Guidelines® as a Category 1 preferred treatment option for primary or adjuvant therapy for stage III-IV* dMMR/MSI-H endometrial carcinoma or as a first-line therapy option for dMMR/MSI-H recurrent disease.[2†]

Category 1—Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

*For stage IIIA, IIIB, or IIIC1 with measurable disease, stage IIIC1 with carcinosarcoma, clear-cell, serous, or mixed histology regardless of the presence of measurable disease, and stage IIIC2 or stage IV regardless of the presence of measurable disease.
†As of November 2023.

For Dostarlimab-gxly (JEMPERLI) Monotherapy[2]

NCCN Guidelines recommend dostarlimab-gxly (JEMPERLI) as a treatment option for patients with dMMR recurrent or advanced endometrial carcinoma that has progressed on or following prior treatment with a platinum-containing regimen.[2]

All recommendations are Category 2A unless otherwise indicated.

Category 2A—Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

IMPORTANT SAFETY INFORMATION (cont'd)

Immune-Mediated Pneumonitis (cont'd)

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.

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%).

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

For Dostarlimab-gxly (JEMPERLI) Monotherapy (cont'd)[2-12]

NCCN Guidelines recommend dostarlimab-gxly (JEMPERLI) as a subsequent-line systemic treatment option for certain patients with dMMR recurrent or advanced*†‡:

- Colon cancer
- Rectal cancer
- Small bowel adenocarcinoma
- Gastric cancer
- Hepatocellular carcinoma§
- Biliary tract cancers§
- Uterine neoplasms
- Ovarian cancer
- Breast cancer
- Occult primary cancers
- Esophageal and esophagogastric junction cancers

*As of November 2023.
†All recommendations are Category 2A unless otherwise indicated.
‡NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way. To view the most recent and complete version of the guidelines, go online to NCCN.org.
§Category 2B recommendation.

Category 2A—Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B—Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

IMPORTANT SAFETY INFORMATION (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- Adrenal Insufficiency (cont'd)

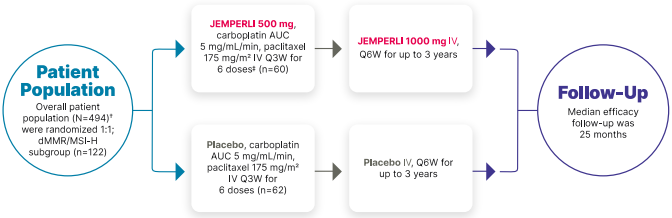
  For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Hypophysitis
  - JEMPERLI can cause immune-mediated hypophysitis. Grade 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.
- 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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

The RUBY Trial Had a Major Efficacy Outcome of PFS* With Additional Efficacy Outcomes of OS, ORR, and DOR[1,13]



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 v1.1.[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 in the RUBY safety section reflects exposure to JEMPERLI in 52 patients with dMMR/MSI-H primary advanced or recurrent EC.[1,13]
‡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.[1,13]

AUC=area under the curve; CP=carboplatin + paclitaxel; dMMR=mismatch repair deficient; DOR=duration of response; IV=intravenous; MMR=mismatch repair; MSI=microsatellite instability; MSI-H=microsatellite instability-high; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; Q3W=every 3 weeks; Q6W=every 6 weeks; RECIST v1.1=Response Evaluation Criteria in Solid Tumors v1.1.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

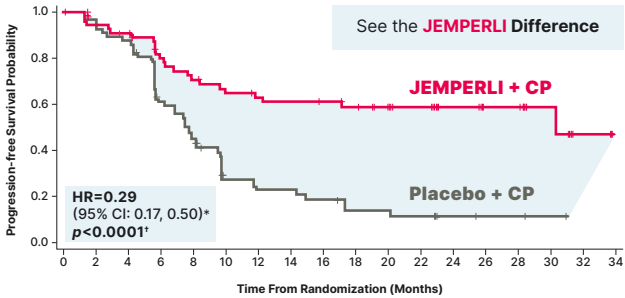
Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

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)[1]**

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

- HR=0.29 (95% CI: 0.13, 0.64)[14]*
- 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[13]
- OS continues to be evaluated in the dMMR/MSI-H subgroup[13]

*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.[13]

Median follow-up time was 25 months.[13]

CI=confidence interval; CP=carboplatin + paclitaxel; dMMR=mismatch repair deficient; HR=hazard ratio; MSI-H=microsatellite instability-high; NR=not reached; PFS=progression-free survival.

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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

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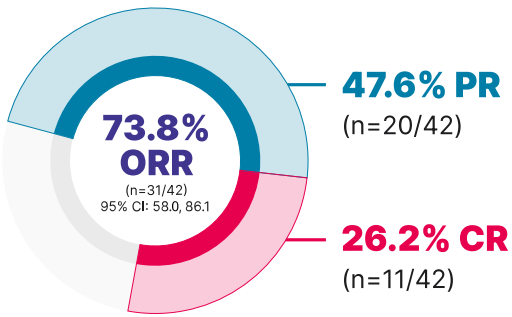
dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

73.8% Objective Response Rate With JEMPERLI + CP After >2 Years of Follow-up[1,13]

~1 Out of 3

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

Objective Response Rate (ORR)[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.[13]

CI=confidence interval; CP=carboplatin + paclitaxel; CR=complete response; dMMR=mismatch repair deficient; MSI-H=microsatellite instability-high; PR=partial response; RECIST v1.1=Response Evaluation Criteria in Solid Tumors v1.1.

IMPORTANT SAFETY INFORMATION (cont'd)

Immune-Mediated Dermatologic Adverse Reactions (cont'd)

- 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. 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.

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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

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dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

Duration of Response With JEMPERLI + CP After >2 Years of Follow-up[1,13*†]

61.3% (n=19/31) of Responders in the JEMPERLI + CP Arm Had a DOR >1 Year[1,13]

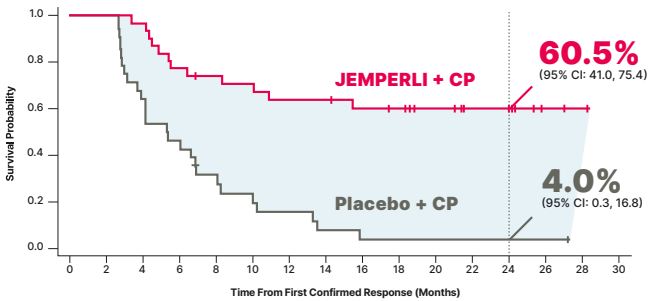
compared with 14.3% (n=4/28) of patients on CP alone; 25 months median follow-up time.

Median DOR Was Not Reached at 2 Years[1,13]

(range: 3.4, 28.3+) after 25 months median follow-up with JEMPERLI + CP compared with median DOR of 5.4 months (range: 2.7, 27.2+) with CP alone.

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

Estimated Probability of Patients Remaining in Response at 2 Years[14‡]



# 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.[13,14]

CI=confidence interval; CP=carboplatin + paclitaxel; dMMR=mismatch repair deficient; DOR=duration of response; MSI-H=microsatellite instability-high; RECIST v1.1=Response Evaluation Criteria in Solid Tumors v1.1, +=ongoing at last assessment.

IMPORTANT SAFETY INFORMATION (cont'd)

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
- *Cardiac/Vascular:* Myocarditis, pericarditis, vasculitis

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

Established Safety Profile With Over 2 Years of Efficacy Follow-up[1,13]

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.

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

- 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]

CP=carboplatin + paclitaxel; dMMR=mismatch repair deficient; MSI-H=microsatellite instability-high.

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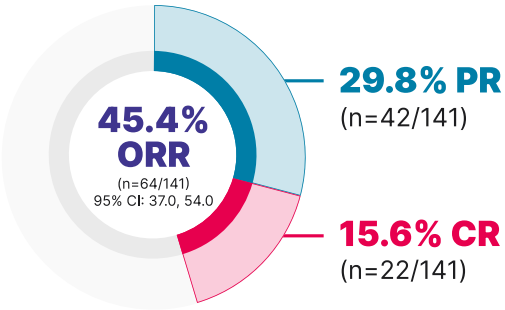
Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR Recurrent or Advanced Endometrial Cancer
Overall Response Rate

JEMPERLI Established Efficacy Over ≥2 Years of Follow-up[1]

Proven Efficacy at Median Follow-up of 27.9 Months[1]*

Overall Response Rate (ORR)



Over One-Third

Of Those Who Responded to JEMPERLI Achieved A Complete Response (n=22/64)[1]

The efficacy of JEMPERLI was investigated in a global, multicenter, multiple cohort, open-label study of 141 patients with dMMR recurrent or advanced endometrial cancer who had progressed on or after treatment with a platinum-containing regimen. Patients received JEMPERLI 500 mg via intravenous infusion every 3 weeks for 4 doses followed by 1000 mg every 6 weeks until disease progression or unacceptable toxicity.[1]

The major efficacy outcome measures were ORR and DOR as assessed by a BICR according to RECIST v1.1.[1]

The efficacy population included patients who had measurable disease at baseline and who enrolled on or before June 1, 2021. Data cutoff date was November 1, 2021.[15]

*Measured from time of first response.[1]

BICR=blinded independent central review; CI=confidence interval; CR=complete response; dMMR=mismatch repair deficient; DOR=duration of response; PR=partial response; RECIST v1.1=Response Evaluation Criteria in Solid Tumors v1.1.

IMPORTANT SAFETY INFORMATION (cont'd)

Other Immune-Mediated Adverse Reactions (cont'd)

- *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

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR Recurrent or Advanced Endometrial Cancer
Duration of Response

JEMPERLI Has Shown Durable Response Over ≥2 Years of Follow-up[1]

At 27.9 months median follow-up,* median duration of response was not reached[1]

85.9% of Responding Patients
demonstrated a duration of response ≥1 year*

54.7% of Responding Patients
demonstrated a duration of response >2 years*

*Measured from time of first response.[1]

dMMR=mismatch repair deficient.

IMPORTANT SAFETY INFORMATION (cont'd)

Other Immune-Mediated Adverse Reactions (cont'd)

- *Musculoskeletal and Connective Tissue:* Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
- *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, other transplant (including corneal graft) rejection.

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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR Recurrent or Advanced Endometrial Cancer
Safety Outcomes for JEMPERLI Monotherapy

Safety Profile Established Over More Than 2 Years[1]

The safety of JEMPERLI was evaluated in GARNET in 150 patients with dMMR recurrent or advanced EC who received at least 1 dose of JEMPERLI.[1]

10% of patients permanently discontinued therapy due to adverse reactions[1]

- Adverse reactions leading to discontinuation were increased transaminases, sepsis, bronchitis, pneumonitis, rash, pruritus, pancreatitis, encephalitis, and nephritis (15 patients total)[1]
- The most common adverse reactions (≥20%) were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash[1]
- Serious adverse reactions occurred in 38% of patients receiving JEMPERLI, including (>2% of patients) urinary tract infection (4%), sepsis (3.3%), acute kidney injury (2.7%), and abdominal pain (2.7%)[1]
- A fatal adverse reaction occurred in one patient (0.7%) who received JEMPERLI, due to concurrent immune-mediated encephalitis and urinary tract infection[1]

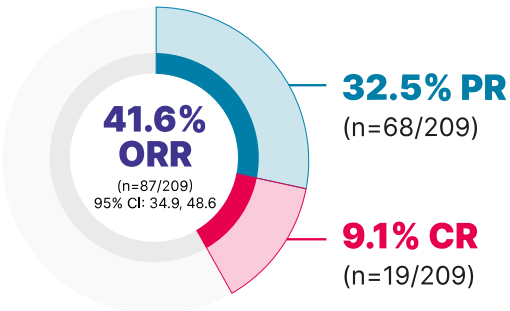
dMMR=mismatch repair deficient; EC=endometrial cancer.

dMMR Recurrent or Advanced Solid Tumors
Overall Response Rate

JEMPERLI Demonstrated Efficacy Across dMMR Recurrent or Advanced Solid Tumors[1]

Median follow-up for duration of response was 17.5 months measured from time of first response.[1]

Overall Response Rate (n=209)



The efficacy of JEMPERLI was investigated in a global, nonrandomized, multicenter, multiple cohort, open-label study of 209 patients with dMMR recurrent or advanced solid tumors who had progressed following systemic therapy and had no satisfactory alternative treatment options.* Patients received JEMPERLI 500 mg via intravenous infusion every 3 weeks for 4 doses followed by 1000 mg every 6 weeks until disease progression or unacceptable toxicity.[1]

The major efficacy outcome measures were ORR and DOR as determined by a BICR according to RECIST v1.1.[1]

The efficacy population included those patients with ≥6 months of follow-up time as of March 1, 2020, and with ≥1 measurable lesion at baseline. Additional follow-up on duration of response and safety was taken on November 1, 2020.[16]

*Patients with dMMR endometrial cancer must have progressed on or after treatment with a platinum-containing regimen. Patients with dMMR colorectal cancer must have progressed after or been intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan.[1]

BICR=blinded independent central review; CI=confidence interval; CR=complete response; dMMR=mismatch repair deficient; DOR=duration of response; ORR=overall response rate; PR=partial response; RECIST v1.1=Response Evaluation Criteria in Solid Tumors v1.1.

IMPORTANT SAFETY INFORMATION (cont'd)

Complications of Allogeneic HSCT (cont'd)

Monitor patients closely for transplant-related complications and intervene promptly.

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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

Response to JEMPERLI Was Observed in a Variety of dMMR Tumor Types[1]*

- Endometrial cancer (n=46/103)
- Colorectal cancer (n=25/69)
- Small intestinal cancer (n=4/12)
- Gastric cancers (n=3/8)
- Biliary neoplasm (n=2/2)
- Liver cancer (n=1/2)
- Ovarian cancer (n=1/2)
- Adrenal cortical (n=1/1)
- Breast cancer (n=1/1)
- Malignant neoplasm of the female genitals (n=1/1)
- Pleural (n=1/1)
- Unknown origin (n=1/1)

*Includes patients with a partial or complete response.

In dMMR Recurrent or Advanced Solid Tumors

JEMPERLI Has Shown Durable Response Over Follow-up[1]

34.7

Months Median Duration of Response
(range: 2.6, 35.8+)

95.4% of Responders
experienced duration of response ≥6 months

- Median follow-up for duration of response was 17.5 months measured from time of first response

IMPORTANT SAFETY INFORMATION (cont'd)

Embryo-Fetal Toxicity and Lactation (cont'd)

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 a 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.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

dMMR Recurrent or Advanced Solid Tumors
Safety Profile

Safety Profile and Tolerability of JEMPERLI Were Evaluated in Patients With dMMR Recurrent or Advanced Solid Tumors (N=267)[1]

9% of patients permanently discontinued therapy due to adverse reactions

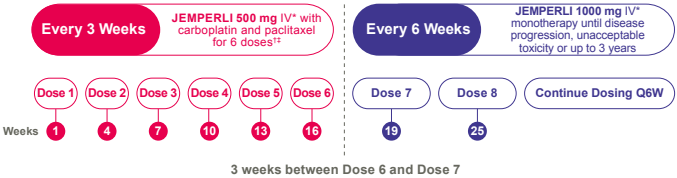
- The most common adverse reaction (≥1%) leading to discontinuation was increased alanine aminotransferase (1.1%)
- The most common adverse reactions (≥20%) were fatigue/asthenia, anemia, diarrhea, and nausea
- Serious adverse reactions occurred in 34% of patients receiving JEMPERLI, including (>2% of patients) abdominal pain (3.7%), sepsis (2.6%), and acute kidney injury (2.2%)
- Fatal adverse reaction due to respiratory failure occurred in 1 patient who received JEMPERLI

dMMR=mismatch repair deficient.

JEMPERLI Dosing[1]

JEMPERLI Given in Combination With CP[1]

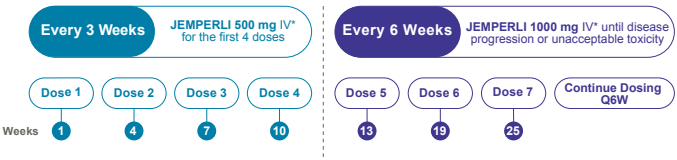
Recommended dosage of JEMPERLI in dMMR/MSI-H primary advanced or recurrent endometrial cancer[1]



3 weeks between Dose 6 and Dose 7

JEMPERLI Given as Monotherapy[1]

Recommended dosage of JEMPERLI in dMMR recurrent or advanced endometrial cancer and dMMR recurrent or advanced solid tumors[1]



3 weeks between Dose 4 and Dose 5

*30-minute intravenous infusion.[1]
†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.[1]
‡Administer JEMPERLI prior to carboplatin and paclitaxel when given on the same day.[1]

Learn more about JEMPERLI as a treatment option here.

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. 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 additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

Access and Support

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One source for GSK access and reimbursement service

Explore the options together—we are here to help

GSK understands the challenges both you and your patients face after their diagnosis. **Together with GSK Oncology** is here to help, offering a variety of access and reimbursement services in one easy-to-access location for all GSK oncology products.

- **Coverage Support**
  - Patient-specific benefits investigation
  - Prior authorization and appeals support
- **Co-pay Assistance Program for commercial patients**
- **Claims assistance**
- **Patient Assistance Program (PAP) for uninsured and Medicare patients**
- **Referral to third-party support services**
  - Patient advocacy organizations
  - Independent co-pay foundations

*See full Terms and Conditions.

Together with
GSK Oncology

Together with GSK Oncology provides resources for patients and healthcare professionals. Specific eligibility requirements are determined by the payer; therefore patients and healthcare professionals should confirm information directly with payers. **Together with GSK Oncology** does not guarantee coverage or payer reimbursement.

IMPORTANT SAFETY INFORMATION (cont'd)

Common Adverse Reactions (cont'd)

The most common adverse reactions (≥20%) in patients with dMMR solid tumors who received JEMPERLI as a single agent were fatigue/asthenia, anemia, diarrhea, and nausea. The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin.

Please see additional Important Safety Information throughout, as well as full Prescribing Information.

Jemperli (dostarlimab-gxly) Injection 500 mg

Your patients can access the information and resources they need at JEMPERLI.com

References

References: 1. JEMPERLI. Prescribing Information. GSK. 2024. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms. V.1.2024. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer. V.1.2024. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed February 2, 2024. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer. V.4.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer. V.1.2024. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed February 2, 2024. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Occult Primary. V.1.2024. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **7.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Bowel Adenocarcinoma. V.1.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer. V.6.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **9.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer. V.3.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **10.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hepatocellular Carcinoma. V.2.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **11.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers. V.3.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **12.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Esophageal and Esophagogastric Junction Cancers. V.4.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 30, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.* **13.** Mirza MR, et al. *N Engl J Med*. 2023;388(23):2145-2158. **14.** Data on file, GSK. **15.** André T, et al. Presented at the American Society of Clinical Oncology annual meeting; June 3-7, 2022; Chicago, IL. Poster 2587. **16.** Berton D, et al. Presented at the American Society of Clinical Oncology virtual meeting; June 4-8, 2021. Poster 2564.

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Please see additional Important Safety Information throughout, as well as full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg