Jemperli (dostarlimab-gxly) Injection 500 mg

Not an actual patient taking JEMPERLI.

Statistically Significant Overall Survival Benefit

JEMPERLI + CP is STILL the FIRST AND ONLY* FDA-approved IO combination with a proven survival benefit in primary advanced or recurrent endometrial cancer[1-6]

RUBY Part 1: A phase 3, randomized, double-blind trial of patients with primary advanced or recurrent endometrial cancer (N=494, all-comers) who were randomized 1:1 to JEMPERLI + CP or placebo + CP Q3W for 6 cycles, followed by JEMPERLI or placebo Q6W, respectively, until disease progression, unacceptable toxicity, or up to 3 years. Major efficacy endpoints were investigator-assessed PFS by RECIST v1.1 in the dMMR/MSI-H and all-comers populations, and overall survival in all-comers.[1]

*All-comers (overall population) overall survival analysis: HR=0.69, 95% CI: 0.54-0.89, *P*=0.002; HR based on stratified Cox regression model and one-sided *P*-value based on stratified log-rank test was statistically significant. Median overall survival with JEMPERLI + CP was 44.6 months (95% CI: 32.6-NR) vs 28.2 months (95% CI: 22.1-35.6) with CP alone.[1]

CI=confidence interval; CP=carboplatin + paclitaxel; dMMR=mismatch repair deficient; HR=hazard ratio; IO=immuno-oncology; MSI-H=microsatellite instability-high; NR=not reached; PFS=progression-free survival; Q3W=every 3 weeks; Q6W=every 6 weeks; RECIST v1.1=Response Evaluation Criteria in Solid Tumors v1.1.

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).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with mismatch repair deficient (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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

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NCCN=National Comprehensive Cancer Network.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

- For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- 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.

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

- 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.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

For JEMPERLI + CP[7]

NCCN
CATEGORY 1
PREFERRED OPTION

Dostarlimab-gxly (JEMPERLI) with carboplatin-paclitaxel is recommended in the NCCN Guidelines® as a category 1 preferred option for primary (stage III-IV*) or recurrent endometrial carcinoma[7†]

- With a statistically significant and clinically meaningful[‡] overall survival benefit in the overall population[§]
- Recommended across MMR status and histologies, including those with MMRp/MSS status and carcinosarcoma

Category 1 – Based upon high-level evidence (≥1 randomized phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.[7] Preferred intervention – Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.[7]

*For adult patients with primary advanced endometrial carcinoma: stage IIIA, IIIB, or IIIC1 with measurable disease post surgery, 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.[7] †For adult patients with recurrent endometrial carcinoma with or without measurable disease.[7] ‡Clinically meaningful defined as at least 20% relative improvement in median overall survival.[8] §All-comers (overall population) overall survival analysis: HR=0.69, 95% CI: 0.54-0.89, *P*=0.002; HR based on stratified Cox regression model and one-sided *P*-value based on stratified log-rank test was statistically significant. Median overall survival with JEMPERLI + CP was 44.6 months (95% CI: 32.6-NR) vs 28.2 months (95% CI: 22.1-35.6) with CP alone.[1]

For JEMPERLI Monotherapy[7]

NCCN
RECOMMENDATION

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.[7]

Category 2A – Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.[7] All recommendations are category 2A unless otherwise indicated.[7]

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Immune-Mediated Hepatitis

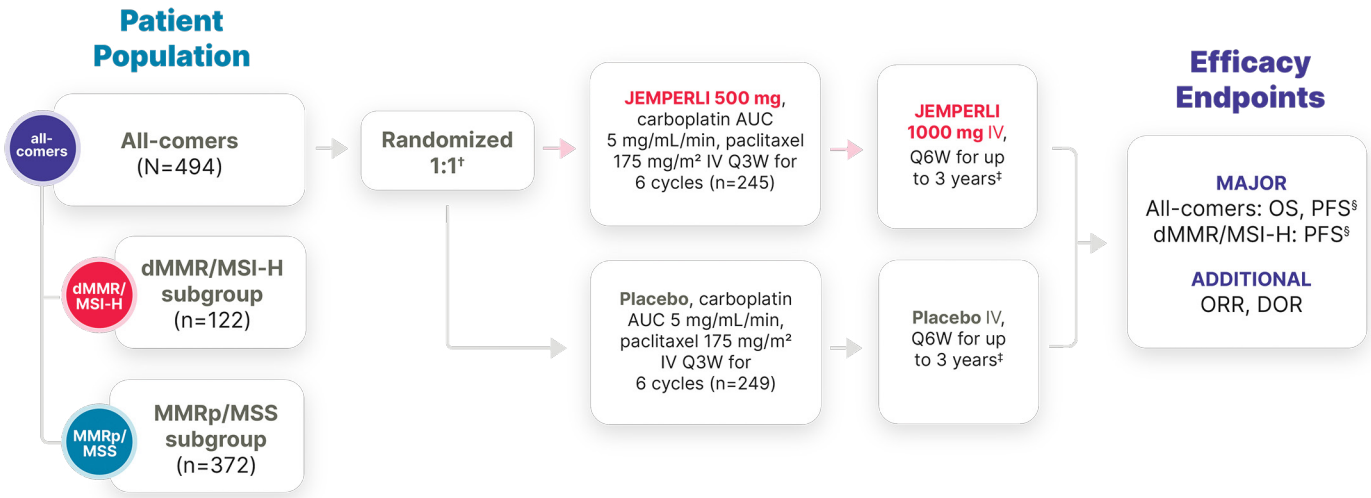
- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.5% (3/605) of patients.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

In All-Comers With Primary Advanced or Recurrent Endometrial Cancer

At 3+ Years, JEMPERLI + CP Has the Longest Median Follow-up for an FDA-Approved Immunotherapy Combination to Date[1-6]*



*Median duration of follow-up, defined as time from randomization to data cutoff, was 37.2 months (cutoff date September 22, 2023).[6] †Randomization was stratified by MMR/MSI status, prior external pelvic radiotherapy, and disease status (recurrent, primary Stage III, or primary Stage IV).[1] ‡Treatment continued until disease progression, unacceptable toxicity, or a maximum of 3 years.[1] §PFS assessed by the investigator according to RECIST v1.1.[1]
AUC=area under the curve; DOR=duration of response; IV=intravenous; MMRp=mismatch repair proficient; MSS=microsatellite stable; ORR=objective response rate; OS=overall survival.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

In Primary Advanced or Recurrent Endometrial Cancer

RUBY Part 1 Included Patients With Broad Disease Characteristics[1,9]

Primary FIGO Stage III or Stage IV disease, including patients with more aggressive histologies such as carcinosarcoma and serous adenocarcinoma[1,9-11]

Measurable Disease[1]*	Measurable* or Non-Measurable Disease[1]
Stage IIIA-IIIC1	Stage IIIC1 patients with carcinosarcoma, clear cell, serous, or mixed histology (≥10% carcinosarcoma, clear cell, or serous histology)
	Stage IIIC2 or IV

First recurrent endometrial cancer with a low potential for cure by radiation therapy or surgery alone or in combination, including those[1]:

- Naïve to systemic anticancer therapy
- Who had received prior neoadjuvant/adjuvant systemic anticancer therapy and who had a recurrence or disease progression ≥6 months after completing treatment (first recurrence)

All patients were anti–PD-1/L1/L2 naïve[12]

*Measurable or evaluable by RECIST v1.1.[1]
FIGO=International Federation of Gynecology and Obstetrics; PD-1=programmed death receptor 1; PD-L1=programmed death ligand 1; PD-L2=programmed death ligand 2.

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% (30/241) 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%).

Immune-Mediated Endocrinopathies (cont'd)

- Thyroid Disorders
  - 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 and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

In Primary Advanced or Recurrent Endometrial Cancer

RUBY Part 1 Included Patients With Diverse Disease Characteristics (N=494)[1,9]

MMR Status

24%
dMMR/MSI-H

76%
MMRp/MSS

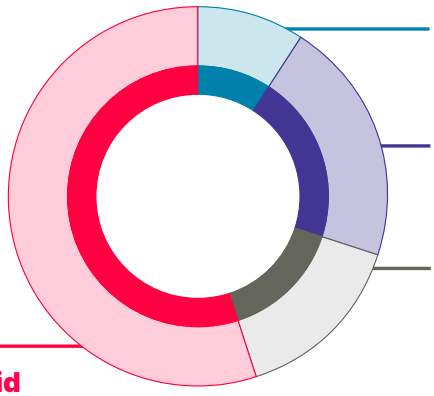
Age

51% 65 Years or Older

Race/Ethnicity

77% White
12% Black
3% Asian
3% Hispanic or Latino

Histologies



8.9%
Carcinosarcoma

20.6%
Serous adenocarcinoma

15.8%
All other histologies
Clear-cell adenocarcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, mixed carcinoma (≥10% of carcinosarcoma, clear-cell, or serous histologic type) or other

54.7%
Endometrioid

Disease Status

18% Primary FIGO Stage III
34% Primary FIGO Stage IV
48% Recurrent Disease

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.

Immune-Mediated Endocrinopathies (cont'd)

- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis
  - 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.

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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

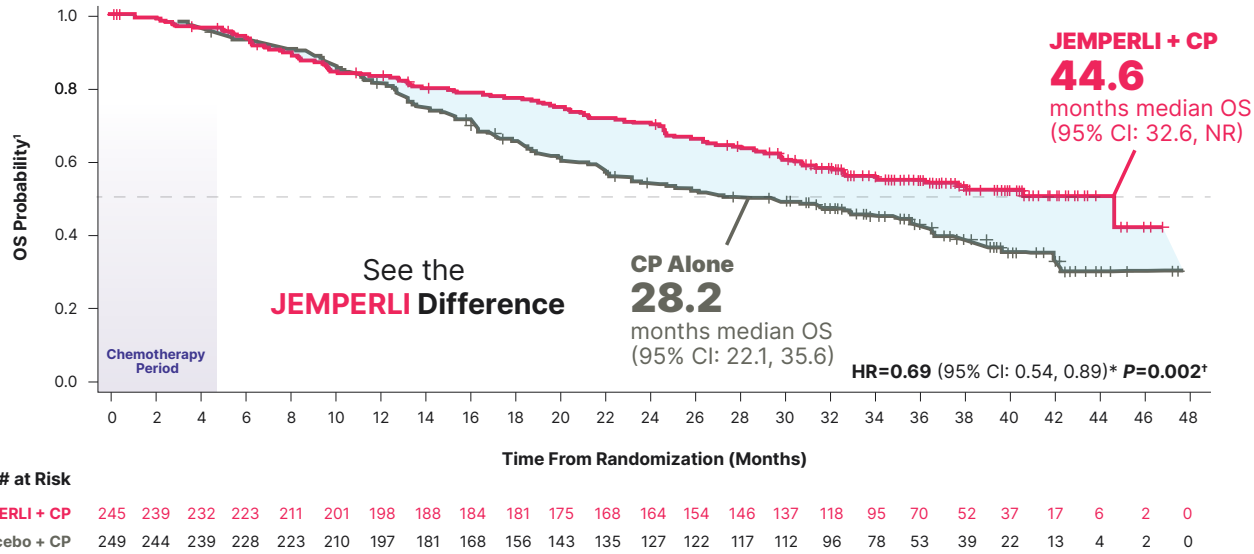
Jemperli (dostarlimab-gxly) Injection 500 mg

Major Endpoints

all-comers

16-Month Improvement in Median Overall Survival vs CP Alone[1]

Statistically significant 31% reduction in the risk of death with JEMPERLI + CP vs CP alone[1]



# at Risk																								
JEMPERLI + CP	245	239	232	223	211	201	198	188	184	181	175	168	164	154	146	137	118	95	70	52	37	17	6	2	0
Placebo + CP	249	244	239	228	223	210	197	181	168	156	143	135	127	122	117	112	96	78	53	39	22	13	4	2	0

- Estimated Kaplan-Meier probability of OS at 24 months was 70.1% (95% CI: 63.8, 75.5) with JEMPERLI + CP and 54.3% (95% CI: 47.8, 60.3) with CP alone[6]
- **All-comers median PFS** was 11.8 months (95% CI: 9.6, 17.1) with JEMPERLI + CP vs 7.9 months (95% CI: 7.6, 9.5) with CP alone (HR=0.64; 95% CI: 0.51, 0.80*; *P*<0.0001†)[1]
- **dMMR/MSI-H subgroup median PFS** was 30.3 months (95% CI: 11.8, NR) with JEMPERLI + CP vs 7.7 months (95% CI: 5.6, 9.7) with CP alone (HR=0.29; 95% CI: 0.17, 0.50*; *P*<0.0001†)[1]

Overall survival data cutoff September 22, 2023.[6] PFS data cutoff September 28, 2022.[9]
*Based on stratified Cox regression model.[1] †One-sided *P*-value based on stratified log-rank test was statistically significant.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

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. 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 and on pages 22-24 and full Prescribing Information, including Medication Guide.

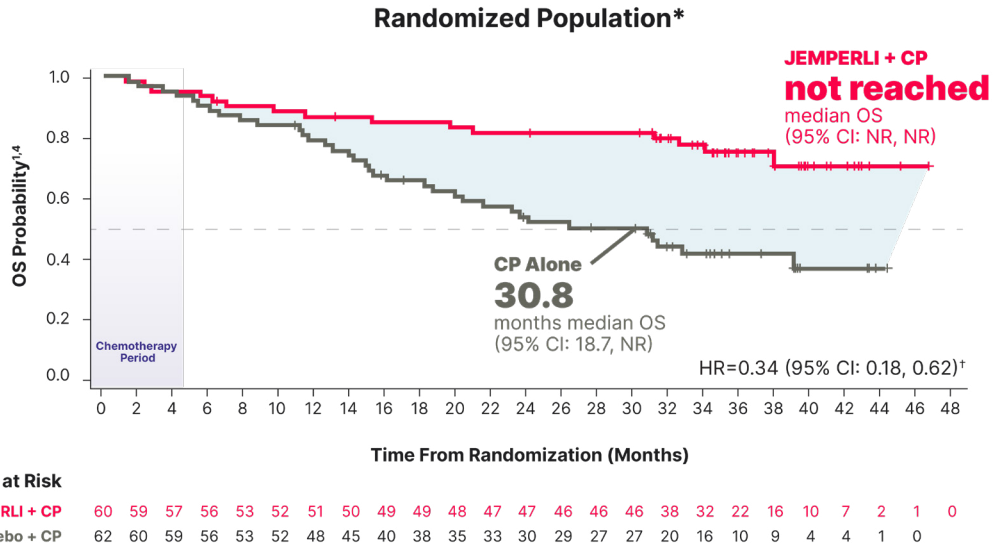
Jemperli (dostarlimab-gxly) Injection 500 mg

Exploratory Analyses

dMMR/ MSI-H

Median Overall Survival Was Not Reached With JEMPERLI + CP and 30.8 Months With CP Alone[1,13]

The prespecified exploratory analyses (randomized and source verified*) for overall survival were not powered to detect treatment differences; results are descriptive[1,6,9]



- Estimated Kaplan-Meier probability of OS at 24 months was 81.4% (95% CI: 68.9, 89.2) with JEMPERLI + CP and 53.6% (95% CI: 40.3, 65.3) with CP alone[13]

OS and PFS in the dMMR/MSI-H source-verified population below were consistent with the randomized population based on post hoc sensitivity analyses[6,9,14-16]*:

- **Median overall survival** was not estimable (95% CI: NE, NE) with JEMPERLI + CP vs 31.4 months (95% CI: 20.3, NE) with CP alone (HR=0.32; 95% CI: 0.17, 0.63)
- Median PFS was not estimable (95% CI: 11.8, NE) with JEMPERLI + CP vs 7.7 months (95% CI: 5.6, 9.7) with CP alone (HR=0.28; 95% CI: 0.16, 0.50)

Overall survival data cutoff September 22, 2023.[6] PFS data cutoff September 28, 2022.[9]
*MMR/MSI status entered at randomization (randomized population, presented in the US Prescribing Information) was later source verified to correct misclassifications (source-verified population). Of the 494 randomized patients, 118 had dMMR/MSI-H tumors confirmed by source-verified classification.[1,6,9] †Based on stratified Cox regression model.[1]
NE=not estimable.

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

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

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

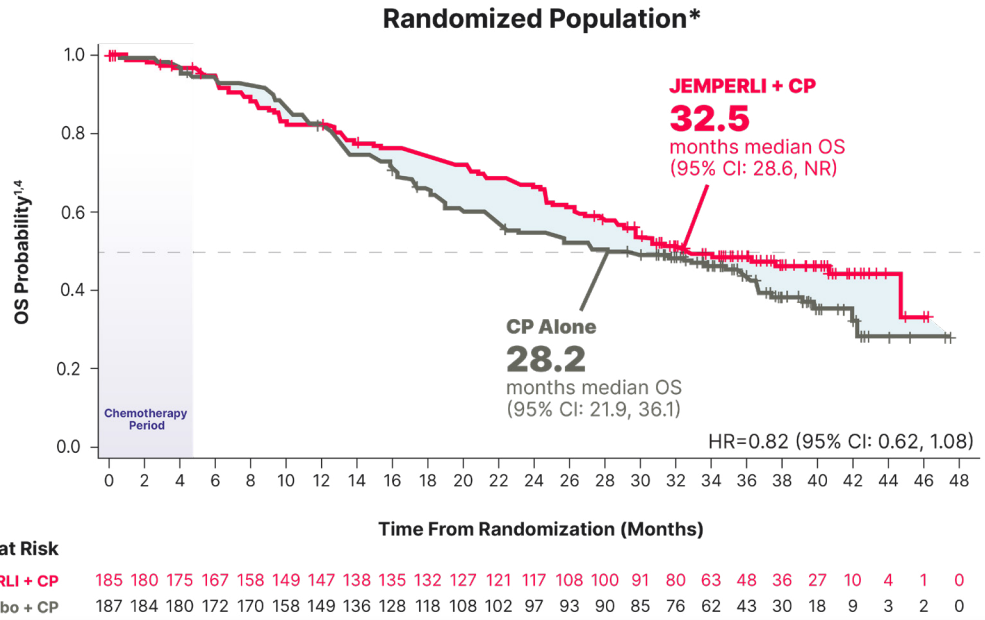
Jemperli (dostarlimab-gxly) Injection 500 mg

Exploratory Analyses

MMRp/MSS

Improvement in Overall Survival Observed With JEMPERLI + CP[1,13]

The prespecified exploratory analyses (randomized and source verified*) for overall survival and PFS were not powered to detect treatment differences; results are descriptive[1,6,9]



- 76% of patients in the overall population had MMRp/MSS biomarker status (n=372)[1]
- Median PFS was 9.8 months (95% CI: 9.0, 12.6) with JEMPERLI + CP (n=185) vs 7.9 months (95% CI: 7.6, 9.8) with CP alone (n=187), and HR=0.78 (95% CI: 0.60, 1.00)[1]

Clinically meaningful† difference in overall survival in the source-verified MMRp/MSS population[6,8,9,14,15]*:

- **7-month improvement in median overall survival** with JEMPERLI + CP (34.0 months, 95% CI: 28.6, NE) vs CP alone (27.0 months, 95% CI: 21.5, 35.6), and HR=0.79 (95% CI: 0.60, 1.04)
- Median PFS was 9.9 months (95% CI: 9.0, 13.3) with JEMPERLI + CP vs 7.9 months (95% CI: 7.6, 9.8) with CP alone (HR=0.76; 95% CI: 0.59, 0.98)

Overall survival data cutoff September 22, 2023.[6] PFS data cutoff September 28, 2022.[9]
*MMR/MSI status entered at randomization (randomized population, presented in the US Prescribing Information) was later source verified to correct misclassifications (source-verified population). Of the 494 randomized patients, 376 had MMRp/MSS tumors confirmed by source-verified classification.[1,6,9] †Clinically meaningful defined as at least 20% relative improvement in median overall survival.[8]

IMPORTANT SAFETY INFORMATION (CONT'D)

Other Immune-Mediated Adverse Reactions (cont'd)

- *Gastrointestinal:* Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis

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

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

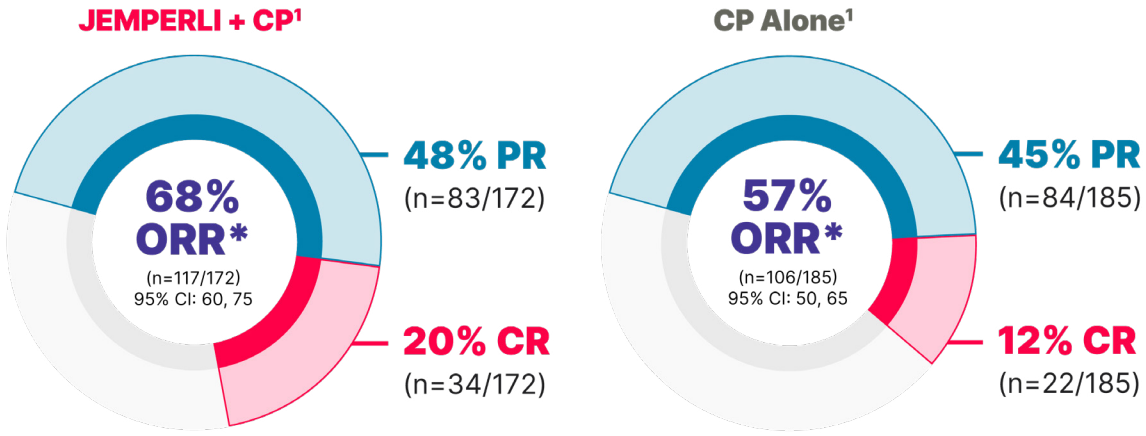
Jemperli (dostarlimab-gxly) Injection 500 mg

Additional Endpoints

ORR and DOR with JEMPERLI + CP vs CP alone[1]*

all-comers

ORR and DOR after 25.4 months median follow-up[1,9†]



- Median DOR with JEMPERLI + CP was 10.8 months (range: 1.3+, 28.9+) compared with 6.4 months (range: 1.4+, 27.2+) with CP alone[1‡]

At baseline, 172 and 185 participants had measurable disease in the JEMPERLI + CP and CP alone groups, respectively.[1]
Data cutoff September 28, 2022.[9]
*Confirmed responses as assessed by investigator according to RECIST v1.1.[1] †Median duration of follow-up is defined as time from randomization to data cutoff.[9,13]
‡For patients with a confirmed partial or complete response.[1]
CR=complete response; PR=partial response.

IMPORTANT SAFETY INFORMATION (CONT'D)

Other Immune-Mediated Adverse Reactions (cont'd)

- *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. 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. 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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

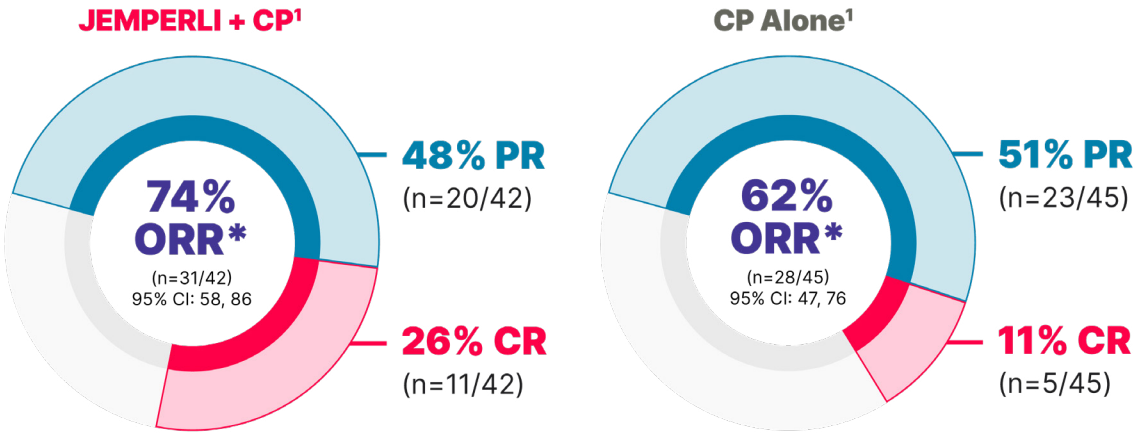
Jemperli (dostarlimab-gxly) Injection 500 mg

Additional Endpoints

ORR and DOR with JEMPERLI + CP vs CP alone[1]*

dMMR/ MSI-H

ORR and DOR after 24.9 months median follow-up[1,13†]



- Median DOR was not reached (range: 3.4, 28.3+) with JEMPERLI + CP compared with 5.4 months (range: 2.7, 27.2+) with CP alone[1‡]

At baseline, 42 and 45 participants had measurable disease in the JEMPERLI + CP and CP alone groups, respectively.[1]
Data cutoff September 28, 2022.[9]
*Confirmed responses as assessed by investigator according to RECIST v1.1.[1] †Median duration of follow-up is defined as time from randomization to data cutoff.[9,13]
‡For patients with a confirmed partial or complete response.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

Common Adverse Reactions

The most common adverse reactions (≥20%), including laboratory abnormalities, in patients with EC who received JEMPERLI in combination with carboplatin and paclitaxel were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting.

Common Adverse Reactions (cont'd)

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.

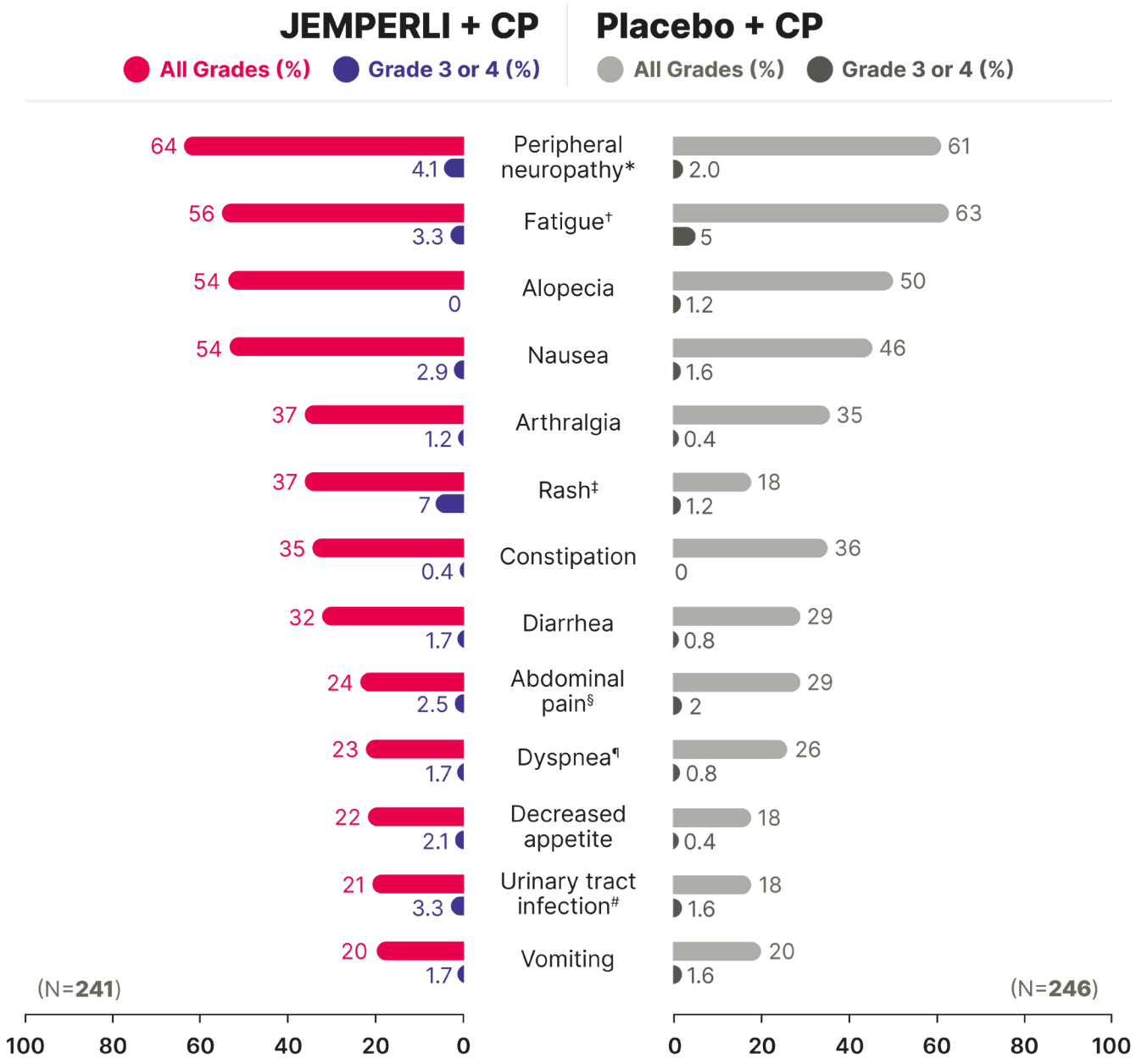
Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

In Primary Advanced or Recurrent Endometrial Cancer

The Safety Profile of JEMPERLI + CP Has Been Well Established in the RUBY Part 1 Trial[1]

Adverse reactions (≥20%) in patients who received JEMPERLI + CP in RUBY Part 1[1]



Graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03.[1]
*Includes neuropathy peripheral and peripheral sensory neuropathy. †Includes fatigue and asthenia.[1] ‡Includes rash, rash maculo-papular, palmar-plantar erythrodysesthesia syndrome, rash pustular, skin exfoliation, and vulvovaginal rash.[1] §Includes abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain, abdominal discomfort, epigastric discomfort, and abdominal tenderness.[1] ¶Includes dyspnea and dyspnea exertional.[1] #Includes urinary tract infection, urinary tract infection bacterial, cystitis, and pyelonephritis.[1]

In Primary Advanced or Recurrent Endometrial Cancer

The Safety Profile of JEMPERLI + CP Has Been Well Established in the RUBY Part 1 Trial (cont'd)[1]

In patients receiving JEMPERLI + CP, 19% (n=46) of patients permanently discontinued JEMPERLI due to adverse reactions[1]

- Adverse reactions that required permanent discontinuation in ≥2 patients included 3 cases (1.2%) of rash maculo-papular, and 2 cases (0.8%) each of increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), diarrhea, pancreatitis, fatigue, pneumonitis, and arthralgia
- The most common adverse reactions, including laboratory abnormalities (≥20%), were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting
- Serious adverse reactions occurred in 39% of patients receiving JEMPERLI + CP; the most common serious adverse reactions were sepsis, including urosepsis (3.7%), and pulmonary embolism (3.3%)
- Fatal adverse reactions occurred in 1.2% of patients receiving JEMPERLI including septic shock (0.8%) and myelosuppression (0.4%)

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.

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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

GARNET Trial Design

JEMPERLI was studied in the largest single-agent immunotherapy trial dataset in previously-treated dMMR recurrent or advanced endometrial cancer, GARNET (n=141)[1,17]

GARNET was a multicenter, multiple cohort, open-label study[1]

Patient Population[1]

- Recurrent or advanced endometrial cancer that had progressed on or following treatment with a platinum-containing regimen
- Tumors that were dMMR as determined by IHC testing. The dMMR tumor status was retrospectively confirmed using the VENTANA MMR RxDx Panel assay
- Efficacy analysis included 141 patients, and safety analysis included 150 patients[1]

Patients received: JEMPERLI 500 mg IV every 3 weeks for 4 doses, followed by 1000 mg IV every 6 weeks[1]*

Major Efficacy Endpoints[1†]

- ORR
- DOR

Key Inclusion Criteria[1,17]	Key Exclusion Criteria[1]
• Recurrent or advanced endometrial cancer • dMMR endometrial cancer as determined by IHC testing • Progression on or after platinum-containing regimen • ≤2 lines of prior anticancer treatment for recurrent or advanced disease‡	• Prior treatment with PD-1/PD-L1–blocking antibodies or other immune checkpoint inhibitor therapy • Autoimmune disease that required systemic treatment within 2 years

*Treatment continued until disease progression or unacceptable toxicity.[1] †As assessed by BICR according to RECIST v1.1.[1] ‡89% of patients had received prior anticancer surgery and 71% had received prior anticancer radiotherapy. Approximately 37% of patients had 2 lines or more of prior anticancer treatment in total.[1]
BICR=blinded independent central review; IHC=immunohistochemistry; IV=intravenous; ORR=overall response rate; PD-1=programmed death receptor 1; PD-L1=programmed death ligand 1.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

GARNET Cohort A1: Patient Baseline Characteristics[1,13]

Efficacy population baseline characteristics (n=141)[1]

Of the 150 patients in the study with dMMR endometrial cancer who received JEMPERLI, 141 were included in the efficacy analysis.

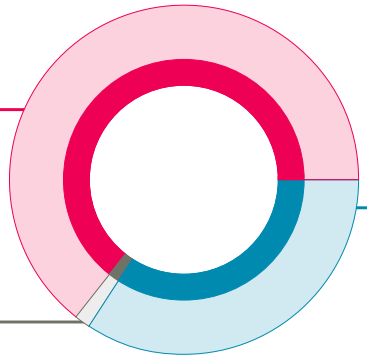
65
Years
Median Age

Prior Treatments

63% of Patients
(n=89) had one prior line of anticancer treatment

34% of Patients
(n=48) received only adjuvant or neoadjuvant treatment before joining the study

Histologies



64.5% Type 1 Endometrioid Carcinoma

34% Type 2 Endometrial Carcinoma

1.4% Unknown

14.9%	Grade 3 Endometrioid	5%	Serous Carcinoma	5%	Mixed
2.8%	Undifferentiated	2.8%	Unspecified	2.1%	Other*
0.7%	Squamous	0.7%	Clear Cell	0%	Carcinosarcoma

ECOG Performance Status

38% ECOG 0 **62%** ECOG 1

Race

77% White **4%** Asian **12%** Other **3%** Black **4%** Hispanic or Latino

The efficacy evaluable population included patients who had measurable disease at baseline and who were followed for ≥6 months. Data cutoff date was November 1, 2021.[17]

*Other includes dedifferentiated, endometrial adenocarcinoma, endometrial adenocarcinoma NOS, endometrial neuroendocrine carcinoma, high-grade uterine carcinoma, and undifferentiated clear cell carcinoma.[13]

ECOG=Eastern Cooperative Oncology Group; NOS=not otherwise specified.

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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

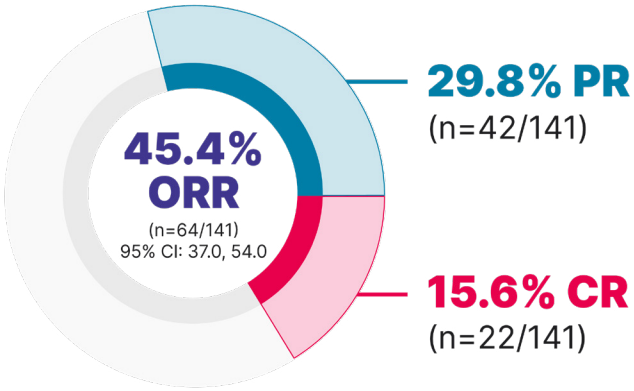
Overall Response Rate

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

Proven efficacy at median follow-up of 27.9 months[1]*

GARNET included the largest single-agent immunotherapy trial dataset in previously-treated dMMR recurrent or advanced endometrial cancer (n=141)[1,17]

Overall Response Rate (ORR)[1†]



- ORRs based on lines of prior therapy[13]:
  - 43.8% (n=39) in those who received 1 prior line (95% CI: 33.3, 54.7)
  - 48.1% (n=25) in those who received ≥2 prior lines (95% CI: 34.0, 62.4)
  - Due to small sample sizes and wide confidence intervals, results should be interpreted with caution
- Responses to JEMPERLI were seen across histologies, including serous, Grade 3 endometrioid, mixed, unspecified, clear cell, undifferentiated, and squamous carcinoma[13,17]

*Measured from time of first response.[1] †Based on confirmed response by blinded independent central review.[1]

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% (30/241) 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.

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

Duration of Response

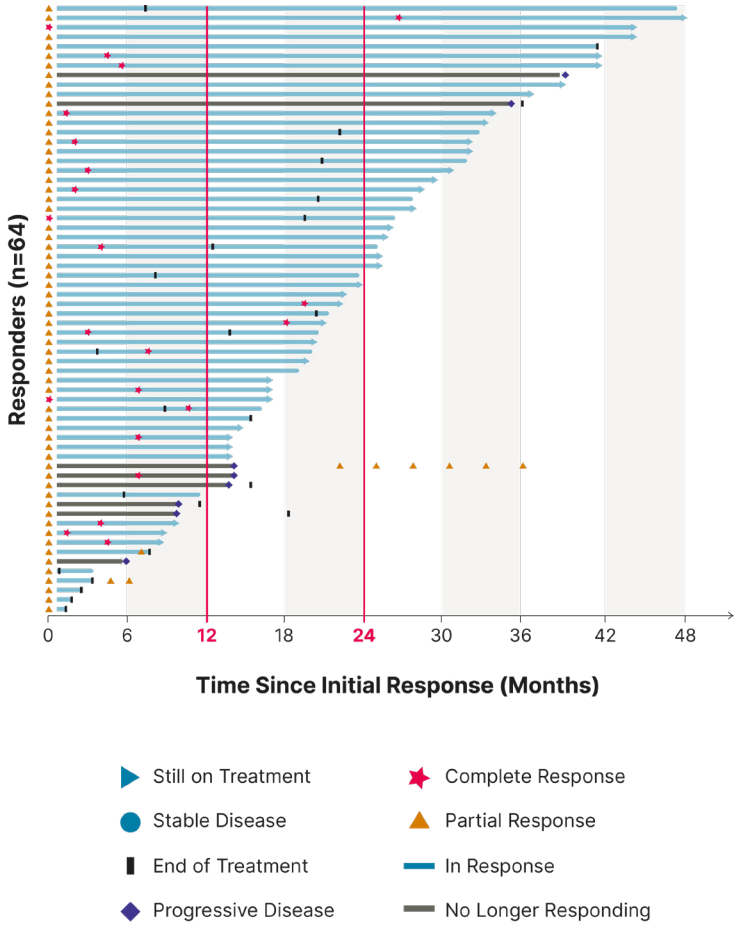
JEMPERLI Has Shown Durable Response Over ≥2 Years of Follow-up[1]

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]

Treatment duration of responders[13]



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.

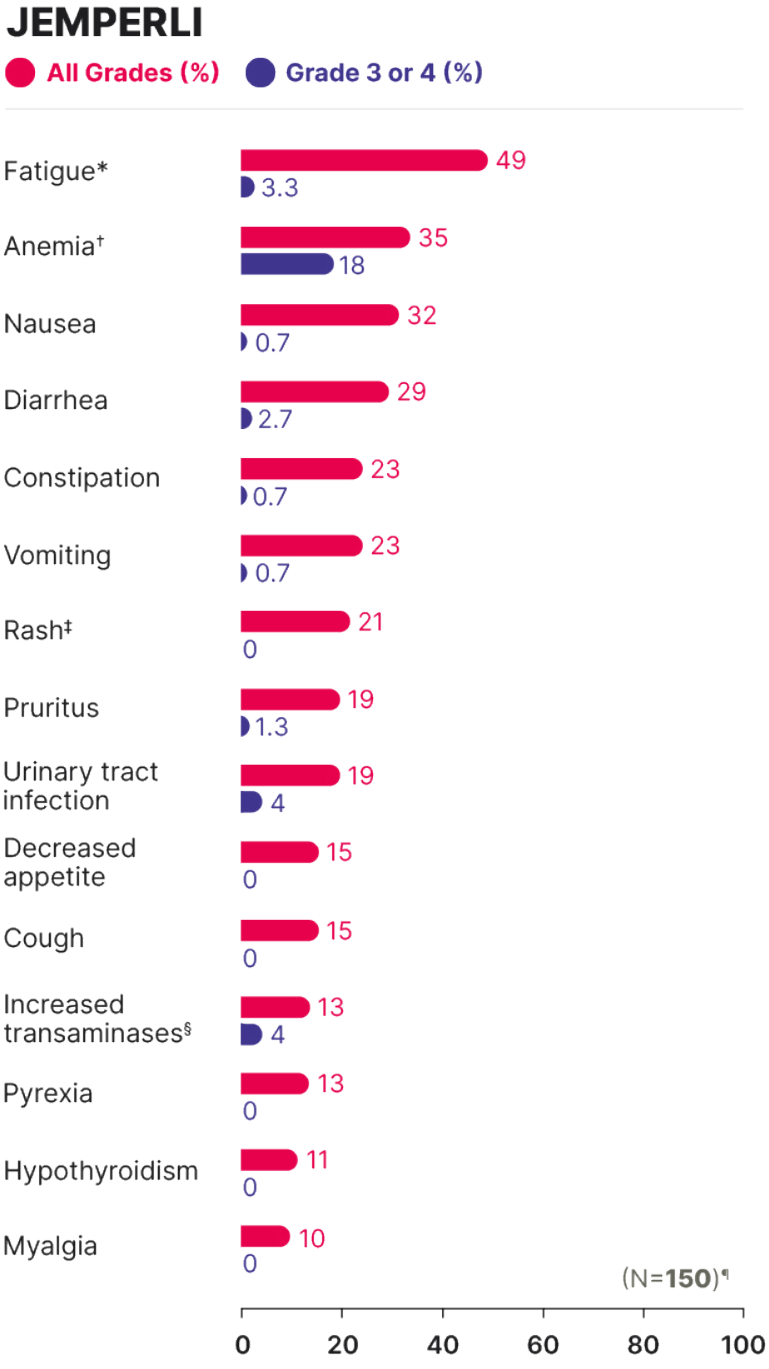
Immune-Mediated Dermatologic Adverse Reactions

- 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. 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.

Jemperli (dostarlimab-gxly) Injection 500 mg

Safety Profile Established Over More Than 2 Years[1]

Adverse reactions (≥10%) in patients with dMMR endometrial cancer who received JEMPERLI in GARNET[1]



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

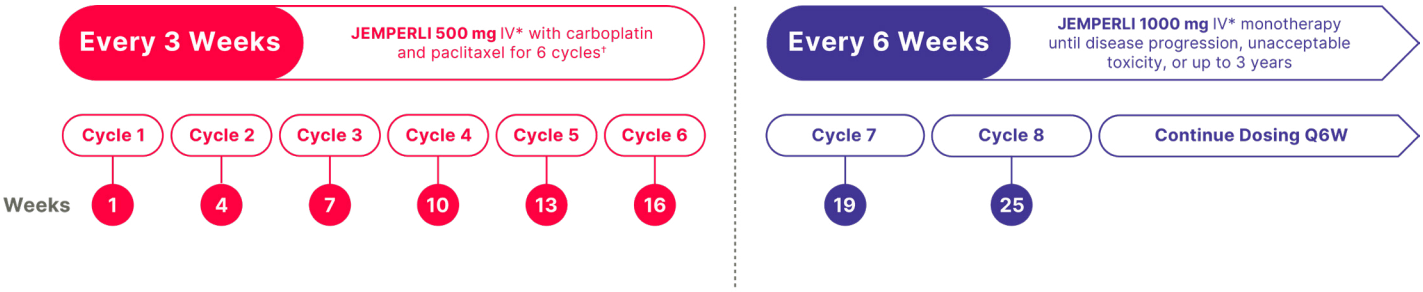
- Adverse reactions leading to discontinuation were increased transaminases, sepsis, bronchitis, pneumonitis, rash, pruritus, pancreatitis, encephalitis, and nephritis (15 patients total)
- The most common adverse reactions (≥20%) were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash
- 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%)
- A fatal adverse reaction occurred in one patient (0.7%) who received JEMPERLI, due to concurrent immune-mediated encephalitis and urinary tract infection

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03.
*Includes fatigue and asthenia.[1] †Includes anemia, decreased hemoglobin, iron deficiency, and iron deficiency anemia.[1] ‡Includes rash, rash maculo-papular, rash pruritic, erythema, and pemphigoid.[1] §Includes increased alanine aminotransferase, increased aspartate aminotransferase, increased transaminases, and hypertransaminasemia.[1] ¶Intent-to-treat population (N=150).[1]

JEMPERLI Dosing[1]

JEMPERLI given in combination with CP[1]

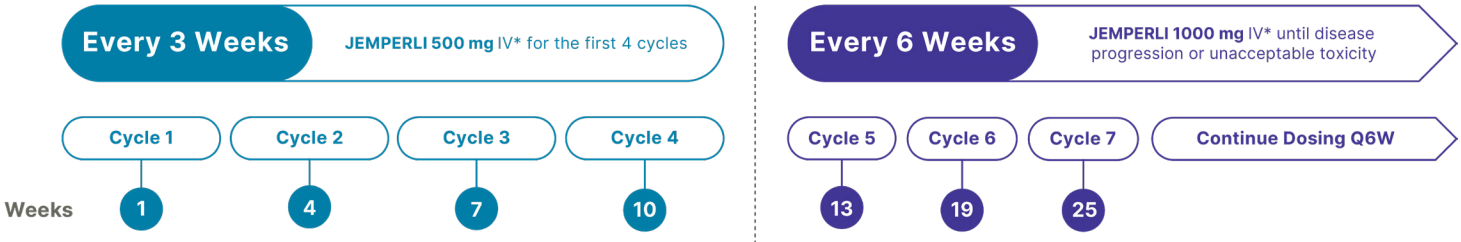
Recommended dosage of JEMPERLI in primary advanced or recurrent endometrial cancer



3 weeks between Cycle 6 and Cycle 7

JEMPERLI given as monotherapy[1]

Recommended dosage of JEMPERLI in dMMR recurrent or advanced endometrial cancer



3 weeks between Cycle 4 and Cycle 5

- 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 dosage[1]
- The Q3W dosing schedule allows for more frequent patient monitoring during the 6-cycle treatment initiation phase[1]
- The number of infusion visits is reduced after transitioning to the Q6W monotherapy phase[1]
  - Additional monitoring may be required per clinical discretion

*30-minute IV infusion.[1] †Administer JEMPERLI prior to carboplatin and paclitaxel when given on the same day. Refer to the Prescribing Information for the agents administered in combination with JEMPERLI, as appropriate.[1]
IL-2=interleukin 2.

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

Please see additional Important Safety Information throughout and on pages 22-24 and full Prescribing Information, including Medication Guide.

Jemperli (dostarlimab-gxly) Injection 500 mg

Together With GSK Oncology*†

One source for GSK access and reimbursement resources

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 support
  - Prior authorization and appeals support
- **Copay assistance for eligible commercially insured patients**
- **Claims assistance**
- **Patient Assistance Program (PAP) is available for patients who meet the eligibility criteria‡**
- **Information about other organizations or independent foundations that may be able to help with JEMPERLI costs**

*See full terms and conditions. ‡The GSK PAP is operated by the GSK Patient Access Programs Foundation, an independent, non-profit organization from GSK.

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.

Get started together—help your patients enroll

1. Obtain the Together with GSK Oncology Enrollment Form

- Ask your GSK Account Specialist or Field Reimbursement Manager for copies
- Visit **www.togetherwithGSKOncology.com** to download the Enrollment Form

2. Complete the form with your patient and return

- Select services requested from **Together with GSK Oncology**
- Complete all Patient and Prescriber Information
- Make sure both you and your patient sign the form
- Fax the completed Enrollment Form, plus copies of your patient's medical and pharmacy insurance cards, to **1-800-645-9043**

3. Receive enrollment confirmation

4. Review summary of benefits

- **Together with GSK Oncology** will conduct a summary-of-benefits call with the patient within 1 to 2 business days
- Your office will receive a faxed copy and a phone call to review the results

Remind patients to promptly return any phone calls received from Together with GSK Oncology.

Additional questions? We're here to help. Call us at 1-844-4GSK-ONC (1-844-447-5662) Monday-Friday (8 AM to 8 PM ET).

This GSK Copay Assistance Program can help eligible patients with their out-of-pocket costs for certain GSK prescription medicines.
You might be eligible for this program if you:
- Have a commercial medical or prescription insurance plan; or
- Are uninsured;

AND
- Are a resident of the US (including the District of Columbia, Puerto Rico, and the US Virgin Islands); and
- Are not eligible for or enrolled in a government-funded program

Jemperli (dostarlimab-gxly) Injection 500 mg

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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).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with mismatch repair deficient (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.
- 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.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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.
- 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.

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% (30/241) 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.
- 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.

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

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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 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%), including laboratory abnormalities, in patients with EC who received JEMPERLI in combination with carboplatin and paclitaxel were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting.

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 and on pages 22-24 and full Prescribing Information, including Medication Guide.

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Jemperli (dostarlimab-gxly) Injection 500 mg