Jemperli
(dostarlimab-gxly) Injection 500 mg

Let their light *Shine* with JEMPERLI

Not an actual patient taking JEMPERLI.

JEMPERLI + CP: The first and only* FDA-approved IO combination with statistically significant OS benefit in primary advanced or recurrent EC[1-6]

RUBY Part 1: A phase 3, randomized, double-blind trial of patients with primary advanced or recurrent EC (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 OS in all-comers.[1]

*All-comers (overall population) OS 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 OS 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; EC=endometrial cancer; HR=hazard ratio; IO=immuno-oncology; MSI-H=microsatellite instability-high; 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.

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 full Prescribing Information, including Medication Guide.

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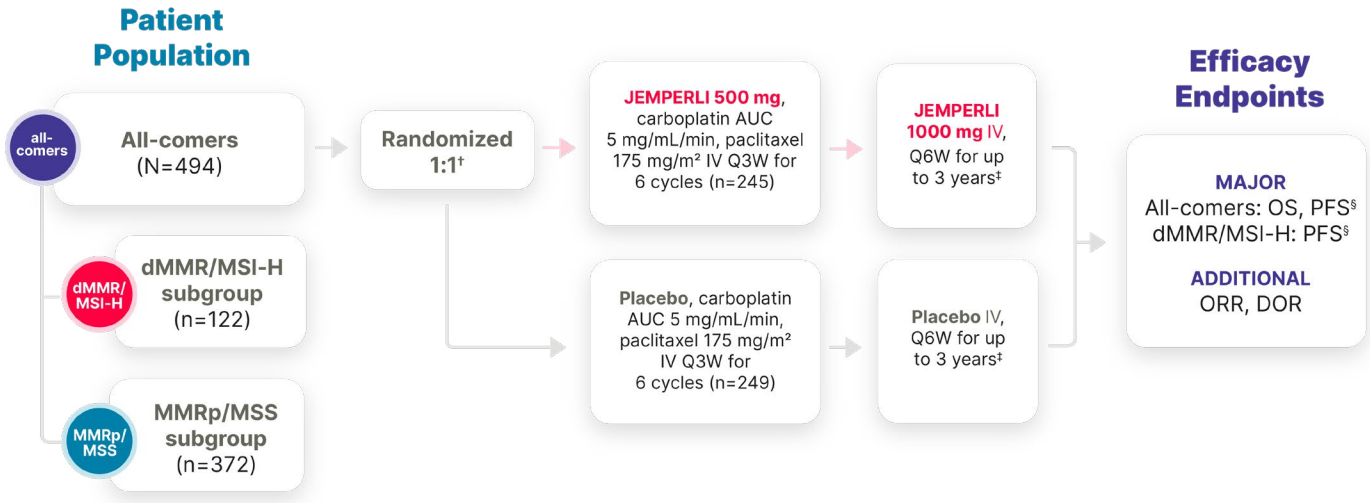
In All-Comers With Primary Advanced or Recurrent EC

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.

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. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

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

Immune-Mediated Colitis

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

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In Primary Advanced or Recurrent EC

RUBY Part 1 Included Patients With Broad Disease Characteristics[1,7]

Primary FIGO Stage III or Stage IV disease, including patients with more aggressive histologies such as carcinosarcoma (9%) and serous adenocarcinoma (21%)[1,7-9]

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[10]

*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 Hepatitis

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

Immune-Mediated Endocrinopathies

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

Immune-Mediated Endocrinopathies (cont'd)

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

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Jemperli (dostarlimab-gxly) Injection 500 mg

In Primary Advanced or Recurrent EC

RUBY Part 1 Included Patients With Diverse Disease Characteristics (N=494)[1,7]

Age

51% 65 Years or Older

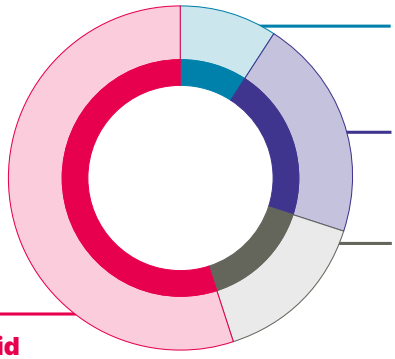
Race/Ethnicity

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

Subgroups

24% dMMR/MSI-H
76% MMRp/MSS

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)

- 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.

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.

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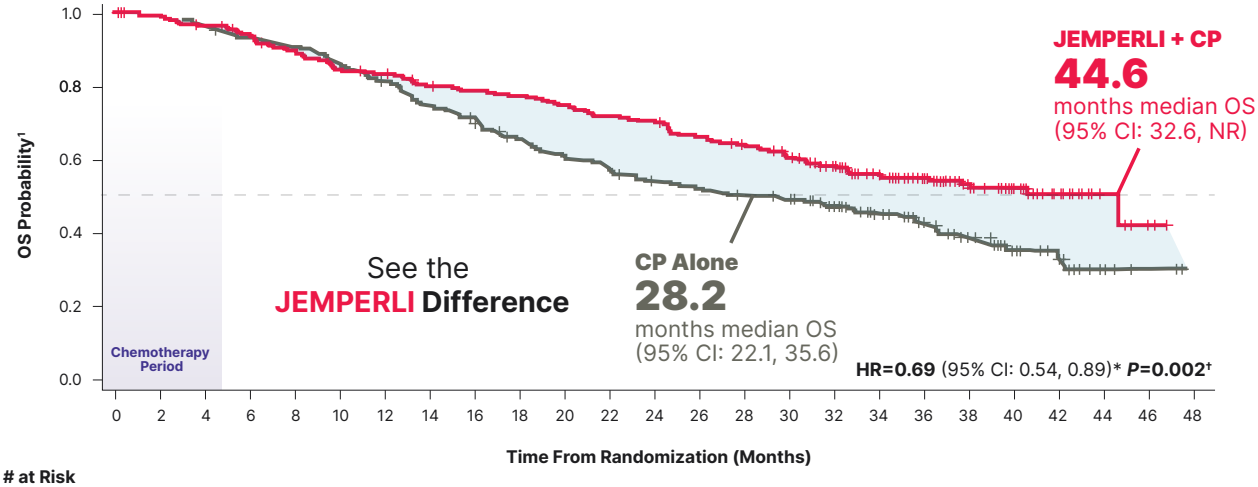
Major Endpoints

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

- 70.1% survival probability with JEMPERLI + CP (95% CI: 63.8, 75.5) at 2 years vs 54.3% with CP alone (95% CI: 47.8, 60.3)[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]

OS data cutoff September 22, 2023.[6] PFS data cutoff September 28, 2022.[7]
*Based on stratified Cox regression model.[1] †One-sided *P*-value based on stratified log-rank test was statistically significant.[1] ‡By Kaplan-Meier method.[6]
NR=not reached.

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.

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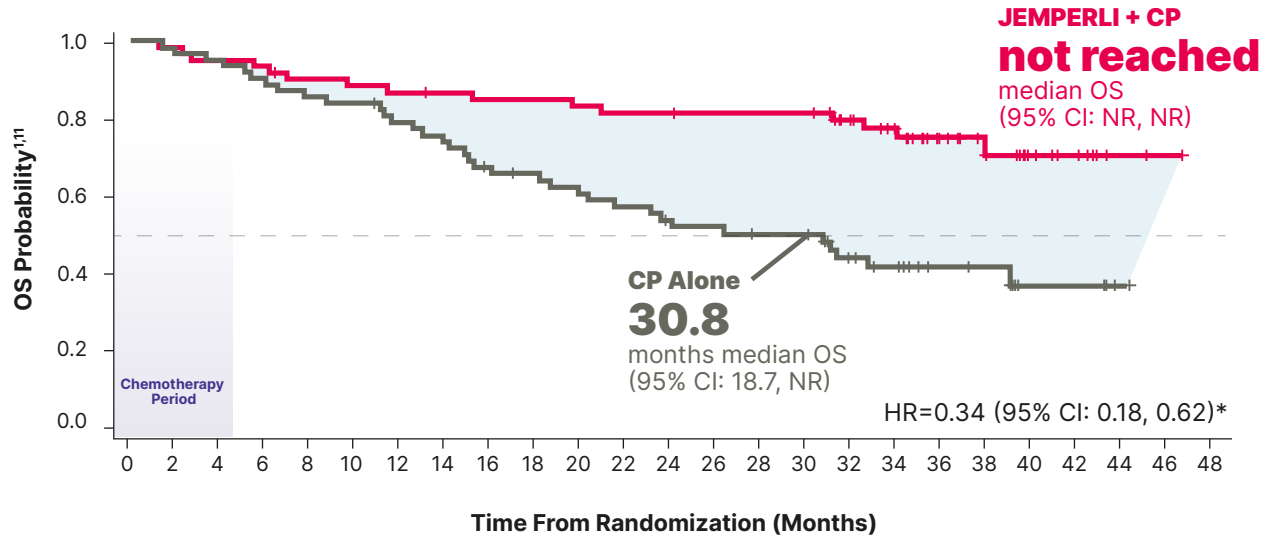
Exploratory Analysis

dMMR/ MSI-H

Median OS Was Not Reached With JEMPERLI + CP and 30.8 Months With CP Alone[1,11]

The prespecified exploratory analysis for OS was not powered to detect treatment differences; results are descriptive[1]



 # at Risk

JEMPERLI + CP	60	59	57	56	53	52	51	50	49	49	48	47	47	46	46	46	38	32	22	16	10	7	2	1	0
Placebo + CP	62	60	59	56	53	52	48	45	40	38	35	33	30	29	27	27	20	16	10	9	4	4	1	0	

- 81.4% survival probability with JEMPERLI + CP (95% CI: 68.9, 89.2) at 2 years vs 53.6% with CP alone (95% CI: 40.3, 65.3)[11†]

Data cutoff September 22, 2023.[6]
*Based on stratified Cox regression model.[1] †By Kaplan-Meier method.[11]

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
- *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

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

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

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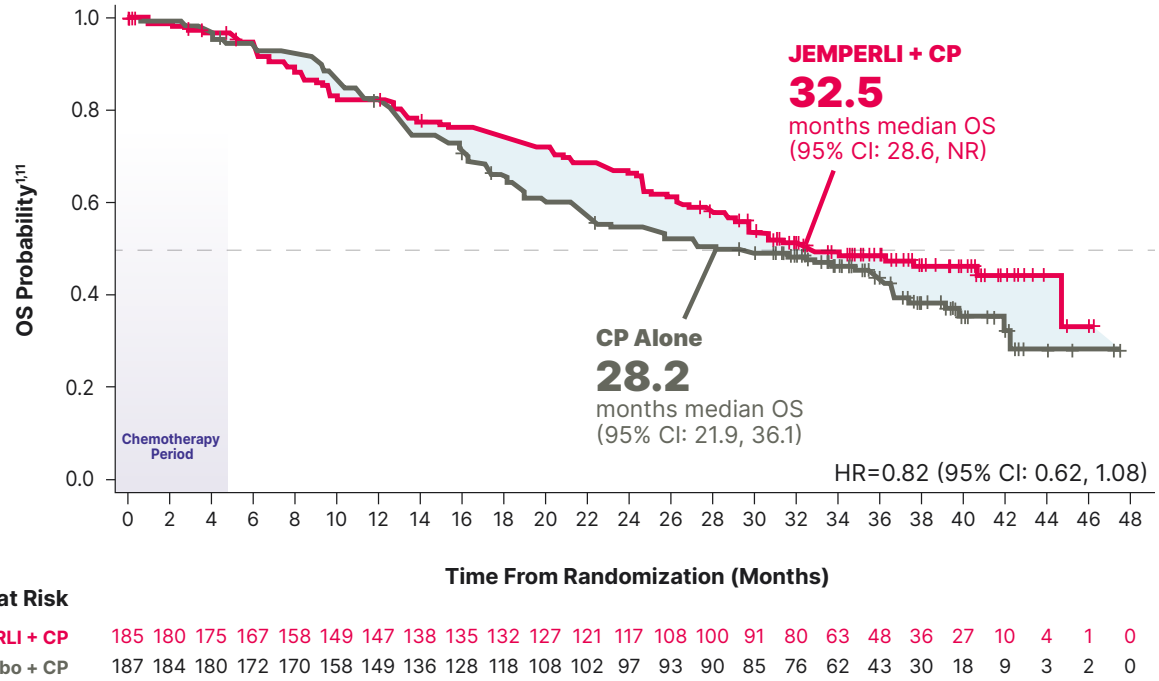
Exploratory Analyses

MMRp/MSS

4-Month Improvement in OS Observed With JEMPERLI + CP[1,11]

The prespecified exploratory analyses for OS and PFS were not powered to detect treatment differences; results are descriptive[1]



# at Risk																								
JEMPERLI + CP	185	180	175	167	158	149	147	138	135	132	127	121	117	108	100	91	80	63	48	36	27	10	4	1	0
Placebo + CP	187	184	180	172	170	158	149	136	128	118	108	102	97	93	90	85	76	62	43	30	18	9	3	2	0

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

OS data cutoff September 22, 2023.[6] PFS data cutoff September 28, 2022.[7]

IMPORTANT SAFETY INFORMATION (CONT'D)

Infusion-Related Reactions

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

Complications of Allogeneic HSCT

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

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In Primary Advanced or Recurrent EC

The Safety Profile of JEMPERLI + CP Has Been Well Established With 3+ Years of Median Efficacy Follow-up[1,6]

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

Adverse Reaction	JEMPERLI + CP (N=241)		Placebo + CP (N=246)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Nervous System Disorders				
Peripheral neuropathy*	64	4.1	61	2.0
General				
Fatigue†	56	3.3	63	5
Gastrointestinal Disorders				
Nausea	54	2.9	46	1.6
Constipation	35	0.4	36	0
Diarrhea	32	1.7	29	0.8
Abdominal pain‡	24	2.5	29	2
Vomiting	20	1.7	20	1.6
Skin and Subcutaneous Tissue				
Alopecia	54	0	50	1.2
Rash§	37	7	18	1.2
Musculoskeletal and Connective Tissue				
Arthralgia	37	1.2	35	0.4
Respiratory, Thoracic and Mediastinal Disorders				
Dyspnea¶	23	1.7	26	0.8
Metabolism and Nutrition Disorders				
Decreased appetite	22	2.1	18	0.4
Infections and Infestations				
Urinary tract infection**	21	3.3	18	1.6

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

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Jemperli (dostarlimab-gxly) Injection 500 mg

In Primary Advanced or Recurrent EC

The Safety Profile of JEMPERLI + CP Has Been Well Established With 3+ Years of Median Efficacy Follow-up (cont'd)[1,6]

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[1]
- 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[1]
- 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%)[1]
- Fatal adverse reactions occurred in 1.2% of patients receiving JEMPERLI including septic shock (0.8%) and myelosuppression (0.4%)[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

Embryo-Fetal Toxicity and Lactation

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in 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.

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 full Prescribing Information, including Medication Guide.

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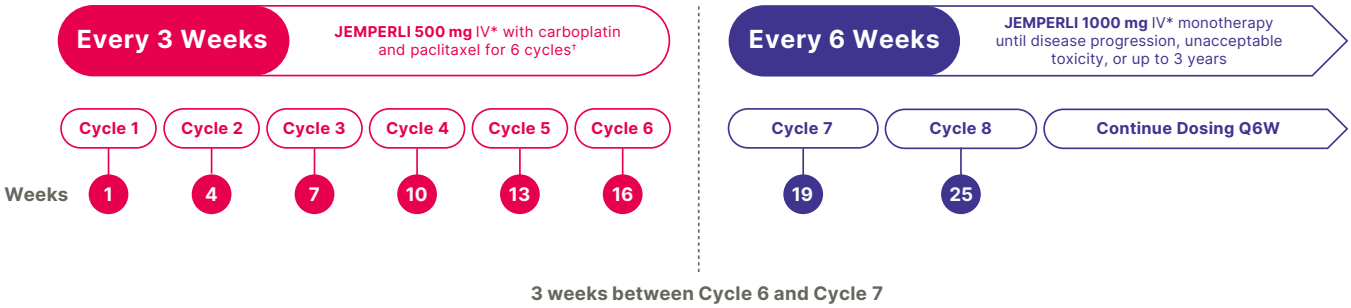
JEMPERLI + CP Dosing Established in RUBY Part 1

Deliver a Proven Regimen: Combination Upfront, Then JEMPERLI Monotherapy[1]

Recommended dosage of JEMPERLI in primary advanced or recurrent endometrial cancer[1]



3 weeks between Cycle 6 and Cycle 7

- 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 intravenous 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

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.

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Jemperli (dostarlimab-gxly) Injection 500 mg

In Patients With Primary Advanced or Recurrent EC

The First and Only IO Combination With a Statistically Significant OS Benefit in All-Comers vs CP Alone[1-6]

16-month improvement in median OS in all-comers vs CP alone[1]

Median OS with JEMPERLI + CP was 44.6 months vs 28.2 months with CP alone

- Significant OS benefit with HR 0.69 (95% CI: 0.54, 0.89*; *P*=0.002†)

Robust trial design that included patients with aggressive histologies[1,7-9]

Well-established safety profile[1]

- The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, nausea, alopecia, arthralgia, rash, constipation, diarrhea, abdominal pain, dyspnea, decreased appetite, urinary tract infection, and vomiting[1]

NCCN RECOMMENDATION

CATEGORY 1
PREFERRED OPTION

Dostarlimab-gxly (JEMPERLI) in combination with carboplatin-paclitaxel is included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as an NCCN Category 1 preferred treatment option for primary or adjuvant therapy for stage III-IV‡ endometrial carcinoma and as an NCCN Category 1 preferred first-line therapy option for recurrent endometrial carcinoma.[12]

Category 1—Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[12]
NCCN=National Comprehensive Cancer Network.
*Based on stratified Cox regression model.[1] †One-sided *P*-value based on stratified log-rank test was statistically significant.[1] ‡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.[12]

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.

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

Jemperli (dostarlimab-gxly) Injection 500 mg

References

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IMPORTANT SAFETY INFORMATION (CONT'D)

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.
- 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.

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.

Please see full Prescribing Information, including Medication Guide.

File name: RUBY Core Summary Brochure

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