

# Let their light *Shine* with JEMPERLI

JEMPERLI + CP is still the **ONLY** FDA-approved IO combination with **a proven 16-month survival** benefit vs CP alone in primary advanced or recurrent endometrial cancer<sup>1-6\*</sup>

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.<sup>1,6</sup>



Actor Portrayal

\*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.<sup>1</sup>

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

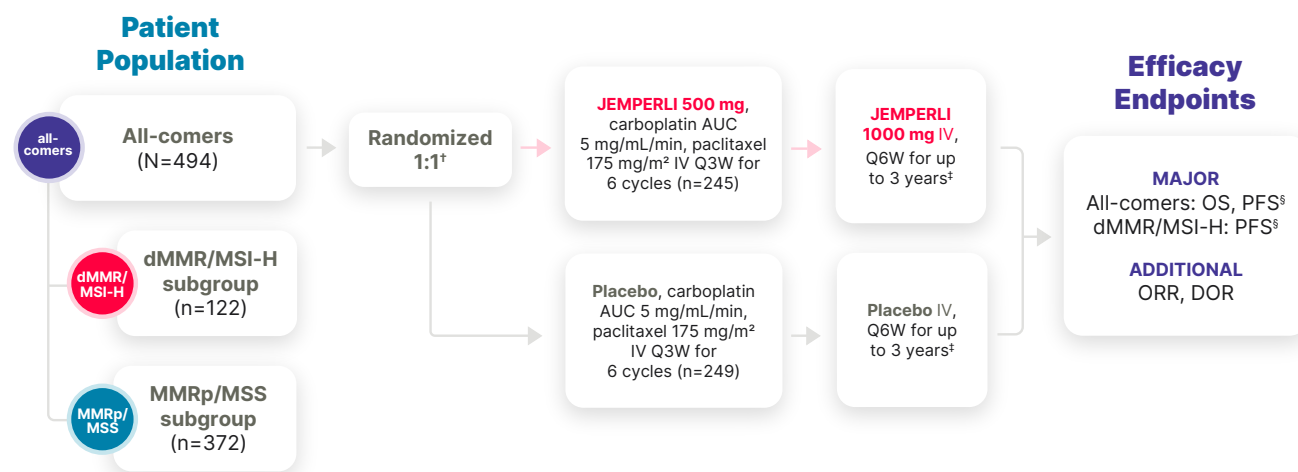
### Severe and Fatal Immune-Mediated Adverse Reactions

- 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 full **Prescribing Information**, including **Medication Guide**.

In Primary Advanced or Recurrent Endometrial Cancer

## After >4 Years, JEMPERLI + CP Still Has the Longest Follow-Up for an FDA-Approved Immunotherapy Combination to Date<sup>1-7\*</sup>



There were 2 different classifications of the MMR/MSI status<sup>1,6,8</sup>:

- Classification at randomization (randomized population): Classification based on the MMR/MSI status entered at randomization and locked in upon randomization, presented in the US Prescribing Information
- Source-verified classification (source-verified population): MMR/MSI status initially entered at randomization was later source-verified to correct misclassifications

\*Median duration of follow-up, defined as time from randomization to data cutoff, was 55.6 months (cutoff date April 22, 2025) in the dMMR/MSI-H subgroup.<sup>7</sup>

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

<sup>‡</sup>Treatment continued until disease progression, unacceptable toxicity, or a maximum of 3 years.<sup>1</sup> <sup>§</sup>PFS assessed by the investigator according to RECIST v1.1.<sup>1</sup>

AUC=area under the curve; DOR=duration of response; IV=intravenous; MMR=mismatch repair; MMRp=mismatch repair proficient; MSI=microsatellite instability; MSS=microsatellite stable; ORR=objective response rate; OS=overall survival.

## 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.

Please see additional Important Safety Information throughout 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<sup>1,8</sup>

**Primary FIGO Stage III or Stage IV disease**, including patients with more aggressive histologies such as carcinosarcoma and serous adenocarcinoma<sup>1,8-10</sup>

Measurable Disease <sup>1*</sup>	Measurable* or Non-Measurable Disease <sup>1</sup>
Stage IIIA-IIIIC1	Stage IIIIC1 patients with carcinosarcoma, clear cell, serous, or mixed histology (≥10% carcinosarcoma, clear cell, or serous histology)
	Stage IIIIC2 or IV

**First recurrent endometrial cancer** with a low potential for cure by radiation therapy or surgery alone or in combination, including those<sup>1</sup>:

- 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<sup>11</sup>**

\*Measurable or evaluable by RECIST v1.1.<sup>1</sup>

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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In Primary Advanced or Recurrent Endometrial Cancer

## RUBY Part 1 Had an Inclusive Trial Population Designed to Include Patients With Aggressive Histologies<sup>1,8-10</sup>

### MMR Status

**24%**  
dMMR/MSI-H

**76%**  
MMRp/MSS

### Age

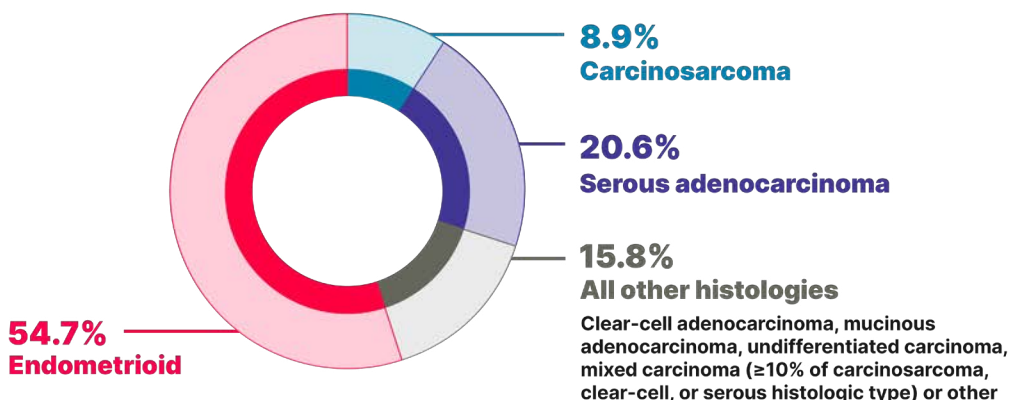
**51%** 65 Years or Older

### Race/Ethnicity

**77%** White   **12%** Black   **3%** Asian

**3%**  
Hispanic or Latino

### Histologies



### Disease Status



## 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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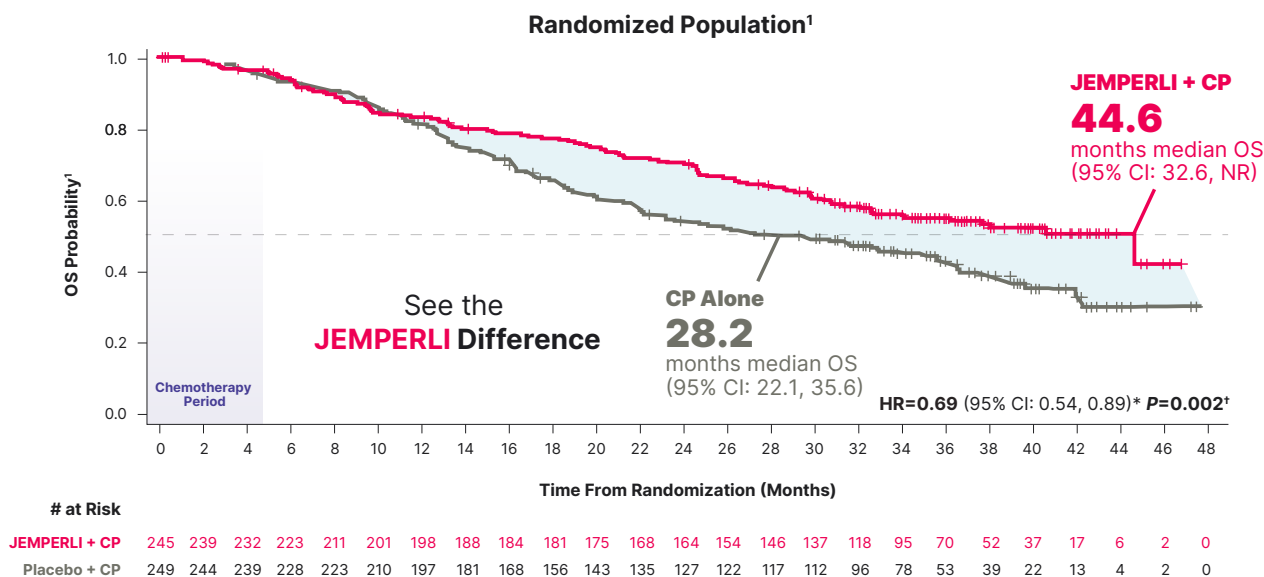
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## Primary Advanced or Recurrent Endometrial Cancer: Major Endpoints



### JEMPERLI + CP Is the Only FDA-Approved IO Regimen With a Proven 16-Month Survival Benefit vs CP Alone<sup>1-6</sup>

Statistically significant 31% reduction in the risk of death with JEMPERLI + CP vs CP alone<sup>1</sup>



- 76% of all-comers had MMRp/MSS biomarker status<sup>1</sup>
- Estimated Kaplan-Meier probability of overall survival 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<sup>6</sup>
- **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<sup>†</sup>)<sup>1</sup>

Overall survival data cutoff September 22, 2023.<sup>6</sup>

\*Based on stratified Cox regression model.<sup>1</sup> †One-sided P-value based on stratified log-rank test was statistically significant.<sup>1</sup>

## 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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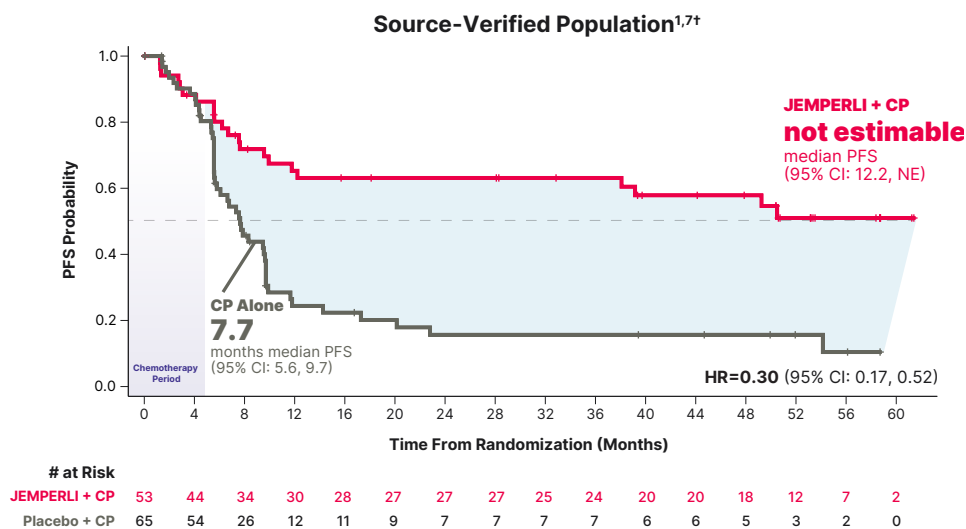
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## Major Endpoint and Post Hoc Analysis

dMMR/  
MSI-H

# A Post Hoc Analysis Reinforces Primary Findings With an Estimated 57.9% of Patients Observed to Be Alive Without Progression on JEMPERLI + CP at 4 Years vs 15.7% With CP Alone<sup>1,7\*</sup>

The post hoc analysis was not powered to detect treatment differences; results are descriptive<sup>8</sup>



### Primary analysis (randomized population)

Median PFS, a powered major endpoint, 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<sup>‡</sup>;  $P < 0.0001$ <sup>§</sup>)<sup>1</sup>

### Initial analysis of source-verified PFS data

was consistent with the randomized population based on post hoc sensitivity analyses. 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)<sup>8,12,13</sup>

- Estimated Kaplan-Meier probability of source-verified PFS at 48 months was 57.9% (95% CI: 42.3, 70.6) with JEMPERLI + CP and 15.7% (95% CI: 7.2, 27.0) with CP alone<sup>7</sup>

Data cutoff of September 28, 2022, for the initial analysis of the randomized and source-verified populations. Data cutoff of April 22, 2025, for the 4-year analysis of the source-verified population.<sup>7,8</sup>

\*Median follow-up of 55.6 months (range 49.9-67.7).<sup>7</sup> †Of the 494 randomized patients, 118 had dMMR/MSI-H tumors confirmed by source-verified classification.<sup>8</sup> ‡Based on stratified Cox regression model.<sup>1</sup> §One-sided  $P$ -value based on stratified log-rank test was statistically significant.<sup>1</sup>

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

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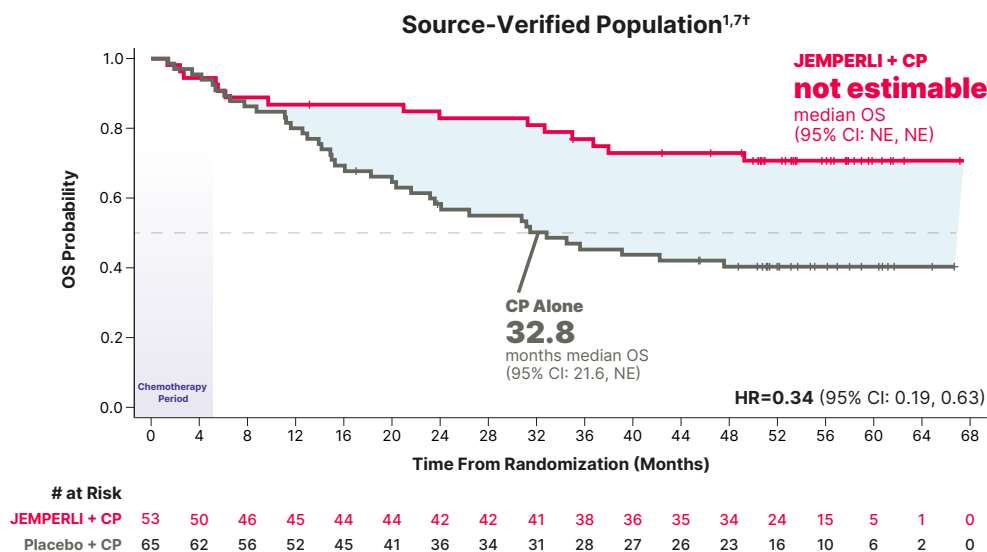
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## Exploratory Analyses

dMMR/  
MSI-H

### After >4 Years in a Post Hoc Analysis, Median Overall Survival Was Still Not Observed With JEMPERLI + CP<sup>7\*</sup>

The exploratory analyses (randomized and source-verified<sup>†</sup>) for overall survival were not powered to detect treatment differences; results are descriptive<sup>1,6,8</sup>



#### Prespecified exploratory analysis from primary analysis (randomized population)

Median OS was not reached (95% CI: NR, NR) with JEMPERLI + CP vs 30.8 months (95% CI: 18.7, NR) with CP alone (HR=0.34; 95% CI: 0.18, 0.62)<sup>1,14‡</sup>

- Estimated Kaplan-Meier probability of source-verified overall survival at 48 months was 72.8% (95% CI: 58.5, 82.9) with JEMPERLI + CP vs 40.3% (95% CI: 28.2, 52.1) with CP alone<sup>7</sup>

Initial analysis of OS in the dMMR/MSI-H source-verified population below was consistent with the randomized population based on post hoc sensitivity analyses<sup>6,8,13,15†</sup>

- 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)

Data cutoff of September 22, 2023, for the initial analysis of the randomized and source-verified populations. Data cutoff of April 22, 2025, for the 4-year analysis of the source-verified population.<sup>6,7</sup>

\*Median follow-up of 55.6 months (range 49.9-67.7).<sup>7</sup> †Of the 494 randomized patients, 118 had dMMR/MSI-H tumors confirmed by source-verified classification.<sup>8</sup>

‡Based on stratified Cox regression model.<sup>1</sup>

## 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 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

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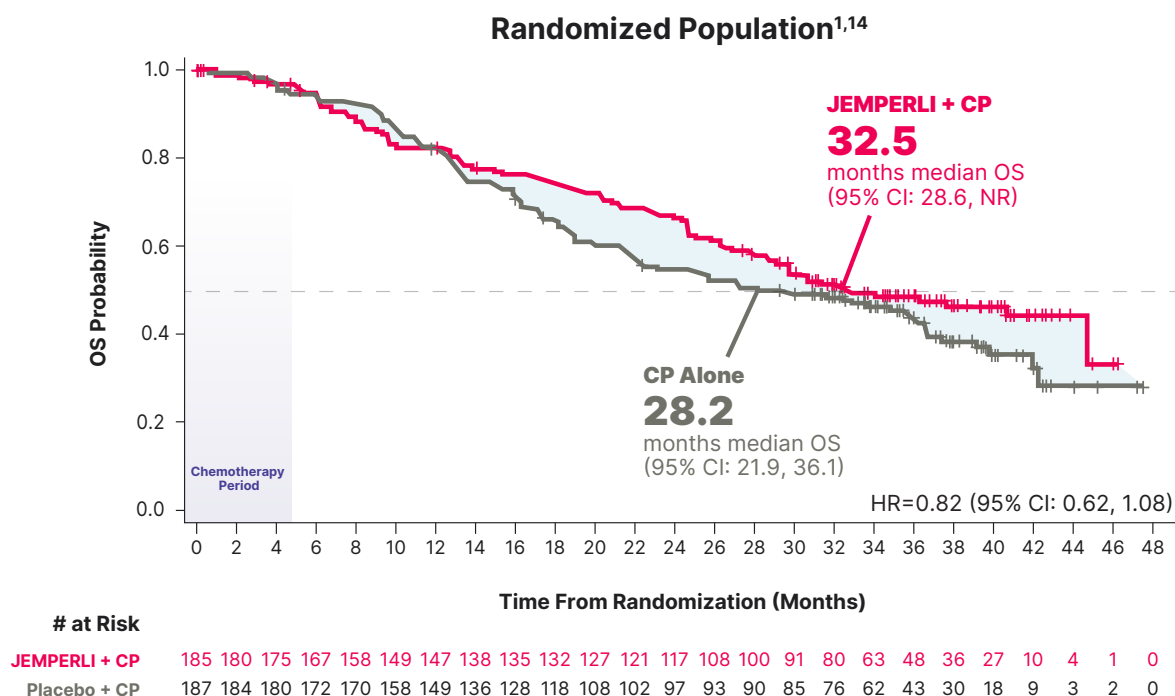
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## Exploratory Analyses



# JEMPERLI + CP Expands Treatment Possibilities for Appropriate Patients With an Observed Improvement in Survival vs CP Alone<sup>1,14</sup>

The prespecified exploratory analyses (randomized) for overall survival and PFS were not powered to detect treatment differences; results are descriptive<sup>1,6,8</sup>



- Median PFS, an exploratory endpoint in the randomized population, 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)<sup>1</sup>

Overall survival data cutoff September 22, 2023.<sup>6</sup> PFS data cutoff September 28, 2022.<sup>8</sup>

## 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.

### 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. 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.

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## Exploratory Analyses



# A Clinically Meaningful 7-Month Survival Improvement Was Observed With JEMPERLI + CP vs CP Alone Based on Source-Verified Data<sup>6,8,12,15,16\*</sup>

The prespecified exploratory analyses (source-verified) for overall survival and PFS were not powered to detect treatment differences; results are descriptive<sup>1,6,8</sup>

- Median OS was 34.0 months (95% CI: 28.6, NE) with JEMPERLI + CP vs 27.0 months (95% CI: 21.5, 35.6) with CP alone (HR=0.79; 95% CI: 0.60, 1.04)<sup>6,8,12,15,16</sup>
- 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)<sup>6,8,12,15,16</sup>



Of the 494 randomized patients, 376 had MMRp/MSS tumors confirmed by source-verified classification<sup>1,6,8</sup>

Overall survival data cutoff September 22, 2023.<sup>6</sup> PFS data cutoff September 28, 2022.<sup>8</sup>

\*Clinically meaningful defined as at least 20% relative improvement in median overall survival.<sup>16</sup>

## IMPORTANT SAFETY INFORMATION (CONT'D)

### Common Adverse Reactions

The most common adverse reactions ( $\geq 20\%$ ), 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 ( $\geq 20\%$ ) 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.

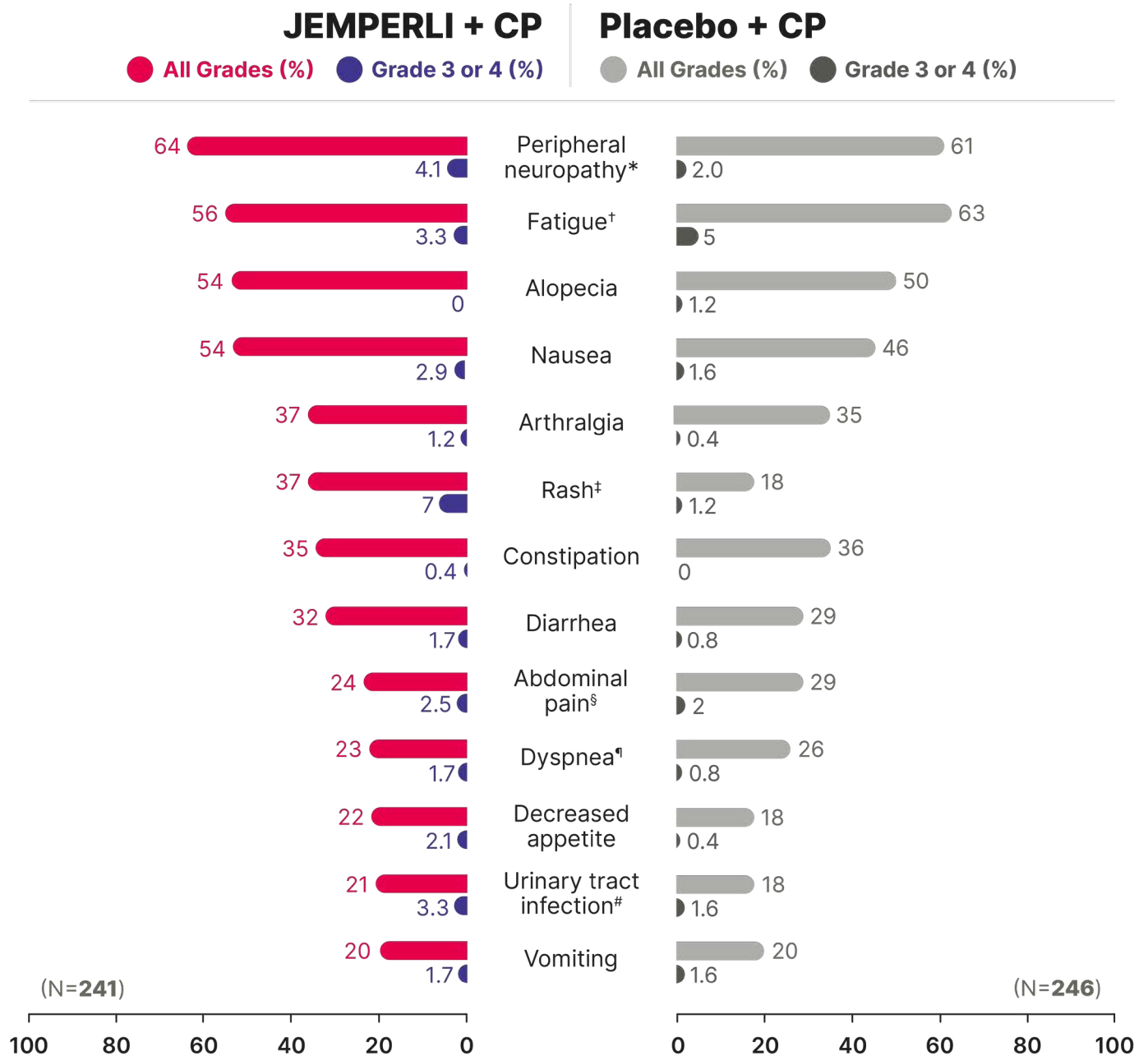
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In Primary Advanced or Recurrent Endometrial Cancer

# The Safety Profile of JEMPERLI + CP Has Been Well Established in RUBY Part 1<sup>1</sup>

Adverse Reactions (≥20%) in Patients Who Received JEMPERLI + CP in RUBY Part 1<sup>1</sup>



Graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03.<sup>1</sup>

\*Includes neuropathy peripheral and peripheral sensory neuropathy.<sup>1</sup> †Includes fatigue and asthenia.<sup>1</sup> ‡Includes rash, rash maculo-papular, palmar-plantar erythrodysesthesia syndrome, rash pustular, skin exfoliation, and vulvovaginal rash.<sup>1</sup> §Includes abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain, abdominal discomfort, epigastric discomfort, and abdominal tenderness.<sup>1</sup> ¶Includes dyspnea and dyspnea exertional.<sup>1</sup> #Includes urinary tract infection, urinary tract infection bacterial, cystitis, and pyelonephritis.<sup>1</sup>

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



## In Primary Advanced or Recurrent Endometrial Cancer

# The Safety Profile of JEMPERLI + CP Has Been Well Established in RUBY Part 1 (cont'd)<sup>1</sup>

- In patients receiving JEMPERLI + CP, 19% (n=46) of patients permanently discontinued JEMPERLI due to adverse reactions<sup>1</sup>
- Adverse reactions that required permanent discontinuation in  $\geq 2$  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<sup>1</sup>
- The most common adverse reactions, including laboratory abnormalities ( $\geq 20\%$ ), 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<sup>1</sup>
- 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%)<sup>1</sup>
- Fatal adverse reactions occurred in 1.2% of patients receiving JEMPERLI including septic shock (0.8%) and myelosuppression (0.4%)<sup>1</sup>



**In the last 2.5 years of follow-up, the safety profile in the dMMR/MSI-H population was observed to be consistent with the established RUBY Part 1 safety profile<sup>1,7</sup>**

## 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  $\leq$ Grade 1. Upon improvement to  $\leq$ 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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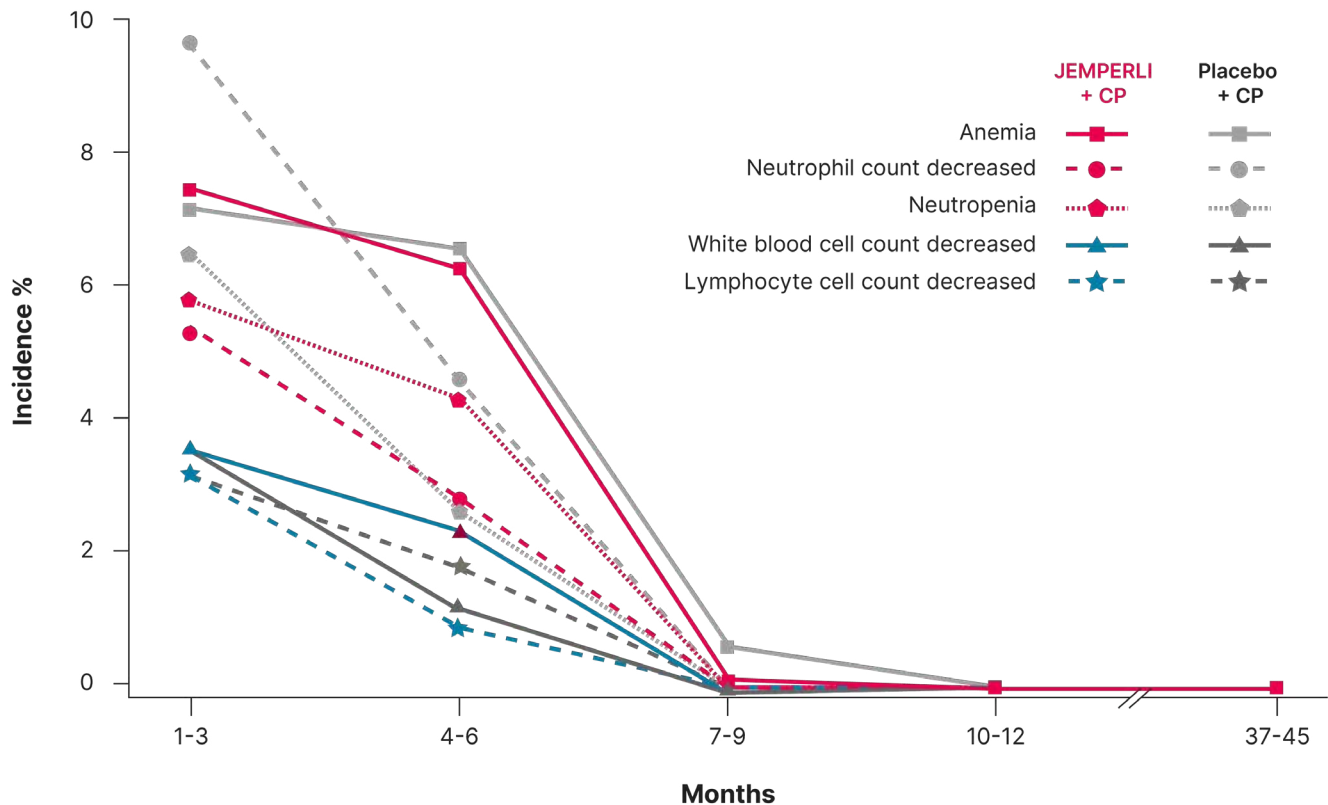
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## In the RUBY Part 1 Trial, the 5 Most Common Grade $\geq 3$ TRAEs Were Observed Primarily During the First 3-6 Months<sup>17</sup>

Treatment-related adverse events (TRAEs) were defined by the investigator as adverse events for which a causal relationship between any study treatment, like JEMPERLI, carboplatin, or paclitaxel, and the adverse event was a reasonable possibility.<sup>18</sup>

- Grade  $\geq 3$  TRAEs in the RUBY Part 1 trial occurred in 53% of patients receiving JEMPERLI + CP (n=128/241) vs 47% of patients receiving placebo + CP (n=115/246)<sup>18</sup>

### Time to onset for the most common Grade $\geq 3$ TRAEs (>4% in either arm)<sup>17</sup>



- The most common Grade  $\geq 3$  TRAEs (>4% in either arm) were anemia, decreased neutrophil count, neutropenia, decreased white blood cell count, and decreased lymphocyte cell count<sup>17</sup>
- Patients received CP in combination with JEMPERLI during the first ~4 months of RUBY Part 1 (Q3W for 6 cycles)<sup>1</sup>

**Monitoring is important, as adverse reactions may occur anytime** during or after discontinuation of treatment and may require corticosteroid or other treatment and interruption or discontinuation of JEMPERLI.<sup>1</sup>

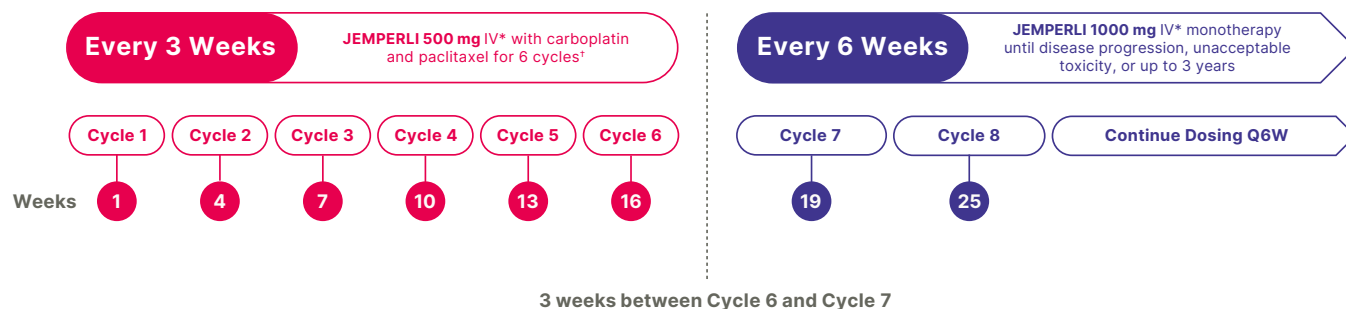
Please see Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#).

**Jemperli**   
(dostarlimab-gxly) Injection 500 mg

## JEMPERLI + CP Dosing Established in RUBY Part 1

# Deliver a Proven Regimen: Combination Upfront, Then JEMPERLI Monotherapy<sup>1</sup>

## Recommended dosage of JEMPERLI in primary advanced or recurrent endometrial cancer<sup>1</sup>



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

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

## 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

# National Comprehensive Cancer Network® (NCCN®)

# NCCN

## CATEGORY 1 PREFERRED OPTION

Dostarlimab-gxly (JEMPERLI) with carboplatin-paclitaxel has the broadest recommendation from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for an IO combination as an NCCN category 1 preferred option for primary (stage III-IV\*) or recurrent endometrial carcinoma<sup>19†</sup>

- With a statistically significant and clinically meaningful<sup>‡</sup> overall survival benefit in the overall population<sup>16</sup>
- 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.<sup>19</sup> Preferred intervention – Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.<sup>19</sup>

\*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.<sup>19</sup> †For adult patients with recurrent endometrial carcinoma with or without measurable disease.<sup>19</sup> ‡Clinically meaningful defined as at least 20% relative improvement in median overall survival.<sup>16</sup>

## 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%).

### Immune-Mediated Endocrinopathies (cont'd)

- Thyroid Disorders (cont'd)
  - 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.

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**Jemperli**   
(dostarlimab-gxly) Injection 500 mg

# JEMPERLI + CP Has the Most Robust Survival Evidence to Date for an IO Regimen vs CP Alone in All-Comers<sup>1-7</sup>

## ONLY JEMPERLI + CP HAD

all-comers

**A statistically significant 16-month improvement in median overall survival vs CP alone** and a significant improvement in PFS vs CP alone<sup>1,6</sup>

- Randomized median OS was 44.6 months vs 28.2 months with CP alone (HR=0.69; 95% CI: 0.54, 0.89\*;  $P=0.002^{\dagger}$ )
- Randomized median PFS was 11.8 months vs 7.9 months with CP alone (HR=0.64; 95% CI: 0.51, 0.80\*;  $P<0.0001^{\dagger}$ )

dMMR/MSI-H

**Improvement in PFS vs CP alone in the primary analysis reinforced by a post hoc analysis<sup>†</sup> of  $\geq 4$  years<sup>1,7,8,12,13§</sup>**

- Primary analysis of randomized median PFS was 30.3 months vs 7.7 months with CP alone (HR=0.29; 95% CI: 0.17, 0.50;  $P<0.0001$ )
- Initial analysis of source-verified median PFS was not estimable vs 7.7 months with CP alone (HR=0.28; 95% CI: 0.16, 0.50)
- 4-year post hoc analysis of source-verified median PFS was not estimable vs 7.7 months with CP alone (HR=0.30; 95% CI: 0.17, 0.52)

MMRp/MSS

**Exploratory analyses with an observed 4-month survival improvement in the randomized population and a clinically meaningful<sup>†</sup> 7-month survival improvement in the source-verified population vs CP alone<sup>1,6,8,15,16†</sup>**

- Randomized median OS was 32.5 months vs 28.2 months with CP alone (HR=0.82; 95% CI: 0.62, 1.08)
- Source-verified median OS was 34.0 months vs 27.0 months with CP alone (HR=0.79; 95% CI: 0.60, 1.04)

\*Based on stratified Cox regression model.<sup>1</sup> †One-sided  $P$ -value based on stratified log-rank test was statistically significant.<sup>1</sup> ‡The exploratory analyses were not powered to detect treatment differences; results are descriptive.<sup>1,6,8</sup> §Median follow-up of 55.6 months (range 49.9–67.7).<sup>7</sup> ¶Clinically meaningful defined as at least 20% relative improvement in median overall survival.<sup>16</sup>

Find JEMPERLI coverage information with our coverage finder tool at [JEMPERLIHCP.com](http://JEMPERLIHCP.com)

## IMPORTANT SAFETY INFORMATION (CONT'D)

### Immune-Mediated Endocrinopathies (cont'd)

- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis (cont'd)
  - 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 full **Prescribing Information**, including **Medication Guide**.

**Jemperli**   
(dostarlimab-gxly) Injection 500 mg

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## IMPORTANT SAFETY INFORMATION (CONT'D)

### Immune-Mediated Endocrinopathies (cont'd)

- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis (cont'd)
  - 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 additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.**

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