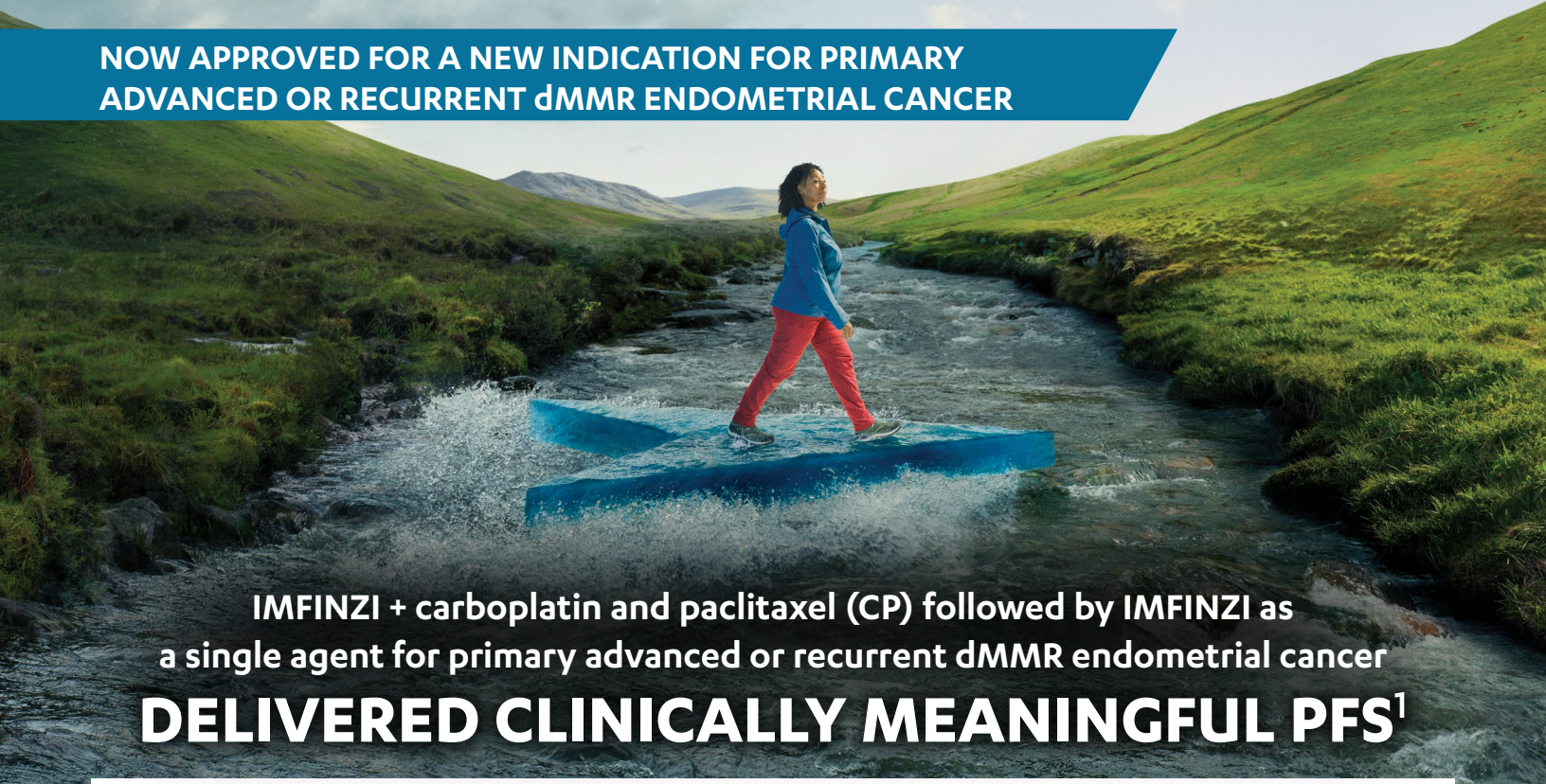
NOW APPROVED FOR A NEW INDICATION FOR PRIMARY ADVANCED OR RECURRENT dMMR ENDOMETRIAL CANCER



IMFINZI + carboplatin and paclitaxel (CP) followed by IMFINZI as a single agent for primary advanced or recurrent dMMR endometrial cancer

DELIVERED CLINICALLY MEANINGFUL PFS[1]

PRESPECIFIED EXPLORATORY ANALYSIS OF PFS IN THE dMMR SUBGROUP[1]

58% REDUCTION IN THE RISK OF PROGRESSION OR DEATH

with IMFINZI + CP

HR=0.42 (95% CI, 0.22-0.80)

NR mPFS
with IMFINZI + CP
(95% CI, NR-NR)

and

7.0 month mPFS
with CP
(95% CI, 6.7-14.8)

FDA approval was based on a prespecified dMMR subgroup (n=95). The prespecified PFS subgroup analysis was exploratory and not designed to assess a statistical difference between treatment groups.[1]

CI=confidence interval; dMMR=deficient mismatch repair; HR=hazard ratio; mPFS=median progression-free survival; NR=not reached; PFS=progression-free survival.

Indication:

IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

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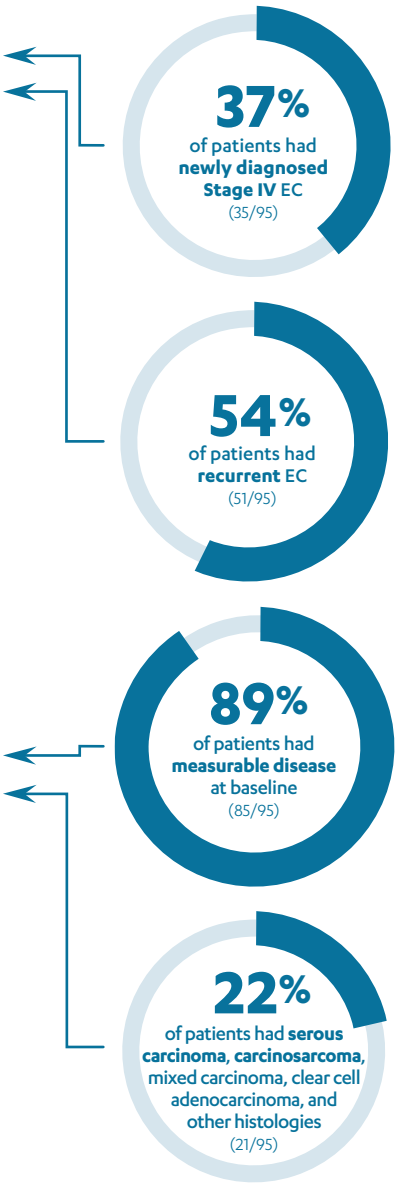
IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

The DUO-E study included dMMR patients with a range of characteristics, including those with aggressive disease[2,3]

PATIENT CHARACTERISTICS IN THE dMMR SUBGROUP[2]

	IMFINZI + CP (n=46)	CP (n=49)
Disease status*		
Newly diagnosed	43%	49%
FIGO Stage III/IV	13%/30%	6%/43%
Recurrent	57%	51%
Region*		
Asia	30%	29%
Rest of the world	70%	71%
Age (years)		
Median (range)	63 (45-84)	63 (34-85)
Race		
White	63%	61%
Asian	30%	31%
Black/African American	0%	4%
American Indian/Alaska Native	2%	0%
Other or not reported	4%	4%
Ethnicity		
Not Hispanic or Latino	89%	92%
Hispanic or Latino	9%	6%
ECOG performance status		
0/1	50%/50%	59%/41%
Measurable disease at baseline		
Yes	91%	86%
Histology type at diagnosis		
Endometrioid	72%	84%
Serous	4%	4%
Carcinosarcoma	7%	4%
Mixed, epithelial	7%	6%
Clear cell	0%	0%
Undifferentiated	2%	0%
Mucinous or other	9%	2%
Prior chemotherapy	13%	10%
Prior radiotherapy	37%	37%
Prior surgery	91%	78%

PATIENTS IN BOTH ARMS HAD CHARACTERISTICS ASSOCIATED WITH AGGRESSIVE DISEASE[3]



Percentages may not total 100% because of rounding. Data on ethnicity was missing for 6 patients; 1 newly diagnosed patient was FIGO Stage I and 1 was FIGO Stage II; 1 patient in the IMFINZI + CP arm had an ECOG PS of 2.

*Stratification factors (MMR status [proficient vs deficient], disease status [newly diagnosed vs recurrent], and geographic region [Asia vs non-Asia]) are in accordance with the randomization code. "Asia" included China, Hong Kong, India, Japan, Singapore, and Republic of Korea.

ECOG=Eastern Cooperative Oncology Group; FIGO=International Federation of Gynecology and Obstetrics; PS=performance status; Q3W=every 3 weeks; Q4W=every 4 weeks.

Study design: The DUO-E study was a global, randomized, double-blind, placebo-controlled, Phase III study of 718 patients with advanced or recurrent endometrial cancer who were randomized 1:1:1. In a prespecified, exploratory subgroup of 143 patients with advanced or recurrent dMMR endometrial cancer, patients received treatment with IMFINZI 1120 mg + CP Q3W followed by IMFINZI 1500 mg monotherapy Q4W (n=46), placebo + CP Q3W followed by placebo (n=49), or an investigational combination regimen (n=48; this investigational regimen is not FDA approved for use). All treatments were given until disease progression or unacceptable toxicity. For patients with recurrent disease, prior chemotherapy was allowed only if it was administered in the adjuvant setting and there was at least 12 months from the date of last dose of chemotherapy administered to the date of subsequent relapse. PFS in patients with dMMR endometrial cancer was a prespecified exploratory endpoint.[1,4]

Please see additional Important Safety Information throughout and click here for Full Prescribing Information including Medication Guide for IMFINZI.

In primary advanced or recurrent dMMR endometrial cancer

IMFINZI + CP cut the risk of progression or death by more than half[1]

PRESPECIFIED EXPLORATORY ANALYSIS OF PFS IN THE dMMR SUBGROUP[1]

58% REDUCTION IN THE RISK OF PROGRESSION OR DEATH
with IMFINZI + CP

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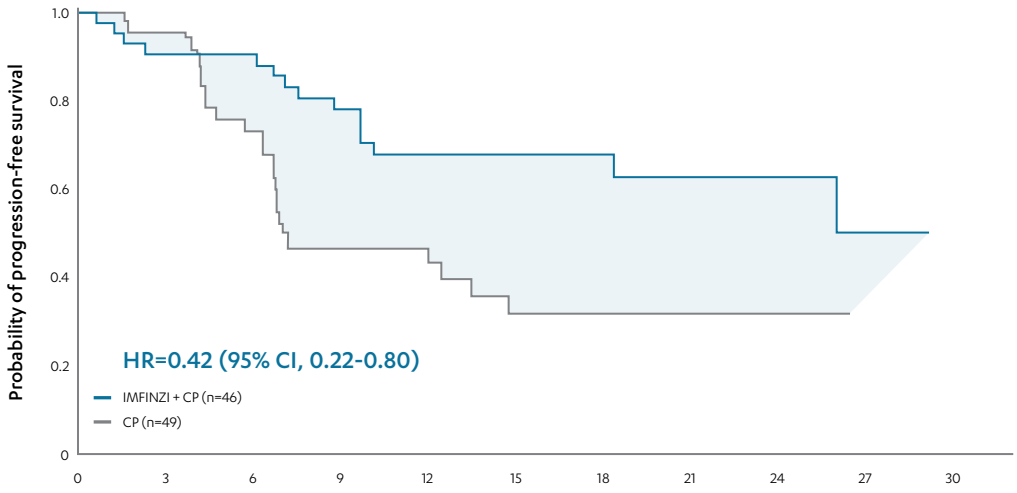

Number of patients at risk

IMFINZI + CP	46	37	36	31	26	19	14	9	5	2	0
CP	49	41	28	17	13	8	5	2	2	0	0

~2 of 3 patients were estimated to be alive and progression free at 18 months with IMFINZI + CP[5]

18-month PFS rate: **67.9% with IMFINZI + CP and 31.7% with CP**

- **FDA approval was based on a prespecified dMMR subgroup (n=95). The prespecified PFS subgroup analysis was exploratory and not designed to assess a statistical difference between treatment groups[1]**
- Median duration of follow-up: 15.5 months for IMFINZI + CP and 10.2 months for CP; data cutoff: April 12, 2023[4,6]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)

Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate. Withhold or permanently discontinue IMFINZI depending on severity.

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IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

In primary advanced or recurrent dMMR endometrial cancer

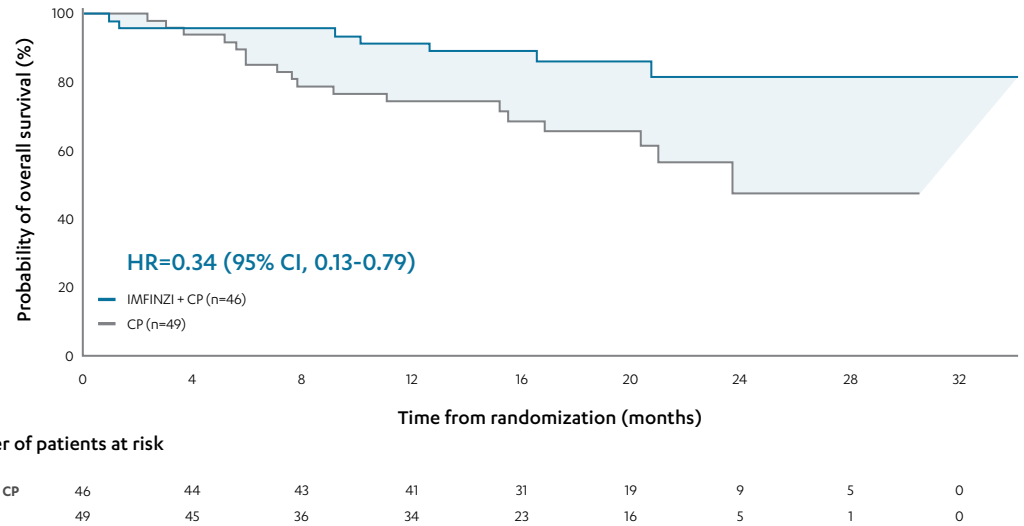
Overall survival results at the interim analysis

POST-HOC EXPLORATORY ANALYSIS OF OS IN THE dMMR SUBGROUP[2]

NR mOS
with IMFINZI + CP
(95% CI, NR-NR)

and

23.7 month mOS
with CP
(95% CI, 16.9-NR)



Number of patients at risk

IMFINZI + CP	46	44	43	41	31	19	9	5	0
CP	49	45	36	34	23	16	5	1	0

86.1% **of patients were estimated to be alive at 18 months with IMFINZI + CP[2]**
18-month OS rate: **86.1% with IMFINZI + CP and 65.8% with CP**

- **FDA approval was based on a prespecified dMMR subgroup (n=95). The post-hoc OS subgroup analysis was exploratory and not designed to assess a statistical difference between treatment groups[1,2]**
- **OS was immature at 26%**; median duration of follow-up: 19.1 months for IMFINZI + CP and 18.4 months for CP; data cutoff: April 12, 2023[1,2]

mOS=median overall survival; OS=overall survival.

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)

See USPI Dosing and Administration for specific details. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

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Safety and tolerability profile

- Serious ARs occurred in 30% of patients who received IMFINZI + CP. The most common serious ARs (≥4%) were constipation (4.5%) and rash (4.5%)[1]
- The most common ARs (>20%), including laboratory abnormalities, were peripheral neuropathy, musculoskeletal pain, nausea, alopecia, fatigue, abdominal pain, constipation, rash, decreased magnesium, increased ALT, increased AST, diarrhea, vomiting, cough, decreased potassium, dyspnea, headache, increased alkaline phosphatase, and decreased appetite[1]
- Permanent discontinuation of IMFINZI due to adverse reactions occurred in 11% of patients. The AR that resulted in permanent discontinuation of IMFINZI (≥4%) was rash (4.5%)[1]
- Dosage interruptions of IMFINZI due to ARs occurred in 52% of patients. ARs that required dosage interruptions of IMFINZI (≥4%) were anemia (11%), thrombocytopenia (9%), neutropenia (9%), COVID-19 (9%), increased ALT (4.5%), and pneumonitis (4.5%)[1]

ALT=alanine aminotransferase; ARs=adverse reactions; AST=aspartate aminotransferase.

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-Mediated Colitis

IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis.

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency***: IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated.

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IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies (continued)

- ***Hypophysitis***: IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated.
- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated.
  - ***IMFINZI with Carboplatin and Paclitaxel***
    - Immune-mediated hypothyroidism occurred in 14% (34/235) of patients receiving IMFINZI in combination with carboplatin and paclitaxel.
- ***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.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis.

Immune-Mediated Dermatology Reactions

IMFINZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/L-1 antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

Other Immune-Mediated Adverse Reactions

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI or were reported with the use of other PD-1/PD-L1 blocking antibodies.

- ***Cardiac/vascular***: Myocarditis, pericarditis, vasculitis.
- ***Nervous system***: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
- ***Ocular***: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- ***Gastrointestinal***: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
- ***Musculoskeletal and connective tissue disorders***: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic.
- ***Endocrine***: Hypoparathyroidism.
- ***Other (hematologic/immune)***: 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

IMFINZI can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI based on the severity. See USPI Dosing and Administration for specific details. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses.

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IMPORTANT SAFETY INFORMATION (continued)

Complications of Allogeneic HSCT after IMFINZI

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on their mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. In females of reproductive potential, verify pregnancy status prior to initiating IMFINZI and advise them to use effective contraception during treatment with IMFINZI and for 3 months after the last dose of IMFINZI.

Lactation

There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for serious adverse reactions in breastfed infants from IMFINZI, advise women not to breastfeed during treatment and for 3 months after the last dose.

Adverse Reactions

- In patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study receiving IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single-agent (n=44), the most common adverse reactions, including laboratory abnormalities (occurring in ≥20% of patients) were peripheral neuropathy (61%), musculoskeletal pain (59%), nausea (59%), alopecia (52%), fatigue (41%), abdominal pain (39%), constipation (39%), rash (39%), decreased magnesium (36%), increased ALT (32%), increased AST (30%), diarrhea (27%), vomiting (27%), cough (27%), decreased potassium (25%), dyspnea (25%), headache (23%), increased alkaline phosphatase (20%), and decreased appetite (18%). The most common Grade 3 or 4 adverse reactions (≥3%) were constipation (4.5%) and fatigue (4.5%).
- In patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study receiving IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single-agent (n=44), permanent discontinuation of IMFINZI due to adverse reactions occurred in 11% of patients. Serious adverse reactions occurred in 30% of patients who received IMFINZI with carboplatin and paclitaxel; the most common serious adverse reactions (≥4%) were constipation (4.5%) and rash (4.5%).

The safety and effectiveness of IMFINZI has not been established in pediatric patients.

You may report side effects related to AstraZeneca products.

References: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **2.** Baurain J-F, Chon HS, Thomes-Pepin J, et al. Durvalumab + carboplatin/paclitaxel followed by durvalumab ± olaparib as a first-line treatment for endometrial cancer: overall survival and additional secondary efficacy endpoints by mismatch repair status in the DUO-E/GOG-3041/ENGOT-EN10 trial. Presented at: Society of Gynecologic Oncology Annual Meeting on Women's Cancer; March 16-18, 2024; San Diego, CA. **3.** Data on File, REF-232005, AstraZeneca Pharmaceuticals LP; 2024. **4.** Westin SN, Moore K, Chon HS, et al; DUO-E Investigators. Durvalumab plus carboplatin/paclitaxel followed by maintenance durvalumab with or without olaparib as first-line treatment for advanced endometrial cancer: the phase III DUO-E trial. *J Clin Oncol*. 2024;42(3):283-299. **5.** Chon HS, Thomes-Pepin J, Sundborg MJ, et al. Durvalumab + carboplatin/paclitaxel followed by durvalumab with or without olaparib as first-line treatment for endometrial cancer (DUO-E/GOG-3041/ENGOT-EN10): objective response rate and duration of response by mismatch repair status presentation. Presented at: Society of Gynecologic Oncology Annual Meeting on Women's Cancer; March 16-18, 2024; San Diego, CA. **6.** Data on File, REF-233132, AstraZeneca Pharmaceuticals LP; 2024.

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IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

NOW APPROVED FOR A NEW INDICATION

IMFINZI + CP in primary advanced or recurrent dMMR endometrial cancer

GIVE YOUR PATIENTS THE CHANCE TO BE PROGRESSION FREE FOR LONGER[1]

58%

58% reduction in risk of progression or death[1]

(HR=0.42; 95% CI, 0.22-0.80)

- mPFS not reached (95% CI, NR-NR) with IMFINZI + CP and 7.0 months (95% CI, 6.7-14.8) with CP

86.1%

86.1% of patients were estimated to be alive at 18 months[2]

- 18-month OS rate: 86.1% with IMFINZI + CP and 65.8% with CP
- mOS was not reached with IMFINZI + CP and was 23.7 months with CP (HR=0.34; 95% CI, 0.13-0.79)

Evaluated in patients with aggressive disease[2,3]

- Patient population included those with newly diagnosed Stage IV disease as well as those with serous carcinoma, carcinosarcoma, mixed carcinoma, clear cell adenocarcinoma, and other histologies

FDA approval was based on a prespecified dMMR subgroup (n=95). The prespecified PFS and post-hoc OS subgroup analyses were exploratory and not designed to assess a statistical difference between treatment groups; OS was immature at 26%.[1,2]

Choose IMFINZI + CP for your patients with primary advanced or recurrent dMMR endometrial cancer

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