IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Immune-Mediated Adverse Reaction Management Guide

Managing immune-mediated adverse reactions associated with IMFINZI + carboplatin and paclitaxel in primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR)

IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent is indicated for the treatment of primary advanced or recurrent dMMR endometrial cancer.

SELECT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

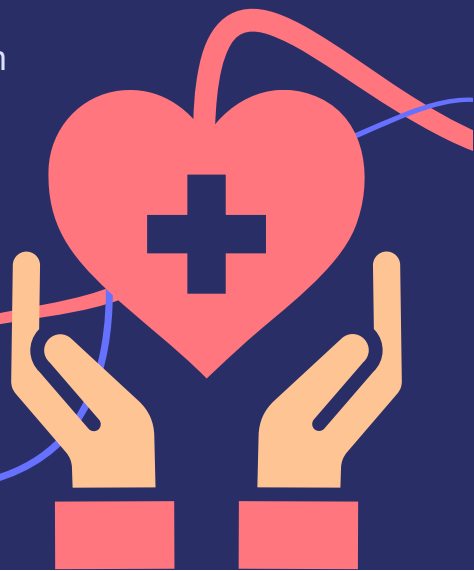
Immune-Mediated Adverse Reactions

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.

Please see Full Prescribing Information, including Medication Guide, for IMFINZI.

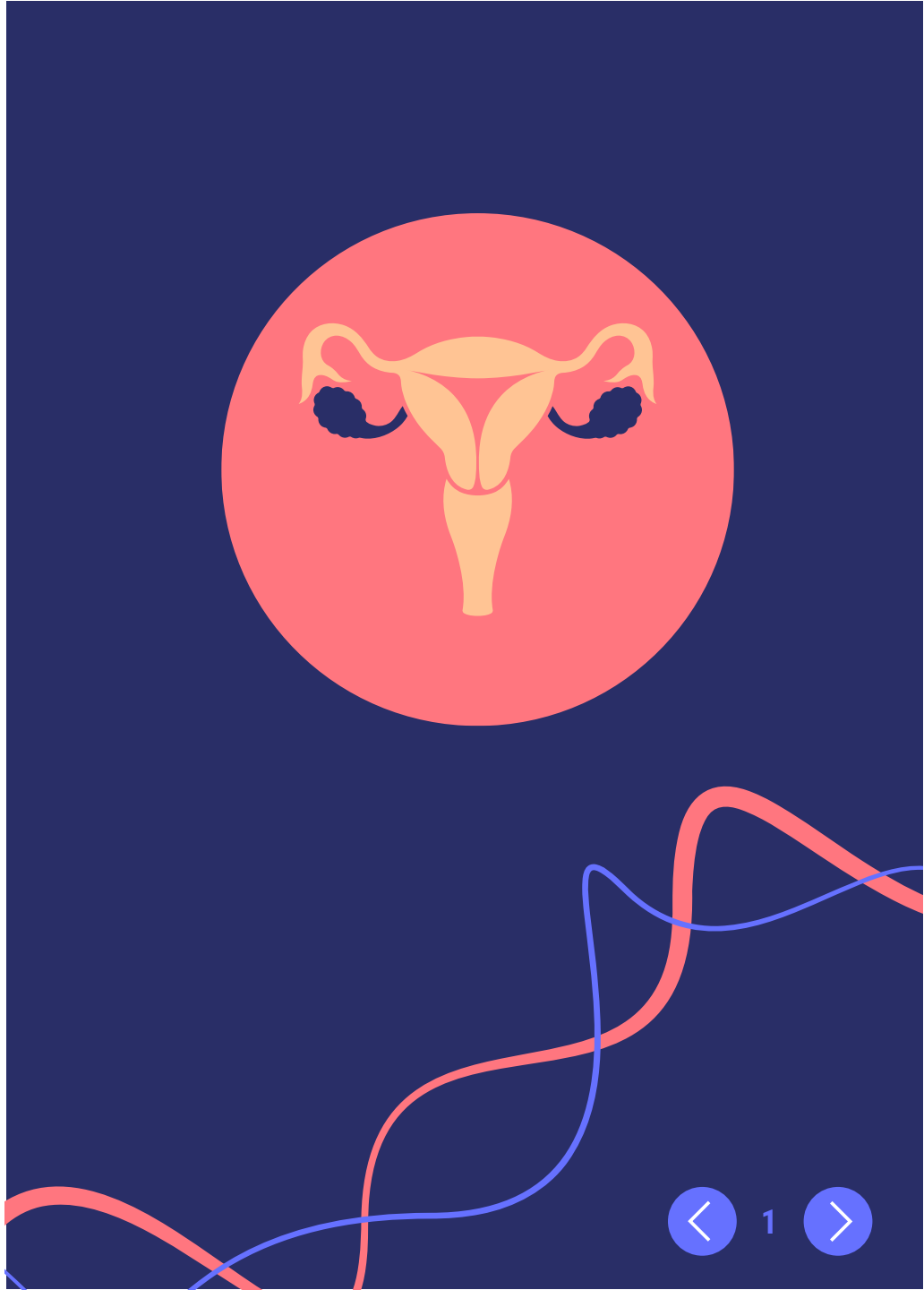
Select a topic from the menu to learn more.

US-98259 Last Updated 6/25



Indication[1]

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) as determined by an FDA-approved test.



FDA=United States Food and Drug Administration.

SELECT 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. See USPI Dosing and Administration for specific details.

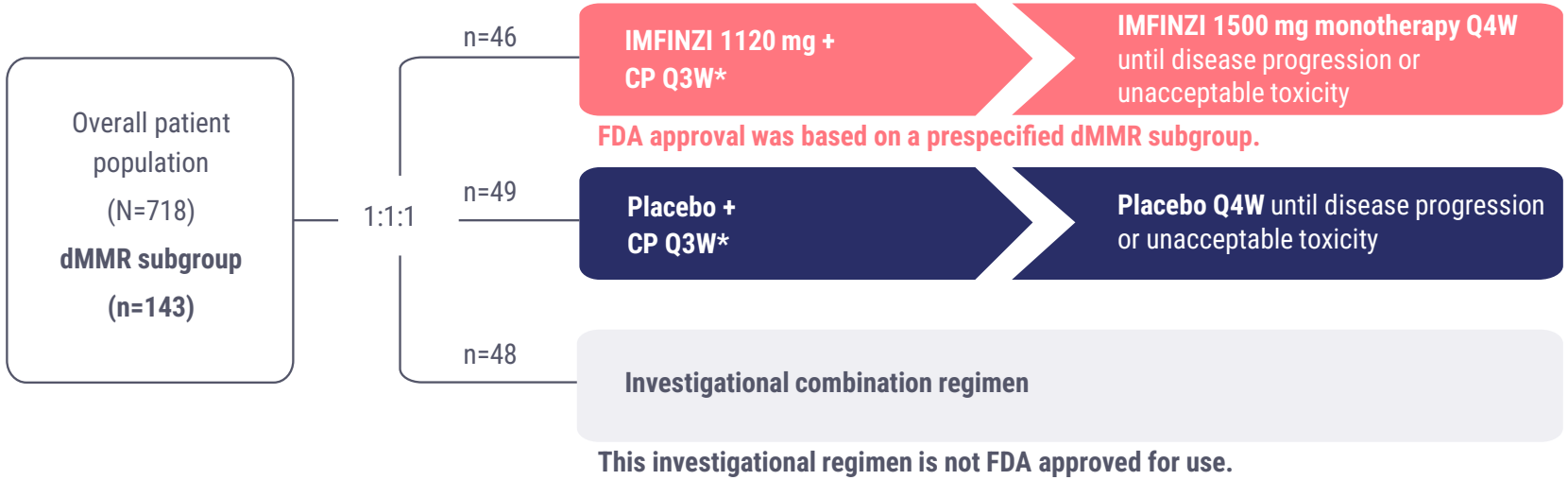
Please see Full Prescribing Information, including Medication Guide, for IMFINZI.

DUO-E Study Design[1-4]

DUO-E was a global, randomized, double-blind, placebo-controlled, phase III study[1,2]

Key eligibility criteria
- Newly diagnosed FIGO Stage III/IV or recurrent endometrial cancer
- Adjuvant chemotherapy allowed if ≥12 months from last treatment to relapse
- All histologies including carcinosarcoma, except sarcomas
- Naïve to 1L systemic anticancer treatment for advanced disease

Stratification factors
- MMR status (proficient vs deficient)†
- Geography (Asia vs rest of the world)‡
- Disease status (newly diagnosed vs recurrent)



FDA approval was based on a prespecified dMMR subgroup.

This investigational regimen is not FDA approved for use.

Select primary endpoint
- Investigator-assessed PFS in ITT population (per RECIST 1.1)
  - IMFINZI + CP vs CP

Secondary endpoints
- OS (key secondary), ORR, and DoR in ITT population

Exploratory endpoints
- Subgroup analyses of PFS (prespecified) and OS, ORR, and DoR (post hoc) by MMR status

*Every 3 weeks for a maximum of 6 cycles.

†MMR status was assessed using immunohistochemistry tumor tissue test.

‡Asia included China, Hong Kong, India, Japan, Republic of Korea, and Singapore. Two patients in India were stratified in error to the Asia subgroup. Rest of the wor d included Australia, Belgium, Brazil, Canada, Colombia, Estonia, Germany, Greece, Hungary, Israel, Lithuania, Mexico, Poland, Russia, Spain, and USA.

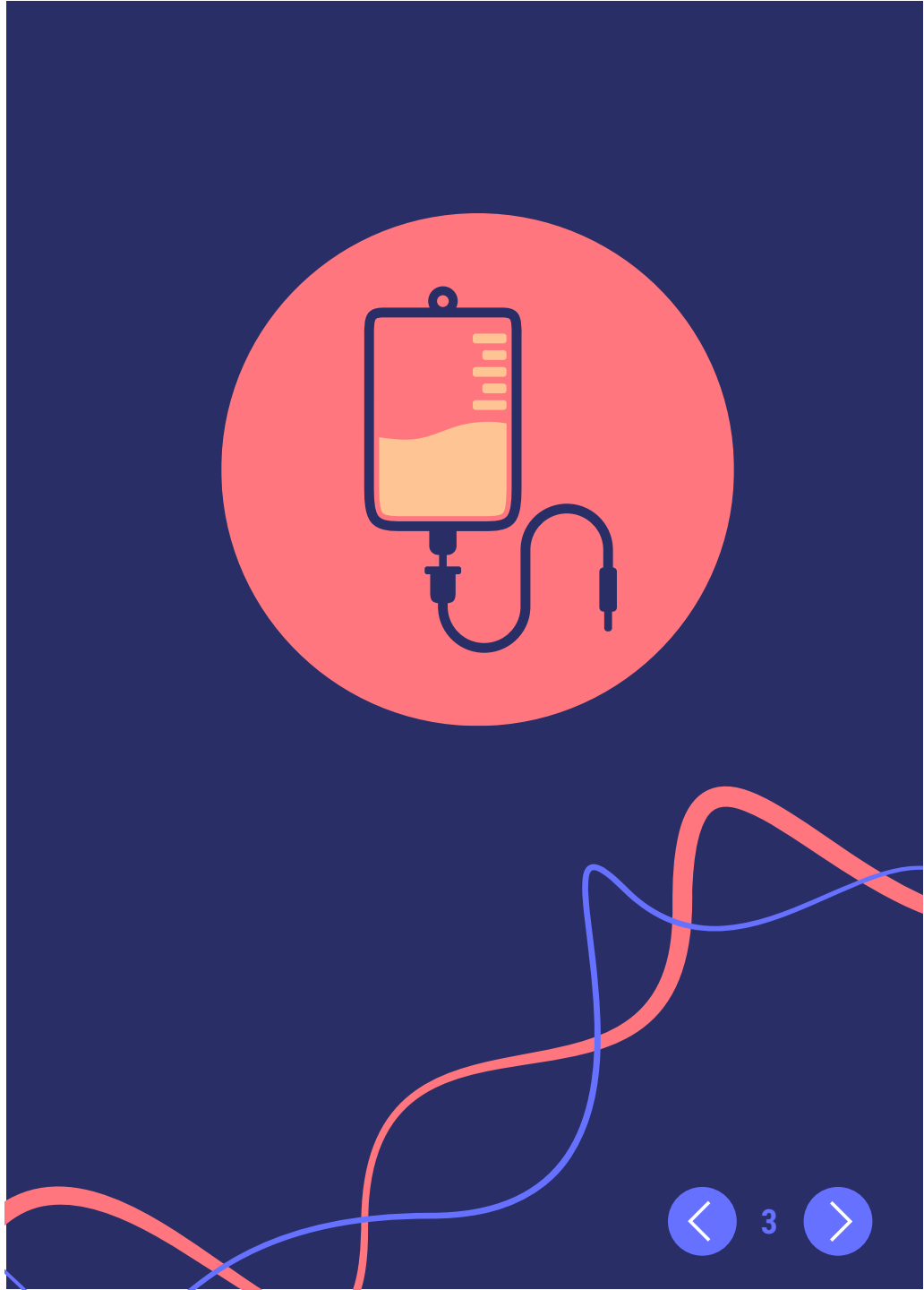
1L=first-line; CP=carboplatin and paclitaxel; dMMR= mismatch repair deficient; DoR=duration of response; FDA=United States Food and Drug Administration; FIGO=International Federation of Gynecology and Obstetrics; ITT=intent to treat; MMR=mismatch repair; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; Q3W=every 3 weeks; Q4W=every 4 weeks; RECIST=Response Evaluation Criteria in Solid Tumors.

SELECT SAFETY INFORMATION (Continued)
Immune-Mediated Adverse Reactions (Continued)
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.

Please see Full Prescribing Information, including Medication Guide, for IMFINZI.

DUO-E Safety Data[1]

- Safety data are available for a total of 44 patients with advanced or recurrent dMMR endometrial cancer who received IMFINZI (1120 mg) with CP (every 3 weeks for up to six 21 day cycles) followed by IMFINZI (1500 mg every 4 weeks [or CP every 3 weeks for up to six 21 day cycles alone]) as a single agent until disease progression or unacceptable toxicity
- The median duration of exposure to IMFINZI with CP was 14.8 months, with a range of 0.7 to 31.7 months, in the dMMR subgroup



CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.

DUO-E Safety Data

IMFINZI + CP Safety Profile Overview[1]

The safety profile of the IMFINZI + CP regimen included ARs described below

30%

- **Serious ARs** occurred in **30%** of patients who received IMFINZI + CP
- The most common serious ARs (≥4%) were:
  - Constipation (4.5%)
  - Rash (4.5%)

- **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
  - Decreased appetite

- **Clinically relevant ARs in <10%** of patients who received IMFINZI + CP:
  - Autoimmune hemolytic anemia
  - Colitis
  - Immune-mediated thyroiditis
  - Infusion-related reaction
  - Interstitial lung disease
  - Myositis
  - Pneumonitis
  - Pulmonary embolism
  - Sepsis

52%

- **Dosage interruptions** of IMFINZI due to ARs occurred in **52%** of patients
- ARs which required dosage interruptions of IMFINZI (≥4%) were:
  - Anemia (11%)
  - Thrombocytopenia (9%)
  - Neutropenia (9%)
  - COVID-19 (9%)
  - Increased ALT (4.5%)
  - Pneumonitis (4.5%)

11%

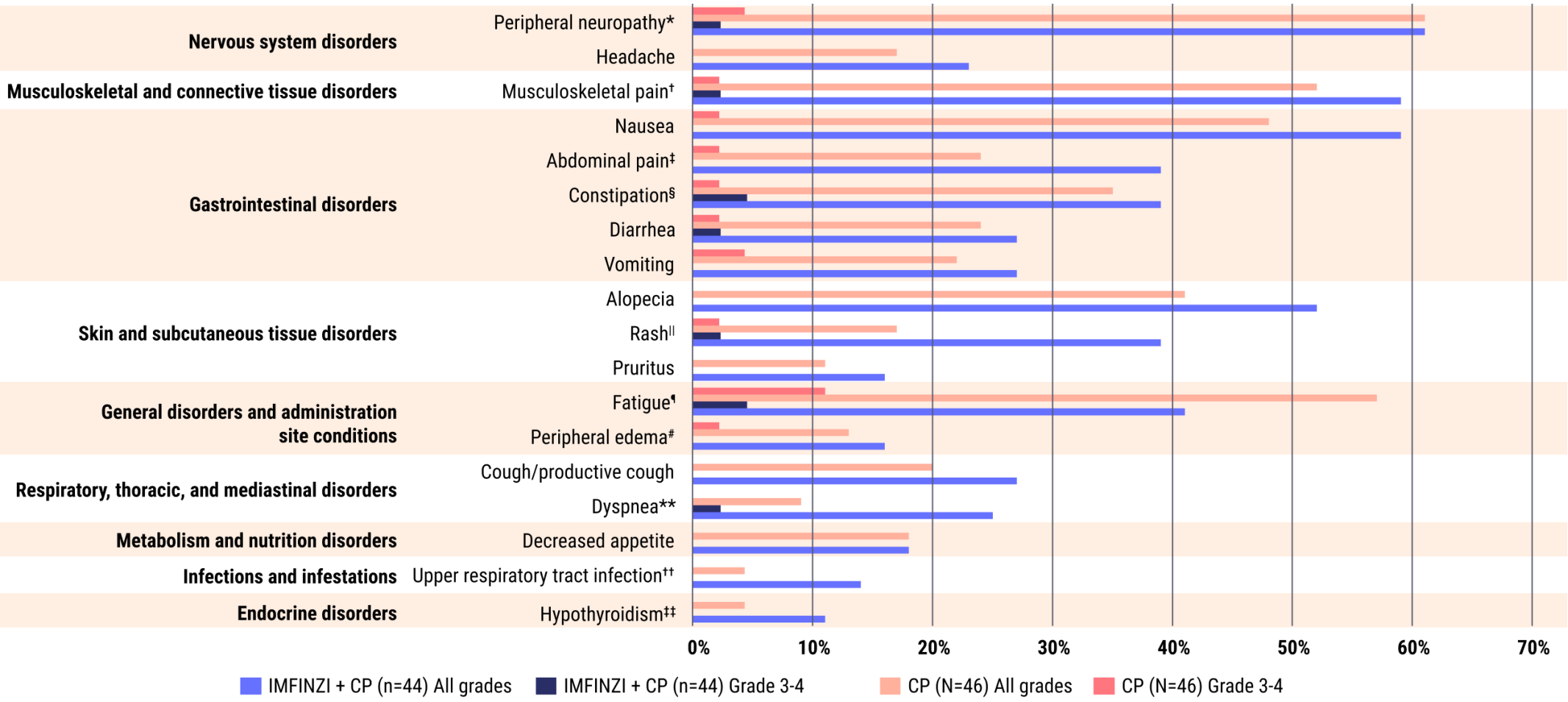
- **Permanent discontinuation** of IMFINZI due to ARs occurred in **11%** of patients
- The AR which resulted in permanent discontinuation of IMFINZI (≥4%) was:
  - Rash (4.5%)

ALT=alanine aminotransferase; AST=aspartate aminotransferase; AR=adverse reaction; CP=carboplatin and paclitaxel.

Please see Full Prescribing Information, including Medication Guide, for IMFINZI.

DUO-E Safety Data

ARs Reported in ≥10% of Patients With dMMR Tumors in DUO-E[1]



*Includes neuropathy peripheral, peripheral sensory neuropathy, hypoesthesia, peripheral motor neuropathy, and paresthesia.

†Includes arthralgia, pain in extremity, back pain, non-cardiac chest pain, myalgia, musculoskeletal pain, musculoskeletal chest pain, arthritis, bone pain, musculoskeletal stiffness, neck pain, musculoskeletal discomfort, and spinal pain.

‡Includes abdominal pain, abdominal pain lower, flank pain, abdominal discomfort, and abdominal pain upper.

§Includes constipation and fecaloma.

||Includes eczema, rash, rash erythematous, rash maculopapular, dermatitis, rash pustular, skin exfoliation, symmetrical drug-related intertriginous, and flexural exanthema.

¶Includes asthenia and fatigue.

#Includes peripheral edema, peripheral swelling, and edema.

**Includes dyspnea and exertional dyspnea.

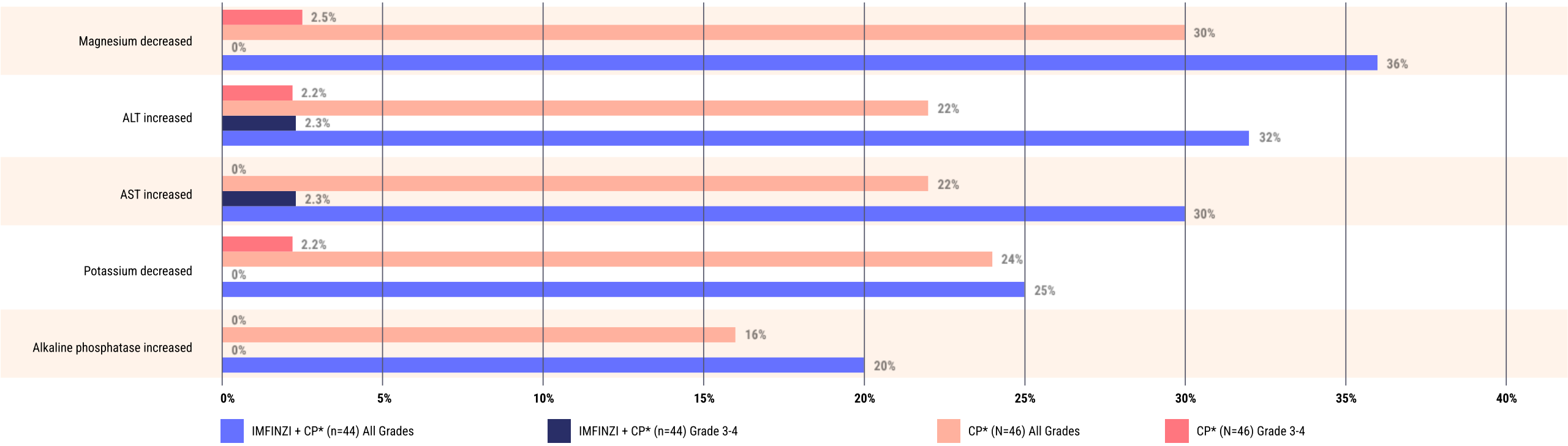
††Includes nasopharyngitis, pharyngitis, rhinitis, sinusitis, tracheobronchitis, and upper respiratory tract infection.

‡‡Includes blood thyroid stimulating hormone increased and hypothyroidism.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.

DUO-E Safety Data

Select Laboratory Abnormalities Worsening From Baseline Occurring in ≥20% of Patients With dMMR Tumors in DUO-E[1]



*Each test incidence is based on the number of patients who had both baseline and at least 1 on-study laboratory measurement available: IMFINZI + CP (range: 40-44) and CP (range: 37-46).

ALT=alanine aminotransferase; AST=aspartate aminotransferase; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.

Please see Full Prescribing Information, including Medication Guide, for IMFINZI.

Monitoring for Adverse Reactions[1]

- Patients and caregivers need counseling on signs and symptoms to look for so they can detect and quickly report any possible AR
- Ideally, it is best to detect, monitor, and manage any Grade 1 AR before it can progress to a higher grade, where it can become more challenging to address
- ARs can happen during or after treatment, underscoring the importance of educating patients and caregivers to look out for new or worsening symptoms

AR=adverse reaction.

Dosage Modifications for Adverse Reactions[1]

General Guidance on Dose Modifications for IMFINZI

- **No dose reduction for IMFINZI is recommended**
- In general, for severe (Grade 3) immune-mediated ARs, IMFINZI should be **withheld**
- For life-threatening (Grade 4) immune-mediated ARs or recurrent severe (Grade 3) immune-mediated ARs that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroid, IMFINZI should be **permanently discontinued**
- Any **dosage modifications** that differ from the general guidelines are summarized in the following table

Recommended IMFINZI Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
Immune-Mediated Adverse Reactions		
Pneumonitis	Grade 2	Withhold†
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2	Withhold†
	Grade 3	Withhold† or permanently discontinue
	Grade 4	Permanently discontinue
Intestinal perforation	Any grade	Permanently discontinue
Hepatitis with no tumor involvement of the liver	ALT or AST increases to more than 3 and up to 8 times the ULN or total bilirubin increases to more than 1.5 and up to 3 times ULN	Withhold†
	ALT or AST increases to more than 8 times ULN or total bilirubin increases to more than 3 times the ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver‡	AST or ALT is more than 1 and up to 3 times ULN at baseline and increases to more than 5 and up to 10 times ULN or AST or ALT is more than 3 and up to 5 times ULN at baseline and increases to more than 8 and up to 10 times ULN	Withhold†
	AST or ALT increases to more than 10 times ULN or total bilirubin increases to more than 3 times ULN	Permanently discontinue
Endocrinopathies	Grade 3 or 4	Withhold until clinically stable or permanently discontinue depending on severity
Nephritis with renal dysfunction	Grade 2 or 3 increased blood creatinine	Withhold†
	Grade 4 increased blood creatinine	Permanently discontinue
Exfoliative dermatologic conditions	Suspected SJS, TEN, or DRESS	Withhold†
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grade 2, 3, or 4	Permanently discontinue
Neurological toxicities	Grade 2	Withhold†
	Grade 3 or 4	Permanently discontinue
Other Adverse Reactions		
Infusion-related reactions	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.

‡If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.

ALT=alanine aminotransferase; AR=adverse reaction; AST=aspartate aminotransferase; DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis; ULN=upper limit normal.

Immune-Mediated Adverse Reactions Overview[1]

IMFINZI removes inhibition of the immune response, potentially breaking tolerance and inducing imARs.

imARs

- IMFINZI is an **immune checkpoint inhibitor** that blocks the PD-1/PD-L1 pathway and **removes inhibition of the immune response**, which potentially breaks peripheral tolerance and induces immune-mediated adverse reactions
- **Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue**
- Immune-mediated ARs can also **occur at any time** after starting treatment with a PD-1/PD-L1 blocking antibody, or even after treatment discontinuation
- Overall, early identification and management of immune-mediated adverse reactions are essential to help promote the safe use of IMFINZI

Monitoring imARs

- The healthcare team should **monitor patients closely** for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions
- It is important to evaluate the patient's **liver enzymes**, **creatinine**, and **thyroid function** at baseline and periodically during treatment with IMFINZI
- Patients should be encouraged to report any **new or worsening symptoms** quickly so clinicians can evaluate and decide on a course of action, which may include monitoring, a workup to exclude any alternative conditions, medical management, or evaluating whether IMFINZI may need to be withheld or discontinued

Managing imARs

- Withhold or permanently discontinue IMFINZI depending on severity
- 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
- *See the next table for more information on management guidelines for specific imARs*

AR=adverse reaction; imAR=immune-mediated adverse reaction; PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1.

Management of Immune-Mediated Adverse Reactions[1]

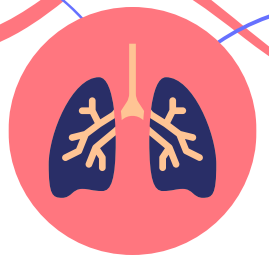
*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.

‡If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.

ALT=alanine aminotransferase; AR=adverse reaction; AST=aspartate aminotransferase; DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; imAR=immune-mediated adverse reaction; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis; ULN=upper limit normal.

imAR	Pneumonitis	Colitis	Hepatitis Without Tumor Involvement of the Liver	Hepatitis With Tumor Involvement of the Liver‡	Endocrinopathies: Adrenal Insufficiency & Hypophysitis	Endocrinopathies: Thyroiditis, Hyperthyroidism, Hypothyroidism	Endocrinopathies: Type 1 Diabetes Mellitus	Nephritis with Renal Dysfunction	Dermatology: Rash	Dermatology: SJS, TEN, or DRESS
Severity* & IMFINZI Dose Modification	Grade 2: **Withhold†**	Grade 2: **Withhold†**	ALT or AST increases to >3-8x the ULN or total bilirubin increases to >1.5-3x ULN: **Withhold†**	AST or ALT is >1-3x ULN at baseline & increases to >5-10x ULN or AST or ALT is >3-5x ULN at baseline & increases to >8-10x ULN: **Withhold†**				Grade 2 or 3 increased blood creatinine: **Withhold†**	**Withhold** or **permanently discontinue** depending on severity	Suspected SJS, TEN, or DRESS: **Withhold†**
	Grade 3 or 4: **Permanently discontinue**	Grade 3: **Withhold†** or **permanently discontinue** Grade 4: **Permanently discontinue**	ALT or AST increases to >8x ULN or total bilirubin increases to >3x ULN: **Permanently discontinue**	AST or ALT increases >10x ULN or total bilirubin increases to >3x ULN: **Permanently discontinue**	Grade 3 or 4: **Withhold** until clinically stable or **permanently discontinue** depending on severity			Grade 4 increased blood creatinine: **Permanently discontinue**		Confirmed SJS, TEN, or DRESS: **Permanently discontinue**
Steroids	• 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 • Toxicity management guidelines for adverse reactions that **do not necessarily require systemic steroids** (eg, **endocrinopathies** and **dermatologic** reactions) are discussed in the row below									
Clinical Management					Initiate **symptomatic treatment**, including hormone replacement as clinically indicated.	Initiate **hormone replacement therapy** for hypothyroidism or institute **medical management** of hyperthyroidism as clinically indicated.	Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with **insulin** as clinically indicated.		If mild to moderate non-exfoliative rashes arise, **topical emollients** and/or **topical corticosteroids** may be adequate to treat.	



Immune-Mediated Pneumonitis[1]

- IMFINZI can cause immune-mediated pneumonitis

Signs and Symptoms

- Cough
- Chest pain
- Dyspnea (ie, shortness of breath)

Incidence

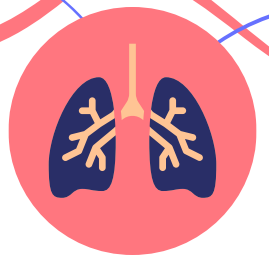
- Note that the incidence of pneumonitis is higher in patients who have received prior thoracic radiation
- Pneumonitis is a **clinically relevant** AR that occurred in **<10%** of patients with advanced or recurrent dMMR endometrial cancer who received IMFINZI + CP in the DUO-E study
- Several symptoms, including **cough** and **dyspnea** are some of the **most common ARs** that occurred in **>20%** of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study (see table)

Incidence of Pneumonitis Symptoms in Patients With dMMR Tumors in DUO-E

AR	IMFINZI + CP (n=44)		CP (n=46)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Cough / productive cough	27	0	20	0
Dyspnea*	25	2.3	9	0

*Includes dyspnea and exertional dyspnea.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.



Immune-Mediated Pneumonitis (Continued)

- IMFINZI can cause immune-mediated pneumonitis[1]

- Pneumonitis led to **dosage interruptions** of IMFINZI in **4.5%** of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study[1]

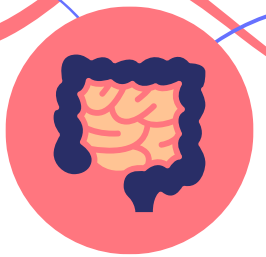
Management of Immune-Mediated Pneumonitis[1,5]

AR	Severity	Description*	IMFINZI Dosage Modification
Pneumonitis	Grade 1	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	-
	Grade 2	• Symptomatic • Medical intervention indicated • Limiting instrumental ADL	Withhold†
	Grade 3	• Severe symptoms • Limiting self-care ADL • Oxygen indicated	Permanently discontinue
	Grade 4	• Life-threatening respiratory compromise • Urgent intervention indicated (eg, tracheotomy or intubation)	

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.



Immune-Mediated Colitis[1]

- IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea
- 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

Signs and Symptoms

- Diarrhea (loose stools) or more frequent bowel movements than usual
- Stools that are black, tarry, sticky, or have blood or mucus
- Severe abdominal pain or tenderness

Incidence

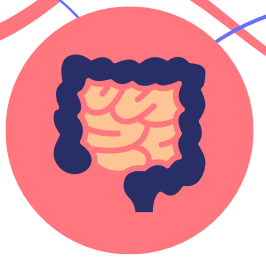
- Colitis is a **clinically relevant** AR that occurred in **<10%** of patients with advanced or recurrent dMMR endometrial cancer who received IMFINZI + CP in the DUO-E study
- Several symptoms, including **abdominal pain** and **diarrhea** are some of the **most common ARs** that occurred in **>20%** of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study (see table)

Incidence of Colitis Symptoms in Patients With dMMR Tumors in DUO-E

AR	IMFINZI + CP (n=44)		CP (n=46)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Abdominal pain*	39	0	24	2.2
Diarrhea	27	2.3	24	2.2

*Includes abdominal pain, abdominal pain lower, flank pain, abdominal discomfort, and abdominal pain upper.

AR=adverse reaction; CMV=cytomegalovirus; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.



Immune-Mediated Colitis (Continued)

- IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea[1]
- CMV infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis[1]
- In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies[1]

Management of Immune-Mediated Colitis[1,5]

AR	Severity	Description*	IMFINZI Dosage Modification
Colitis	Grade 1	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	-
	Grade 2	• Abdominal pain • Mucus or blood in stool	Withhold†
	Grade 3	• Severe abdominal pain • Change in bowel habits • Medical intervention indicated • Peritoneal signs	Withhold† or permanently discontinue
	Grade 4	• Life-threatening consequences • Urgent intervention indicated	Permanently discontinue

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.

AR=adverse reaction; CMV=cytomegalovirus; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.

Immune-Mediated Hepatitis[1]

- IMFINZI can cause immune-mediated hepatitis

Signs and Symptoms

- Jaundice (yellowing of skin or whites of eyes)
- Severe nausea or vomiting
- Pain on the right side of abdomen
- Dark urine (tea colored)
- Easy bruising or bleeding

Incidence

- Several symptoms, including nausea, abdominal pain, and vomiting are some of the most common ARs that occurred in >20% of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study (see table)

Incidence of Hepatitis Symptoms in Patients With dMMR Tumors in DUO-E

AR	IMFINZI + CP (n=44)		CP (n=46)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Nausea	59	0	48	2.2
Abdominal pain*	39	0	24	2.2
Vomiting	27	0	22	4.3

*Includes abdominal pain, abdominal pain lower, flank pain, abdominal discomfort, and abdominal pain upper.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.

Please see Full Prescribing Information, including Medication Guide, for IMFINZI.

Immune-Mediated Hepatitis (Continued)[1]

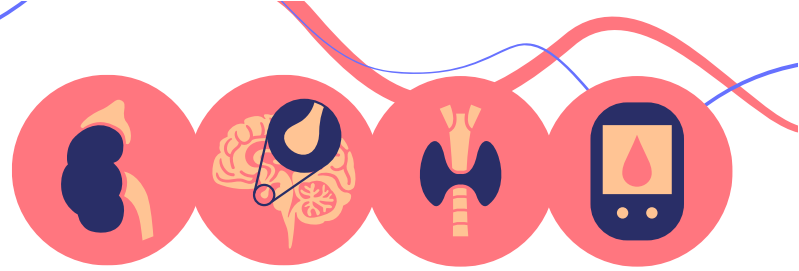
- IMFINZI can cause immune-mediated hepatitis

Management of Immune-Mediated Hepatitis

AR	Severity*	IMFINZI Dosage Modification
Hepatitis with no tumor involvement of the liver	• ALT or AST increases to more than 3 and up to 8 times the ULN or • Total bilirubin increases to more than 1.5 and up to 3 times ULN	Withhold†
	• ALT or AST increases to more than 8 times ULN or • Total bilirubin increases to more than 3 times the ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver‡	• AST or ALT is more than 1 and up to 3 times ULN at baseline and increases to more than 5 and up to 10 times ULN or • AST or ALT is more than 3 and up to 5 times ULN at baseline and increases to more than 8 and up to 10 times ULN	Withhold†
	• AST or ALT increases to more than 10 times ULN or • Total bilirubin increases to more than 3 times ULN	Permanently discontinue

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.
†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.
‡If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.

ALT=alanine aminotransferase; AR=adverse reaction; AST=aspartate aminotransferase; ULN=upper limit normal.



Immune-Mediated Endocrinopathies

- IMFINZI can cause[1]:
  - Primary or secondary adrenal insufficiency
  - 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
  - Immune-mediated **thyroid disorders** (thyroiditis, hypothyroidism, hyperthyroidism). Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism
  - Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes

Signs & Symptoms of Adrenal Insufficiency[1,6]

- Chronic fatigue (extreme tiredness)
- Muscle weakness
- Loss of appetite
- Weight loss
- Abdominal pain

Signs & Symptoms of Hypophysitis[1]

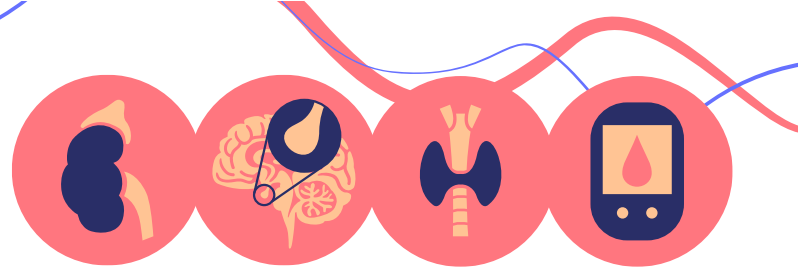
- Acute symptoms associated with mass effect such as:
  - Headache
  - Photophobia
  - Visual field cuts

Signs & Symptoms of Thyroid Disorders[1,7-9]

- Fatigue (extreme tiredness)
- Weight gain or weight loss
- Changes in appetite
- Rapid heartbeat
- Feeling cold
- Hair loss

Signs & Symptoms of Type 1 Diabetes Mellitus[1,10]

- Hyperglycemia
- Other signs and symptoms of diabetes including:
  - Polyuria
  - Polydipsia
  - Weight loss



Immune-Mediated Endocrinopathies (Continued)

- IMFINZI can cause[1]:
  - Primary or secondary adrenal insufficiency
  - 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
  - Immune-mediated **thyroid disorders** (thyroiditis, hypothyroidism, hyperthyroidism). Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism
  - Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes

Incidence

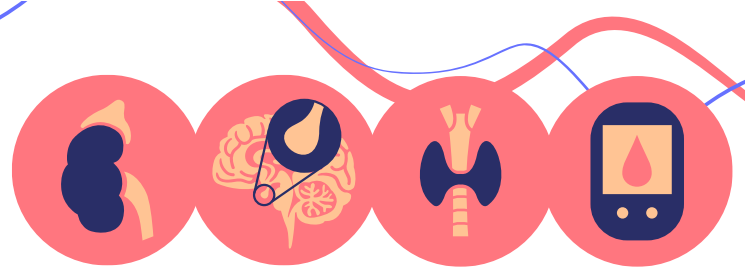
- **Hypothyroidism** is an AR that occurred in **11%** of patients with advanced or recurrent dMMR endometrial cancer who received IMFINZI + CP in the DUO-E study (n=**44**; see table)[1]
- **Hypothyroidism** occurred in **14% (34/235)** of all patients receiving IMFINZI + CP in the DUO-E study[1]
- **Immune-mediated thyroiditis** is a **clinically relevant AR** that occurred in **<10%** of patients with advanced or recurrent dMMR endometrial cancer who received IMFINZI + CP in the DUO-E study[1]
- **Fatigue**, a symptom of **thyroid disorders**, was one of the **most common ARs** that occurred in **>20%** of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study (see table)[1,7-9]

Incidence of Thyroid Disorder Symptom and Hypothyroidism in Patients With dMMR Tumors in DUO-E[1]

AR	IMFINZI + CP (n=44)		CP (n=46)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Fatigue*	41	4.5	57	11
Hypothyroidism†	11	0	4.3	0

*Includes asthenia and fatigue.
†Includes blood thyroid stimulating hormone increased and hypothyroidism.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.



Immune-Mediated Endocrinopathies (Continued)

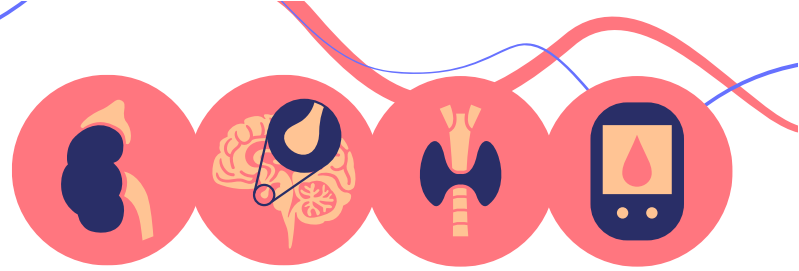
- IMFINZI can cause[1]:
  - Primary or secondary adrenal insufficiency
  - Immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism
  - Immune-mediated **thyroid disorders** (thyroiditis, hypothyroidism, hyperthyroidism). Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism
  - Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes

Management of Adrenal Insufficiency or Immune-Mediated Hypophysitis[1,5]

AR	Severity	Description*	IMFINZI Dosage Modifications	Clinical Management
Adrenal Insufficiency or Hypophysitis	Grade 1	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	-	-
	Grade 2	• Moderate symptoms • Medical intervention indicated	-	Initiate symptomatic treatment, including hormone replacement as clinically indicated
	Grade 3	• Severe symptoms • Hospitalization indicated	Withhold until clinically stable or permanently discontinue depending on severity	
	Grade 4	• Life-threatening consequences • Urgent intervention indicated		

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

AR=adverse reaction.



Immune-Mediated Endocrinopathies (Continued)

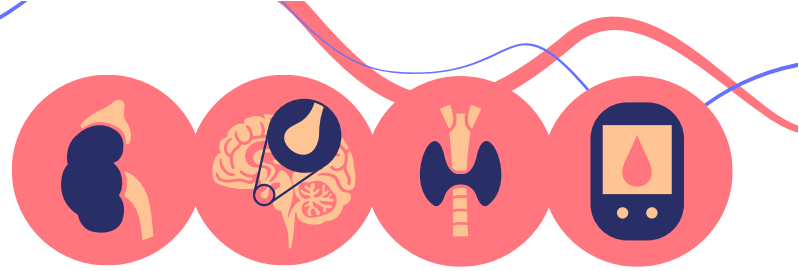
- IMFINZI can cause[1]:
  - Primary or secondary adrenal insufficiency
  - Immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism
  - Immune-mediated **thyroid disorders** (thyroiditis, hypothyroidism, hyperthyroidism). Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism
  - Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes

Management of Immune-Mediated Thyroid Disorders (Thyroiditis, Hyperthyroidism & Hypothyroidism)[1,5]

AR	Severity	Description*	IMFINZI Dosage Modifications	Clinical Management
Thyroiditis, Hyperthyroidism, Hypothyroidism	Grade 1	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	-	-
	Grade 2	• Symptomatic • Thyroid suppression or replacement therapy indicated (for hyper- or hypothyroidism, respectively) • Limiting instrumental ADL	-	Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated
	Grade 3	• Severe symptoms • Limiting self-care ADL • Hospitalization indicated	Withhold until clinically stable or permanently discontinue depending on severity	
	Grade 4	• Life-threatening consequences • Urgent intervention indicated		

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

AR=adverse reaction.



Immune-Mediated Endocrinopathies (Continued)[1]

- IMFINZI can cause:
  - Primary or secondary adrenal insufficiency
  - 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
  - Immune-mediated **thyroid disorders** (thyroiditis, hypothyroidism, hyperthyroidism). Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism
  - Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes

Management of Type 1 Diabetes Mellitus

AR	Severity*	IMFINZI Dosage Modification	Clinical Management
Type 1 Diabetes Mellitus	Grade 1	-	-
	Grade 2	-	Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated.
	Grade 3	Withhold until clinically stable or permanently discontinue depending on severity	
	Grade 4		

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

AR=adverse reaction.

Immune-Mediated Nephritis with Renal Dysfunction[1]

- IMFINZI can cause immune-mediated nephritis

Signs and Symptoms

- Decreased urine
- Swelling of ankles
- Blood in urine
- Loss of appetite

Incidence

- A symptom, **decreased appetite**, is one of the **most common ARs** that occurred in **>20%** of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study (see table)

Incidence of a Nephritis Symptom in Patients With dMMR Tumors in DUO-E

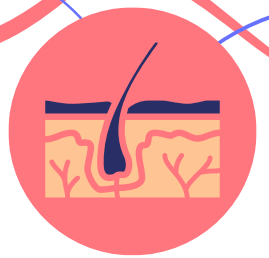
AR	IMFINZI + CP (n=44)		CP (n=46)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Decreased appetite	18	0	18	0

Management of Immune-Mediated Nephritis With Renal Dysfunction

AR	Severity*	IMFINZI Dosage Modification
Nephritis with Renal Dysfunction	Grade 1	-
	Grade 2 or 3 increased blood creatinine	Withhold†
	Grade 4 increased blood creatinine	Permanently discontinue

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.
†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient.



Immune-Mediated Dermatology Reactions[1]

- 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

Signs and Symptoms

- Rash
- Itching
- Skin blistering or peeling
- Painful sores in the mouth, nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

Incidence

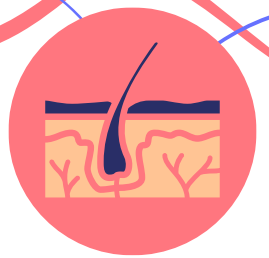
- **Rash** is one of the **most common serious adverse reactions** that occurred in **4.5%** of patients with advanced or recurrent dMMR endometrial cancer that received **IMFINZI + CP** in the DUO-E study
- **Rash** is also one of the **most common adverse reactions** that occurred in **>20%** of patients **overall** with advanced or recurrent dMMR endometrial cancer in the DUO-E study (see table)

Incidence of Rash in Patients With dMMR Tumors in DUO-E

AR	IMFINZI + CP (n=44)		CP (n=46)	
	All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Rash*	39	2.3	17	2.2

*Includes eczema, rash, rash erythematous, rash maculo-papular, dermatitis, rash pustular, skin exfoliation, and symmetrical drug-related intertriginous, and flexural exanthema.

AR=adverse reaction; CP=carboplatin and paclitaxel; dMMR=mismatch repair deficient; DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis.



Immune-Mediated Dermatology Reactions (Continued)[1]

- 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

- Rash led to the **highest percentage of permanent discontinuations** of IMFINZI in **4.5%** of patients with advanced or recurrent dMMR endometrial cancer in the DUO-E study

Management of Immune-Mediated Dermatology Reactions

AR	Severity*	IMFINZI Dosage Modification	Clinical Management
Rash	-	Withhold or permanently discontinue depending on severity	If mild to moderate non-exfoliative rashes arise, topical emollients and/or topical corticosteroids may be adequate to treat
SJS, TEN, or DRESS	Suspected SJS, TEN, or DRESS	Withhold†	-
	Confirmed SJS, TEN, or DRESS	Permanently discontinue	

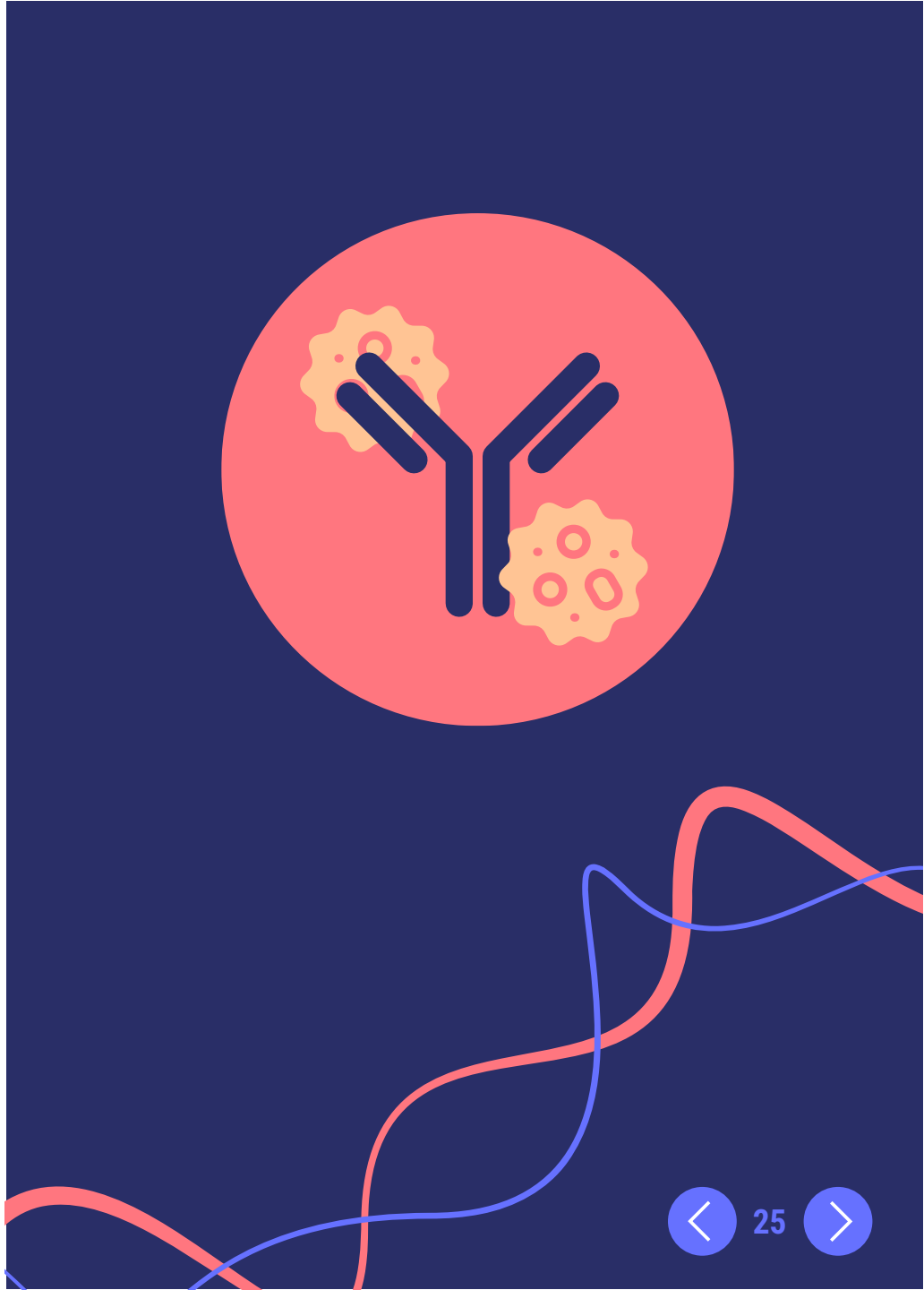
*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.
†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.

AR=adverse reaction; dMMR=mismatch repair deficient; DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis.

Other Immune-Mediated Adverse Reactions[1]

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



PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1.

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.
- ***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.

Important Safety Information (Continued)

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.

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.

Important Safety Information (Continued)

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.

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) as determined by an FDA-approved test.

Please see full Prescribing Information, including Medication Guide, for IMFINZI

You are encouraged to report side effects related to AstraZeneca products by calling 1-800-236-9933. If you prefer to report these to the FDA, please call 1-800-FDA-1088.

Select a glossary term to return to its location.

Glossary

adrenal insufficiency: a disorder that occurs when the adrenal cortex does not produce enough cortisol, and in some cases, aldosterone. It may be due to a disorder of the adrenal cortex, such as Addison's disease or primary adrenal insufficiency[5]

colitis: a disorder characterized by inflammation of the colon[5]

hepatitis: a disorder characterized by a viral pathologic process involving the liver parenchyma[5]

hyperthyroidism: a disorder characterized by excessive levels of thyroid hormone in the body. Common causes include an overactive thyroid gland or thyroid hormone overdose[5]

hypophysitis: inflammation of the pituitary gland[10]

hypothyroidism: a disorder characterized by a decrease in production of thyroid hormone by the thyroid gland[5]

nephritis: inflammation of the kidneys[10]

pneumonitis: a disorder characterized by inflammation focally or diffusely affecting the lung parenchyma[5]

Stevens-Johnson Syndrome (SJS): a disorder characterized by less than 10% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes[5]

toxic epidermal necrolysis (TEN): a disorder characterized by >30% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes[5]

thyroiditis: inflammation of the thyroid gland[10]

Type 1 Diabetes Mellitus: a chronic metabolic disorder marked by hyperglycemia that results from failure of the pancreas to produce insulin[10]

Abbreviations

1L=first-line

ADL=activities of daily living

ALT=alanine aminotransferase

AR=adverse reaction

AST=aspartate aminotransferase

CI=confidence interval

CMV=cytomegalovirus

CP=carboplatin and paclitaxel

dMMR=mismatch repair deficient

DoR=duration of response

DRESS=Drug Rash with Eosinophilia and Systemic Symptoms

FDA=United States Food and Drug Administration

FIGO=International Federation of Gynecology and Obstetrics

imAR=immune-mediated adverse reaction

ITT=intent to treat

MMR=mismatch repair

ORR=objective response rate

OS=overall survival

PD-1=programmed death-receptor 1

PD-L1=programmed death-ligand 1

PFS=progression-free survival

Q3W=every 3 weeks

Q4W=every 4 weeks

RECIST=Response Evaluation Criteria in Solid Tumors

SJS=Stevens-Johnson Syndrome

TEN=toxic epidermal necrolysis

ULN=upper limit normal

References

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