IMFINZI

IMFINZI + IMJUDO

DOSING GUIDE

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab) or IMJUDO® (tremelimumab-actl).

Severe and Fatal 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. Evaluate clinical chemistries including liver enzymes, creatinine, adrenocorticotropic hormone (ACTH) level, and thyroid function at baseline and before each dose. 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 and IMJUDO depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI and IMJUDO 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 additional Important Safety Information throughout and click here for Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

Lung Indications

UNRESECTABLE STAGE III NON-SMALL CELL LUNG CANCER (NSCLC)

IMFINZI, as a single agent, is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

METASTATIC NSCLC (mNSCLC)

IMFINZI, in combination with IMJUDO and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations.

RESECTABLE NSCLC

IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

EXTENSIVE-STAGE SMALL CELL LUNG CANCER (ES-SCLC)

IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Pneumonitis

IMFINZI and IMJUDO can cause immune-mediated pneumonitis, which may be fatal. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

- ***IMFINZI as a Single Agent***
  - In patients who did not receive recent prior radiation, the incidence of immune-mediated pneumonitis was 2.4% (34/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions. In patients who received recent prior radiation, the incidence of pneumonitis (including radiation pneumonitis) in patients with unresectable Stage III NSCLC following definitive chemoradiation within 42 days prior to initiation of IMFINZI in PACIFIC was 18.3% (87/475) in patients receiving IMFINZI and 12.8% (30/234) in patients receiving placebo. Of the patients who received IMFINZI (475), 1.1% were fatal and 2.7% were Grade 3 adverse reactions.

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

SCLC=small cell lung cancer.

Unresectable Stage III NSCLC

IMFINZI weight-based and fixed dosing following cCRT

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG

WEIGHT-BASED DOSING Q2W

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Cycle	**1**		**2**		**3**		**4**		**5**		**6**		**7**		**8**
IMFINZI 10 mg/kg*	✓		✓		✓		✓		✓		✓		✓		✓

Continue IMFINZI until disease progression, unacceptable toxicity, or up to 12 months.†

OR

FIXED DOSE Q4W

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Cycle	**1**				**2**				**3**				**4**		
IMFINZI 1500 mg*‡	✓				✓				✓				✓		

Continue IMFINZI until disease progression, unacceptable toxicity, or up to 12 months.†

- Patients with a body weight of <30 kg must receive weight-based dosing, equivalent to IMFINZI 10 mg/kg Q2W
- IMFINZI is administered as a 60-minute IV infusion with no premedication required
- There are no anticipated clinically meaningful differences in efficacy and safety between Q2W and Q4W dosing with IMFINZI‡

*For patients with body weight of ≥30 kg.
†Refer to Prescribing Information for information on dosage modifications.
‡Based on the modeling of pharmacokinetic data and exposure relationships for safety in patients weighing >30 kg with NSCLC. The steady state AUC is 6% higher, the C_{trough} is 19% lower, and C_{max} is 55% higher in those who received 1500 mg Q4W compared with those who received 10 mg/kg Q2W.

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

AUC=area under the curve; cCRT=concurrent chemoradiotherapy; IV=intravenous; Q2W=every 2 weeks; Q4W=every 4 weeks.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

Unresectable Stage III NSCLC

IMFINZI vials needed with least amount of waste

WEIGHT-BASED DOSING

Average patient weight: 87-98 kg

1 × 500 mg/10 mL

4 × 120 mg/2.4 mL

Vials are not shown to actual size or scale.

Patients with a body weight of <30 kg must receive weight-based dosing, equivalent to IMFINZI 10 mg/kg every 2 weeks.
See dosing calculator on page 23

FIXED DOSE

3 × 500 mg/10 mL

Vials are not shown to actual size or scale.

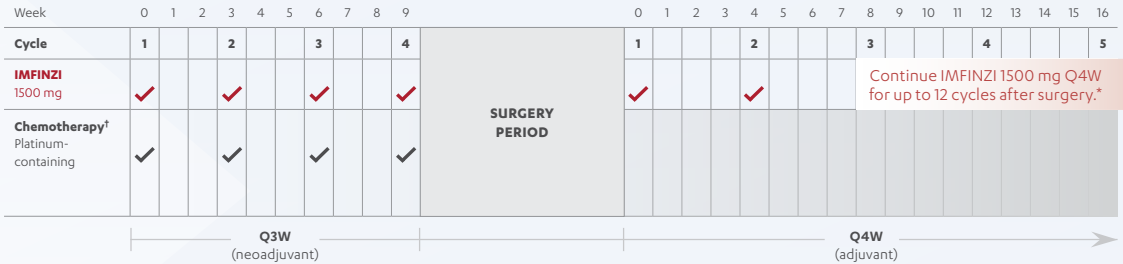
Please see additional Important Safety Information throughout and click here for Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

Resectable NSCLC

IMFINZI fixed dosing

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG



*Treat until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery.
†Administer IMFINZI prior to chemotherapy on the same day.

- In the AEGEAN study, surgery was expected within 40 days of the last dose of neoadjuvant treatment. Adjuvant treatment was expected to commence as soon as clinically feasible and within 10 weeks from surgery

For patients with a body weight of <30 kg:

Neoadjuvant: IMFINZI 20 mg/kg in combination with CT Q3W for up to 4 cycles prior to surgery.

Adjuvant: IMFINZI 20 mg/kg Q4W for up to 12 cycles as a single agent after surgery.

- IMFINZI is administered as a 1500-mg fixed dose over 60 minutes Q3W presurgery (neoadjuvant) and continues Q4W after surgery (adjuvant)

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

CT=chemotherapy; Q3W=every 3 weeks.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

IMFINZI vials needed with least amount of waste

CALCULATING VIALS REQUIRED

3 × 500 mg/10 mL

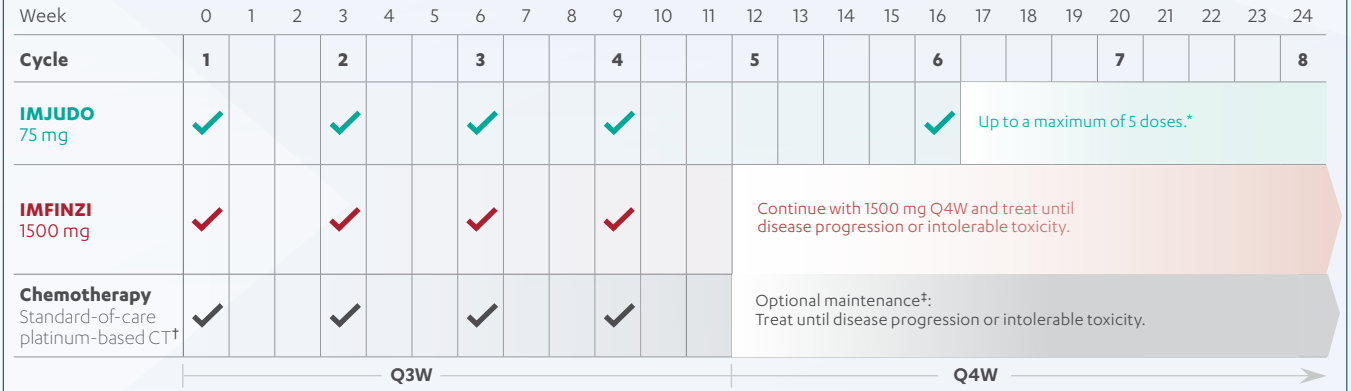
Vials are not shown to actual size or scale.

Patients with a body weight of <30 kg must receive weight-based dosing. See dosing calculator on page 23

Metastatic NSCLC

IMJUDO and IMFINZI fixed dosing

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG



- Patients with a body weight of <30 kg must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg Q3W for Cycles 1 through 4 in combination with IMJUDO 1 mg/kg and platinum-based chemotherapy.† For Cycle 5 and later, administer IMFINZI 20 mg/kg Q4W as a single agent until disease progression or intolerable toxicity and optional histology-based pemetrexed maintenance‡ Q4W—and a fifth dose of IMJUDO 1 mg/kg alongside IMFINZI only in Cycle 6 (Week 16)
- IMFINZI and IMJUDO are each administered as a 60-minute IV infusion
- Weigh patients prior to each infusion
- Administer IMJUDO, followed by IMFINZI and then chemotherapy, all on the same day
- For dosing and administration of chemotherapy, please refer to the Prescribing Information for that treatment

*If patients receive fewer than 4 cycles of platinum-based CT, the remaining cycles of IMJUDO should be given after platinum-based CT phase in combination with IMFINZI Q4W.
†Platinum-based CT is given Q3W for 4 cycles. Options include pemetrexed + carboplatin/cisplatin (nonsquamous); gemcitabine + carboplatin/cisplatin (squamous); or nab-paclitaxel + carboplatin (either histology). Starting in Week 12, nonsquamous patients who received pemetrexed as part of the first-line regimen can continue pemetrexed maintenance Q4W until disease progression or intolerable toxicity.
‡Pemetrexed maintenance for nonsquamous patients who received treatment with pemetrexed and carboplatin/cisplatin.

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

mNSCLC=metastatic non-small cell lung cancer.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

mNSCLC

Metastatic NSCLC

IMJUDO and IMFINZI vials needed with least amount of waste

CALCULATING VIALS REQUIRED

3 × 25 mg/1.25 mL IMJUDO

3 × 500 mg/10 mL IMFINZI

Vials are not shown to actual size or scale.

Patients with a body weight of <30 kg must receive weight-based dosing. See dosing calculator on pages 23 and 24

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

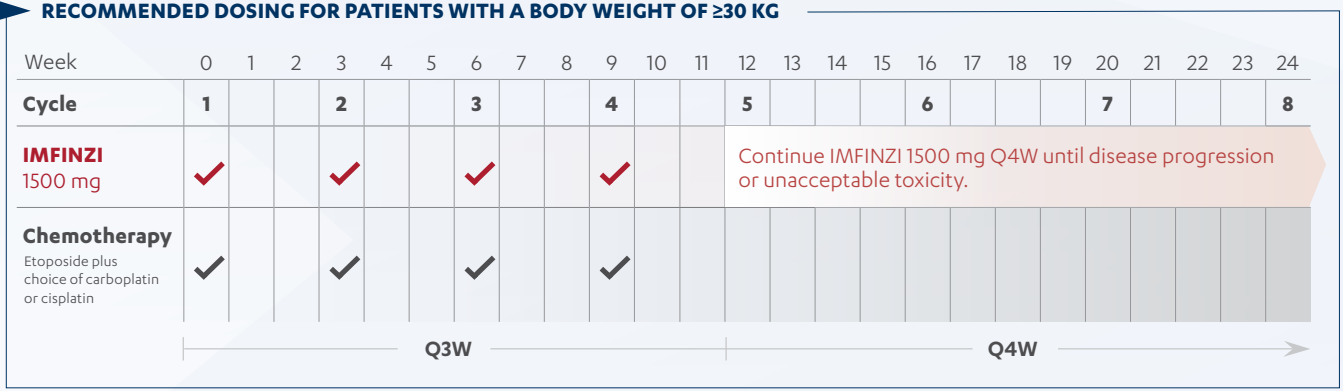
IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

mNSCLC

Extensive-stage SCLC

IMFINZI fixed dosing

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG



Patients with a body weight of <30 kg must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg in combination with chemotherapy Q3W (21 days) for 4 cycles, followed by 10 mg/kg Q2W as a single agent. EP consists of etoposide 80 mg/m² to 100 mg/m² with either carboplatin AUC 5 mg/mL/min or 6 mg/mL/min or cisplatin 75 mg/m² to 80 mg/m². For more information, please refer to the Prescribing Information for each treatment.

- IMFINZI is administered as a 60-minute IV infusion with no premedication required
- Administer IMFINZI prior to chemotherapy on the same day
- Administer IMFINZI + EP Q3W for 4 cycles followed by Q4W IMFINZI maintenance
- For dosing and administration of chemotherapy, please refer to the Prescribing Information for that treatment

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

EP=etoposide and either carboplatin or cisplatin.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

Extensive-stage SCLC

IMFINZI vials needed with least amount of waste

CALCULATING VIALS REQUIRED

3 × 500 mg/10 mL IMFINZI

Vials are not shown to actual size or scale.

Patients with a body weight of <30 kg must receive weight-based dosing. See dosing calculator on page 23

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

ES-SCLC

Hepatobiliary Indications

LOCALLY ADVANCED OR METASTATIC BILIARY TRACT CANCERS (BTCs)

IMFINZI, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).

UNRESECTABLE HEPATOCELLULAR CARCINOMA (uHCC)

IMFINZI in combination with IMJUDO is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Pneumonitis (continued)

- ***IMFINZI as a Single Agent* (continued)**
  - The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar in patients who received IMFINZI as a single agent or with ES-SCLC or BTC when given in combination with chemotherapy.
- ***IMFINZI with IMJUDO***
  - Immune-mediated pneumonitis occurred in 1.3% (5/388) of patients receiving IMFINZI and IMJUDO, including fatal (0.3%) and Grade 3 (0.2%) adverse reactions.

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

HCC=hepatocellular carcinoma.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

Locally Advanced or Metastatic Biliary Tract Cancers

IMFINZI fixed dosing

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG

- Patients with a body weight of <30 kg: 20 mg/kg in combination with gemcitabine and cisplatin every 3 weeks (21 days) for up to 8 cycles, followed by 20 mg/kg every 4 weeks as a single agent
- In the TOPAZ-1 study, IMFINZI 1500 mg was administered on Day 1 of each cycle in combination with gemcitabine 1000 mg/m^2 and cisplatin 25 mg/m^2 on Days 1 and 8 of each 21-day cycle for up to 8 cycles, followed by IMFINZI 1500 mg every 4 weeks until disease progression or unacceptable toxicity
- IMFINZI is administered as a 60-minute IV infusion after dilution
- Administer IMFINZI prior to chemotherapy on the same day
- Refer to the Prescribing Information for appropriate chemotherapeutic agent for dosing information

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

Gem-cis=gemcitabine-cisplatin.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

Locally Advanced or Metastatic Biliary Tract Cancers

IMFINZI vials needed with least amount of waste

CALCULATING VIALS REQUIRED

3 × 500 mg/10 mL IMFINZI

Vials are not shown to actual size or scale.

Patients with a body weight of <30 kg must receive weight-based dosing of 20 mg/kg. See dosing calculator on page 23

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

Unresectable Hepatocellular Carcinoma

IMJUDO and IMFINZI fixed dosing

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Cycle	**1**				**2**				**3**				**4**				**5**				**6**				**7**
IMJUDO 300 mg	✓																								
IMFINZI 1500 mg	✓				✓				✓				✓				✓				Continue IMFINZI Q4W until disease progression or unacceptable toxicity.				

- The STRIDE Regimen (Single Tremelimumab Regular Interval Durvalumab): A single dose of IMJUDO 300 mg followed by IMFINZI 1500 mg on Day 1 of Cycle 1; continue IMFINZI 1500 mg as a single agent Q4W
- Patients with a body weight of <30 kg must receive weight-based dosing equivalent to 4 mg/kg of IMJUDO and 20 mg/kg of IMFINZI at Day 1 of Cycle 1 followed by IMFINZI as a single agent Q4W, until body weight is ≥30 kg
- IMJUDO and IMFINZI are each administered as a 60-minute IV infusion with no premedication required
- Administer IMJUDO prior to IMFINZI on the same day (Day 1)
- Observe patient for 60 minutes following completion of IMJUDO infusion. Then administer IMFINZI as a separate IV infusion over 60 minutes on the same day

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

uHCC

Unresectable Hepatocellular Carcinoma

IMJUDO and IMFINZI vials needed with least amount of waste

CALCULATING VIALS REQUIRED

1 × 300 mg/15 mL IMJUDO

3 × 500 mg/10 mL IMFINZI

Vials are not shown to actual size or scale.

Patients with a body weight of <30 kg must receive weight-based dosing of 4 mg/kg for IMJUDO and 20 mg/kg for IMFINZI. See dosing calculator on pages 23 and 24

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

uHCC

Endometrial Indications

PRIMARY ADVANCED OR RECURRENT MISMATCH REPAIR DEFICIENT ENDOMETRIAL CANCER (dMMR EC)

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 (continued)

Immune-Mediated Pneumonitis (continued)

- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated pneumonitis occurred in 3.5% (21/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including fatal (0.5%), and Grade 3 (1%) adverse reactions.

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

Primary Advanced or Recurrent dMMR Endometrial Cancer

IMFINZI fixed dosing

RECOMMENDED DOSING FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Cycle	**1**			**2**			**3**			**4**			**5**			**6**			**7**				**8**		
IMFINZI 1120 mg for 6 cycles	✓			✓			✓			✓			✓			✓			Continue with IMFINZI monotherapy Q4W 1500 mg until disease progression or unacceptable toxicity.						
Carboplatin	✓			✓			✓			✓			✓			✓									
Paclitaxel	✓			✓			✓			✓			✓			✓									
	Q3W																		Q4W						

- Patients with a body weight of <30 kg: IMFINZI 15 mg/kg in combination with carboplatin and paclitaxel every 3 weeks (21 days) for 6 cycles, followed by IMFINZI 20 mg/kg every 4 weeks as a single agent
- IMFINZI is administered as a 60-minute IV infusion
- Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information of the appropriate chemotherapeutic agent for dosage information
- Select patients for treatment based on the presence of dMMR in tumor specimens*

*An FDA-approved test for the detection of dMMR in tumor specimens from patients with primary advanced or recurrent endometrial cancer for treatment with IMFINZI is not available.

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

EC

Primary Advanced or Recurrent dMMR Endometrial Cancer

IMFINZI vials needed with least amount of waste

CALCULATING VIALS REQUIRED

Vials required during the CP combination phase

10 × 120 mg/2.4 mL IMFINZI*

Vials required during the IMFINZI monotherapy phase

3 × 500 mg/10 mL IMFINZI*

Vials are not shown to actual size or scale.

*Per cycle.

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

CP=carboplatin and paclitaxel.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

EC

IMFINZI Administration

Preparation

Visually inspect drug product for particulate matter and discoloration prior to administration whenever solution and container permit. Discard the vial if the solution is cloudy, discolored, or visible particles are observed

Do not shake the vial

Withdraw the required volume from the vial(s) of IMFINZI and transfer into an IV bag containing 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake the solution. The final concentration of the diluted solution should be between 1 mg/mL and 15 mg/mL

Discard partially used or empty vials of IMFINZI

Administration

Administer infusion solution intravenously over 60 minutes through an IV line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter

For combination therapy, administer all drug products as separate IV infusions. Use separate infusion bags and filters for each drug product

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

USP=United States Pharmacopeia.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

IMFINZI Storage

IMFINZI does not contain a preservative. The time from preparation until completion of the infusion should not exceed:

- 28 days in a refrigerator at 2°C to 8°C (36°F to 46°F)
- 8 hours at room temperature up to 25°C (77°F)
- Do not freeze
- Do not shake

IMFINZI® (durvalumab) is supplied as single-use vials that contain:

- 120 mg/2.4 mL (50 mg/mL)
- 500 mg/10 mL (50 mg/mL)

Vials are not shown to actual size or scale.

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

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

IMJUDO Administration

Preparation

Visually inspect drug product for particulate matter and discoloration whenever solution and container permit. Discard the vial if the solution is cloudy, discolored, or visible particles are observed

Discard partially used or empty vials

Do not shake the vial

Withdraw the required volume from the vial(s) of IMJUDO and transfer into an IV bag containing 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake the solution.

The final concentration of the diluted solution should be between 0.1 mg/mL and 10 mg/mL

- For patients weighing ≥30 kg and IMJUDO doses of 75 mg or 300 mg, the maximum volume of diluent is 150 mL
- For patients weighing <30 kg and doses of IMJUDO at 1 mg/kg or 4 mg/kg, the maximum volume of diluent is 80 mL

Administration

Administer infusion solution intravenously over 60 minutes through an IV line containing a sterile, low-protein binding 0.2 or 0.22 micron filter

Do not co-administer other drugs through the same infusion line. Use separate infusion bags and filters for each drug product

IMJUDO Storage

IMJUDO does not contain a preservative. The total time from preparation to the start of administration should not exceed:

- 24 hours in a refrigerator at 2°C to 8°C (36°F to 46°F)
- 24 hours at room temperature up to 30°C (86°F)
- Do not freeze
- Do not shake

IMJUDO® (tremelimumab-actl) is supplied as single-use vials that contain:

- 25 mg/1.25 mL (20 mg/mL)
- 300 mg/15 mL (20 mg/mL)

Vials are not shown to actual size or scale.

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

IMJUDO® tremelimumab-actl
Injection for Intravenous Use 20 mg/mL

IMFINZI weight-based dosing calculator*

DOSING FOR UNRESECTABLE STAGE III NSCLC, FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG

Patients with a body weight of <30 kg must receive weight-based dosing

STEP 1 **Determine dose**	10 mg/kg × patient weight (kg) = **Total mg**
STEP 2 **Identify volume**	**Total mg** ÷ 50 mg/mL = **Total volume**
STEP 3 **Calculate vials**	**Total volume** ÷ 10-mL vials *or* 2.4-mL vials = **Total vials**

DOSING ACROSS INDICATIONS FOR PATIENTS WITH A BODY WEIGHT OF <30 KG

Patients with a body weight of <30 kg must receive weight-based dosing; dose dependent on indication as depicted below

	Unresectable Stage III NSCLC/ ES-SCLC (monotherapy)	EC (combination therapy)	Resectable NSCLC/Metastatic NSCLC/ ES-SCLC (combination therapy)/ Unresectable HCC/BTCs/ EC (monotherapy)
STEP 1 **Determine dose**	10 mg/kg × patient weight (kg) = **Total mg**	15 mg/kg × patient weight (kg) = **Total mg**	20 mg/kg × patient weight (kg) = **Total mg**
STEP 2 **Identify volume**	**Total mg** ÷ 50 mg/mL = **Total volume**	**Total mg** ÷ 50 mg/mL = **Total volume**	**Total mg** ÷ 50 mg/mL = **Total volume**
STEP 3 **Calculate vials**	**Total volume** ÷ 10-mL vials *or* 2.4-mL vials = **Total vials**	**Total volume** ÷ 10-mL vials *or* 2.4-mL vials = **Total vials**	**Total volume** ÷ 10-mL vials *or* 2.4-mL vials = **Total vials**

*Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage modifications.

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

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL +/- IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL

Dosing Calculator

IMJUDO weight-based dosing calculator

DOSING ACROSS INDICATIONS FOR PATIENTS WITH A BODY WEIGHT OF <30 KG

Patients with a body weight of <30 kg must receive weight-based dosing; dose dependent on indication as depicted below

	Metastatic NSCLC	uHCC
STEP 1 **Determine dose**	1 mg/kg × patient weight (kg) = **Total mg**	4 mg/kg × patient weight (kg) = **Total mg**
STEP 2 **Identify volume**	**Total mg** ÷ 20 mg/mL = **Total volume**	**Total mg** ÷ 20 mg/mL = **Total volume**
STEP 3 **Calculate vials**	**Total volume** ÷ 15-mL vials *or* 1.25-mL vials = **Total vials**	**Total volume** ÷ 15-mL vials *or* 1.25-mL vials = **Total vials**

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Colitis

IMFINZI with IMJUDO and platinum-based chemotherapy can cause immune-mediated colitis, which may be fatal.
IMFINZI and IMJUDO 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.

- ***IMFINZI as a Single Agent***
  - Immune-mediated colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Immune-mediated colitis or diarrhea occurred in 6% (23/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (3.6%) adverse reactions. Intestinal perforation has been observed in other studies of IMFINZI and IMJUDO.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated colitis occurred in 6.5% (39/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy including fatal (0.2%) and Grade 3 (2.5%) adverse reactions. Intestinal perforation and large intestine perforation were reported in 0.1% of patients.

Immune-Mediated Hepatitis

IMFINZI and IMJUDO can cause immune-mediated hepatitis, which may be fatal.

- ***IMFINZI as a Single Agent***
  - Immune-mediated hepatitis occurred in 2.8% (52/1889) of patients receiving IMFINZI, including fatal (0.2%), Grade 4 (0.3%) and Grade 3 (1.4%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Immune-mediated hepatitis occurred in 7.5% (29/388) of patients receiving IMFINZI and IMJUDO, including fatal (0.8%), Grade 4 (0.3%) and Grade 3 (4.1%) adverse reactions.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated hepatitis occurred in 3.9% (23/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including fatal (0.3%), Grade 4 (0.5%), and Grade 3 (2%) adverse reactions.

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IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency***: IMFINZI and IMJUDO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated.
  - ***IMFINZI as a Single Agent***
    - Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
  - ***IMFINZI with IMJUDO***
    - Immune-mediated adrenal insufficiency occurred in 1.5% (6/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (0.3%) adverse reactions.
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated adrenal insufficiency occurred in 2.2% (13/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.8%) adverse reactions.
- ***Hypophysitis***: IMFINZI and IMJUDO 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.
  - ***IMFINZI as a Single Agent***
    - Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
  - ***IMFINZI with IMJUDO***
    - Immune-mediated hypophysitis/hypopituitarism occurred in 1% (4/388) of patients receiving IMFINZI and IMJUDO.
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated hypophysitis occurred in 1.3% (8/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.5%) adverse reactions.
- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: IMFINZI and IMJUDO 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 as a Single Agent***
    - Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
    - Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
    - Immune-mediated hypothyroidism occurred in 8.3% (156/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

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IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies (continued)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)* (continued)**
  - ***IMFINZI with IMJUDO***
    - Immune-mediated thyroiditis occurred in 1.5% (6/388) of patients receiving IMFINZI and IMJUDO.
    - Immune-mediated hyperthyroidism occurred in 4.6% (18/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (0.3%) adverse reactions.
    - Immune-mediated hypothyroidism occurred in 11% (42/388) of patients receiving IMFINZI and IMJUDO.
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated thyroiditis occurred in 1.2% (7/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy.
    - Immune-mediated hyperthyroidism occurred in 5% (30/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.2%) adverse reactions.
    - Immune-mediated hypothyroidism occurred in 8.6% (51/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.5%) adverse reactions.
  - ***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.
  - ***IMFINZI as a Single Agent***
    - Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.
  - ***IMFINZI with IMJUDO***
    - Two patients (0.5%, 2/388) had events of hyperglycemia requiring insulin therapy that had not resolved at last follow-up.
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated Type 1 diabetes mellitus occurred in 0.5% (3/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy including Grade 3 (0.3%) adverse reactions.

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IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI and IMJUDO can cause immune-mediated nephritis.

- ***IMFINZI as a Single Agent***
  - Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Immune-mediated nephritis occurred in 1% (4/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (0.5%) adverse reactions.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated nephritis occurred in 0.7% (4/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.2%) adverse reactions.

Immune-Mediated Dermatology Reactions

IMFINZI and IMJUDO 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 and CTLA-4 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

- ***IMFINZI as a Single Agent***
  - Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Immune-mediated rash or dermatitis occurred in 4.9% (19/388) of patients receiving IMFINZI and IMJUDO, including Grade 4 (0.3%) and Grade 3 (1.5%) adverse reactions.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated rash or dermatitis occurred in 7.2% (43/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.3%) adverse reactions.

Immune-Mediated Pancreatitis

IMFINZI in combination with IMJUDO can cause immune-mediated pancreatitis. Immune-mediated pancreatitis occurred in 2.3% (9/388) of patients receiving IMFINZI and IMJUDO, including Grade 4 (0.3%) and Grade 3 (1.5%) adverse reactions.

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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 and IMJUDO or were reported with the use of other immune-checkpoint inhibitors.

- ***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 and IMJUDO 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 and IMJUDO 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.

- ***IMFINZI as a Single Agent***
  - Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Infusion-related reactions occurred in 10 (2.6%) patients receiving IMFINZI and IMJUDO.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Infusion-related reactions occurred in 2.9% (17/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.3%) adverse reactions.

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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 and IMJUDO 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 IMJUDO and advise them to use effective contraception during treatment with IMFINZI and IMJUDO and for 3 months after the last dose of IMFINZI and IMJUDO.

Lactation

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

Adverse Reactions

Unresectable Stage III NSCLC

- In patients with Stage III NSCLC in the PACIFIC study receiving IMFINZI (n=475), the most common adverse reactions (≥20%) were cough (40%), fatigue (34%), pneumonitis or radiation pneumonitis (34%), upper respiratory tract infections (26%), dyspnea (25%), and rash (23%). The most common Grade 3 or 4 adverse reactions (≥3%) were pneumonia (7%) and pneumonitis/radiation pneumonitis (3.4%).
- In patients with Stage III NSCLC in the PACIFIC study receiving IMFINZI (n=475), discontinuation due to adverse reactions occurred in 15% of patients in the IMFINZI arm. Serious adverse reactions occurred in 29% of patients receiving IMFINZI. The most frequent serious adverse reactions (≥2%) were pneumonitis or radiation pneumonitis (7%) and pneumonia (6%). Fatal pneumonitis or radiation pneumonitis and fatal pneumonia occurred in <2% of patients and were similar across arms.

Resectable NSCLC

- In patients with resectable NSCLC in the AEGEAN study, the most common adverse reactions (occurring in ≥20% of patients) were anemia, nausea, constipation, fatigue, musculoskeletal pain, and rash.

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IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

Resectable NSCLC (continued)

- In patients with resectable NSCLC in the neoadjuvant phase of the AEGEAN study receiving IMFINZI in combination with platinum-containing chemotherapy (n=401), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 6.7% of patients. Serious adverse reactions occurred in 21% of patients. The most frequent (≥1%) serious adverse reactions were pneumonia (2.7%), anemia (1.5%), myelosuppression (1.5%), vomiting (1.2%), neutropenia (1%), and acute kidney injury (1%). Fatal adverse reactions occurred in 2% of patients, including death due to COVID-19 pneumonia (0.5%), sepsis (0.5%), myocarditis (0.2%), decreased appetite (0.2%), hemoptysis (0.2%), and death not otherwise specified (0.2%). Of the 401 IMFINZI treated patients who received neoadjuvant treatment and 398 placebo-treated patients who received neoadjuvant treatment, 1.7% (n=7) and 1% (n=4), respectively, did not receive surgery due to adverse reactions.
- In patients with resectable NSCLC in the adjuvant phase of the AEGEAN study receiving IMFINZI as a single agent (n=265), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 8% of patients. Serious adverse reactions occurred in 13% of patients. The most frequent serious adverse reactions reported in >1% of patients were pneumonia (1.9%), pneumonitis (1.1%), and COVID-19 (1.1%). Four fatal adverse reactions occurred during the adjuvant phase of the study, including COVID-19 pneumonia, pneumonia aspiration, interstitial lung disease and aortic aneurysm.

Metastatic NSCLC

- In patients with mNSCLC in the POSEIDON study receiving IMFINZI and IMJUDO plus platinum-based chemotherapy (n=330), the most common adverse reactions (occurring in ≥20% of patients) were nausea (42%), fatigue (36%), musculoskeletal pain (29%), decreased appetite (28%), rash (27%), and diarrhea (22%).
- In patients with mNSCLC in the POSEIDON study receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy (n=330), permanent discontinuation of IMFINZI or IMJUDO due to an adverse reaction occurred in 17% of patients. Serious adverse reactions occurred in 44% of patients, with the most frequent serious adverse reactions reported in at least 2% of patients being pneumonia (11%), anemia (5%), diarrhea (2.4%), thrombocytopenia (2.4%), pyrexia (2.4%), and febrile neutropenia (2.1%). Fatal adverse reactions occurred in a total of 4.2% of patients.

Extensive-stage Small Cell Lung Cancer

- In patients with extensive-stage SCLC in the CASPIAN study receiving IMFINZI plus chemotherapy (n=265), the most common adverse reactions (≥20%) were nausea (34%), fatigue/asthenia (32%), and alopecia (31%). The most common Grade 3 or 4 adverse reaction (≥3%) was fatigue/asthenia (3.4%).
- In patients with extensive-stage SCLC in the CASPIAN study receiving IMFINZI plus chemotherapy (n=265), IMFINZI was discontinued due to adverse reactions in 7% of the patients receiving IMFINZI plus chemotherapy. Serious adverse reactions occurred in 31% of patients receiving IMFINZI plus chemotherapy. The most frequent serious adverse reactions reported in at least 1% of patients were febrile neutropenia (4.5%), pneumonia (2.3%), anemia (1.9%), pancytopenia (1.5%), pneumonitis (1.1%), and COPD (1.1%). Fatal adverse reactions occurred in 4.9% of patients receiving IMFINZI plus chemotherapy.

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IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

Locally Advanced or Metastatic Biliary Tract Cancers

- In patients with locally advanced or metastatic BTC in the TOPAZ-1 study receiving IMFINZI (n=338), the most common adverse reactions (occurring in ≥20% of patients) were fatigue (42%), nausea (40%), constipation (32%), decreased appetite (26%), abdominal pain (24%), rash (23%), and pyrexia (20%).
- In patients with locally advanced or metastatic BTC in the TOPAZ-1 study receiving IMFINZI (n=338), discontinuation due to adverse reactions occurred in 6% of the patients receiving IMFINZI plus chemotherapy. Serious adverse reactions occurred in 47% of patients receiving IMFINZI plus chemotherapy. The most frequent serious adverse reactions reported in at least 2% of patients were cholangitis (7%), pyrexia (3.8%), anemia (3.6%), sepsis (3.3%) and acute kidney injury (2.4%). Fatal adverse reactions occurred in 3.6% of patients receiving IMFINZI plus chemotherapy. These include ischemic or hemorrhagic stroke (4 patients), sepsis (2 patients), and upper gastrointestinal hemorrhage (2 patients).

Unresectable Hepatocellular Carcinoma

- In patients with unresectable HCC in the HIMALAYA study receiving IMFINZI and IMJUDO (n=388), the most common adverse reactions (occurring in ≥20% of patients) were rash (32%), diarrhea (27%), fatigue (26%), pruritus (23%), musculoskeletal pain (22%), and abdominal pain (20%).
- In patients with unresectable HCC in the HIMALAYA study receiving IMFINZI and IMJUDO (n=388), serious adverse reactions occurred in 41% of patients. Serious adverse reactions in >1% of patients included hemorrhage (6%), diarrhea (4%), sepsis (2.1%), pneumonia (2.1%), rash (1.5%), vomiting (1.3%), acute kidney injury (1.3%), and anemia (1.3%). Fatal adverse reactions occurred in 8% of patients who received IMFINZI and IMJUDO, including death (1%), hemorrhage intracranial (0.5%), cardiac arrest (0.5%), pneumonitis (0.5%), hepatic failure (0.5%), and immune-mediated hepatitis (0.5%). Permanent discontinuation of treatment regimen due to an adverse reaction occurred in 14% of patients.

Primary advanced or Recurrent dMMR Endometrial Cancer

- 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 and IMJUDO have not been established in pediatric patients.

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Indications:

IMFINZI, as a single agent, is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

IMFINZI, in combination with IMJUDO and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations.

IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

IMFINZI, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).

IMFINZI in combination with IMJUDO is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).

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).

You may report side effects related to AstraZeneca products.

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IMFINZI

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