UNRESECTABLE STAGE III NSCLC FOLLOWING CRT

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Nurse Guide to Managing Pneumonitis

For your patients on the PACIFIC Regimen

Indication:

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 (cCRT).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Immune-Mediated Adverse Reactions

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

CRT=chemoradiotherapy; NSCLC=non-small cell lung cancer.

In unresectable Stage III NSCLC following CRT

The PACIFIC Regimen: A comprehensive treatment plan for up to 12 months of IMFINZI following CRT in unresectable Stage III NSCLC[1-3*†]

THE PACIFIC REGIMEN[1,3*]

CONCURRENT PLATINUM-BASED
CRT
~6 weeks
(≥2 cycles CT administered concurrently with RT; 60 Gy)

IMFINZI
up to 12 months
or until disease progression or unacceptable toxicity[‡]

Study design: The PACIFIC study was a large, Phase III, randomized, double-blind, placebo-controlled, international study of 713 patients with unresectable Stage III NSCLC who had not progressed following concurrent, platinum-based CRT. Patients had completed at least 2 cycles of concurrent CRT within 42 days prior to initiation of the study drug and had a WHO performance status of 0 or 1. Randomization at enrollment was stratified according to age, sex, and smoking history. Patients were randomized 2:1 to receive 10 mg/kg of IMFINZI or placebo every 2 weeks for up to 12 months or until unacceptable toxicity or confirmed disease progression. Coprimary endpoints were PFS (measured based on RECIST v1.1 criteria by BICR) and OS. Secondary endpoints included: Percentage of patients alive without disease progression at 12 and 18 months, ORR, DoR, and TTDM.[1,3]

*In patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemoradiotherapy.[1]

†PACIFIC study enrollment was based on the *Staging Manual in Thoracic Oncology*, version 7, of the International Association for the Study of Lung Cancer. The 8th edition of the International Association for the Study of Lung Cancer *Staging Manual in Thoracic Oncology* includes the addition of Stage IIIC; in the PACIFIC study, these patients were categorized as Stage IIIB.[2-4]

‡Refer to Prescribing Information for information on dosage modifications.

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

BICR=blinded independent central review; CI=confidence interval; CT=chemotherapy; DoR=duration of response; Gy=gray; HR=hazard ratio; mOS=median overall survival; NR=not reached; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; RECIST=Response Evaluation Criteria in Solid Tumors; RT=radiotherapy; TTDM=time to death or distant metastasis; WHO=World Health Organization.

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In unresectable Stage III NSCLC following CRT

IMFINZI demonstrated consistent overall survival in 2-year and 5-year analyses[1,5]

2-year primary overall survival analysis (25.2 months median follow-up): mOS not reached with IMFINZI vs 28.7 months with placebo (HR=0.68; 95% CI, 0.53-0.87; *P*=0.0025)[1,6§]

5-YEAR OS RATE POST-HOC ANALYSIS[5‖]

43% with the **PACIFIC Regimen** VS **33%** with placebo following CRT

- Median OS was 47.5 months with IMFINZI (95% CI, 38.1-52.9) vs 29.1 months with placebo (95% CI, 22.1-35.1); HR=0.72; 95% CI, 0.59-0.89

- **The post-hoc 5-year OS analysis was conducted at ~5 years after the last patient was randomized, and was not powered to show statistical significance**

§The primary 2-year OS analysis was conducted after 299 deaths for 42% maturity (61% of targeted events) with a median follow-up of 25.2 months. Reduction in the risk of death vs placebo was 32% (95% CI, 0.53-0.87) with a log-rank test stratified by sex, age, and smoking history. Median OS was NR with IMFINZI (95% CI, 34.7-NR) vs 28.7 months with placebo (95% CI, 22.9-NR).[1,6]

‖The post-hoc 5-year OS analysis was conducted at ~5 years after the last patient was randomized, and was not powered to show statistical significance. Median OS was 47.5 months with IMFINZI (95% CI, 38.1-52.9) vs 29.1 months with placebo (95% CI, 22.1-35.1). Reduction in the risk of death vs placebo was 28% (HR=0.72; 95% CI, 0.59-0.89) with a log-rank test stratified by sex, age, and smoking history. OS rates with IMFINZI vs placebo were: 83% (95% CI, 79.4-86.2) vs 75% (95% CI, 68.5-79.7) at 12 months, 66% (95% CI, 61.8-70.4) vs 55% (95% CI, 48.6-61.4) at 24 months, 57% (95% CI, 52.0-61.1) vs 44% (95% CI, 37.1-49.9) at 36 months, 50% (95% CI, 45.0-54.2) vs 36% (95% CI, 30.1-42.6) at 48 months, and 43% (95% CI, 38.2-47.4) vs 33% (95% CI, 27.3-39.6) at 60 months.[5]

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. 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.

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In unresectable Stage III NSCLC following CRT

Pneumonitis may require interruption or discontinuation of IMFINZI[1]

In the PACIFIC trial, most patients who developed pneumonitis experienced either Grade 1 or Grade 2 symptoms[7]

- Pneumonitis included acute interstitial pneumonitis, interstitial lung disease, pneumonitis, pulmonary fibrosis, radiation pneumonitis, alveolitis, and diffuse alveolar damage[7]
- Pneumonitis (any grade and all causes, including radiation pneumonitis) occurred in 34% of patients treated with IMFINZI and 25% with placebo[7]

PNEUMONITIS INCIDENCE BY GRADE IN THE PACIFIC STUDY[7]

Pneumonitis grade	IMFINZI (n=476)	Placebo (n=237)
Grade 1	14%	11%
Grade 2	15%	9%
Grade 3	4%	3%
Grade 4	0%	0%
Grade 5	1%	2%

Additional post-hoc exploratory analyses were performed[7]*

- 89% of IMFINZI-treated patients with Grade 2 to 4 pneumonitis were treated with corticosteroids[7†]

INTERRUPTION AND DISCONTINUATION RATES PER TRIAL ARM AMONG PATIENTS WHO EXPERIENCED PNEUMONITIS[7]

	IMFINZI				
	Grade 1 (n=67)	**Grade 2 (n=72)**	**Grade 3 (n=17)**	**Grade 4 (n=0)**	**Grade 5 (n=5)**
Interruption	**16%**	**63%**	**24%**	**N/A**	**0%**
Discontinuation	**3%**	**17%**	**65%**	**N/A**	**100%**
	Placebo				
	Grade 1 (n=25)	Grade 2 (n=22)	Grade 3 (n=6)	Grade 4 (n=0)	Grade 5 (n=5)
Interruption	16%	68%	50%	N/A	0%
Discontinuation	0%	14%	67%	N/A	60%

Support your patients receiving IMFINZI through proper management of pneumonitis

*The "as-treated" population.[7]
†Pneumonitis occurring on study treatment and within 90 days of the final dose, or prior to initiation of subsequent anticancer therapy, whichever occurred earlier.[7]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Pneumonitis (continued)

Of the patients who received IMFINZI (475), 1.1% were fatal and 2.7% were Grade 3 adverse reactions. 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.

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

IMPORTANT SAFETY INFORMATION (continued)

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 colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.

N/A=not applicable.

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Early identification and management of pneumonitis can help your patients receiving IMFINZI

The role of nurses is important in helping patients during their IMFINZI treatment. Here's how you can help.

1. Collaborate with the medical and radiation oncologists[8-13]

Working together as early as possible is crucial to early identification and management of pneumonitis

- Because the mechanisms of pneumonitis are largely unknown but may be a result of direct cytotoxic effects, oxidative stress, or immune-mediated reactions, multidisciplinary communication and continued monitoring are recommended[14,15]

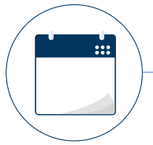
2. Recognize the symptoms[8,16,17]

Symptoms may include shortness of breath, cough, congestion, chest pain, and fever

- ~15% of patients going through CRT experience radiation pneumonitis, usually developing symptoms 1 to 3 months after completing radiation

3. Teach patients and caregivers the importance of reporting symptoms

Let patients know about what symptoms to watch out for, so that any symptoms that occur are reported as soon as possible. Caregivers may be able to identify symptoms if the patient does not—reinforce to caregivers their role in helping patients complete treatment



4. Be aware of timing[16,18]

It's important to be extra vigilant when pneumonitis is at its highest prevalence

- The median time to onset of pneumonitis (from last dose of radiotherapy) was 2.3 months (70 days; IQR, 50-104 days) for patients in the PACIFIC trial

5. Proactively manage pneumonitis

Communicate and coordinate with the MDT to treat pneumonitis at the earliest signs

- Patients with Grade 1 pneumonitis should be monitored clinically and radiologically for worsening symptoms. No intervention is indicated; infectious evaluation is recommended to rule out any additional causes of pulmonary infection[18-20]
- **Withhold IMFINZI** for Grade 2 pneumonitis. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper[1,18]
- **Permanently discontinue IMFINZI**[1,18]
  - If Grade 2:
    - When pneumonitis does not improve to ≤Grade 1 within 12 weeks of initiating corticosteroids
    - When prednisone (or equivalent) cannot be reduced to ≤10 mg/day within 12 weeks of initiating corticosteroids
  - If Grade 3 or 4 pneumonitis develops

Pneumonitis (Grade 2) may be managed with corticosteroids and by withholding IMFINZI until Grade ≤1[1]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis. 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.

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. Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

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

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies (continued)

- ***Hypophysitis***: IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated. Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
- ***Thyroid Disorders***: 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.

IQR=interquartile range; MDT=multidisciplinary team.

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Grading pneumonitis is key to early management

Nurses work closely with patients and are often first in identifying pneumonitis

GRADE 1 PNEUMONITIS MAY BE ASYMPTOMATIC[21]

	Grade 1	Grade 2	Grade 3	Grade 4
Definition[21]*	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	• Symptomatic • Medical intervention indicated • Limiting instrumental ADLs†	• Severe symptoms • Limiting self-care ADLs‡ • Supplementary oxygen indicated	• Life-threatening respiratory compromise • Urgent intervention indicated (eg, tracheotomy or intubation)
IMFINZI dosage modifications[1]	**Continue treatment with IMFINZI**	**Withhold IMFINZI** Until ≤Grade 1 and corticosteroid dose is less than or equal to prednisone 10 mg per day (or equivalent), then resume treatment with IMFINZI	**Permanently discontinue IMFINZI**	
Corticosteroids[1,22,23]		Initial recommended minimum dose (1 mg/kg/day) to 2 mg/kg/day prednisone or equivalent	Initial recommended minimum dose (1 mg/kg/day) to 4 mg/kg/day prednisone or equivalent	

*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), v5.0.[21]
†Instrumental ADLs refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.[21]
‡Self-care ADLs refer to bathing, dressing and undressing, self-feeding, using the toilet, taking medications, and not being bedridden.[21]

FOLLOW-UP: WORSENING OR NO IMPROVEMENT[1]

Withhold IMFINZI[§]	➢ **If pneumonitis worsens to Grade 2** **– Re-initiate treatment when pneumonitis has resolved to ≤Grade 1 after corticosteroid taper**
Permanently discontinue IMFINZI	➢ If Grade 2: – When pneumonitis does not improve to ≤Grade 1 within 12 weeks of initiating corticosteroids – When prednisone (or equivalent) cannot be reduced to ≤10 mg/day within 12 weeks of initiating corticosteroids ➢ If Grade 3 or 4 pneumonitis develops

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

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Endocrinopathies (continued)

- ***Thyroiditis***: Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Hyperthyroidism***: Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
- ***Hypothyroidism***: 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)

- ***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. Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

ADLs=activities of daily living.

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Help your patients actively monitor and report respiratory symptoms[8,9]

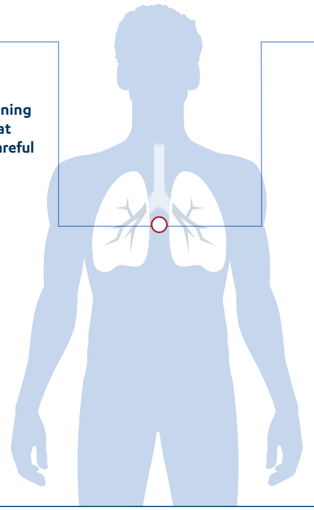
PNEUMONITIS PRESENTS AS FOCAL OR DIFFUSE INFLAMMATION OF THE LUNG PARENCHYMA[22]

Patient symptoms[8,19,22]

- **Shortness of breath**
- **Cough**
- **Chest pain**

New or worsening symptoms that may require careful management

- Wheezing
- Reduced exercise tolerance
- Fatigue with activities of daily living
- New/increasing need for supplementary oxygen
- Fever



Additional signs and symptoms

- **Decreased blood oxygen saturation[24]**
- Fine inspiratory crackles[9]
- Radiographic changes on computed tomography scan or x-ray[22]

The radiographic appearance of pneumonitis may not be associated with clinical symptoms[19]

Establish baseline symptoms and pulmonary function for all patients to ensure exclusion of other diagnoses prior to treating with IMFINZI[19,22]

Pneumonitis may occur at any time during or after treatment, so early detection is key to helping patients[19,22]

Working together with the MDT is essential to helping your patients manage pneumonitis

If your patient is presenting with ≥Grade 2 pneumonitis, withhold IMFINZI and treat with corticosteroids to help prevent worsening and manage improvement to ≤Grade 1[1]

Initial recommended minimum corticosteroid dose of 1 mg/kg/day to 2 mg/kg/day of prednisone or equivalent

➤ **Resolved to ≤Grade 1** ➤

Slowly taper over ≥1 month until corticosteroid dose is ≤10 mg/day of prednisone or equivalent

WHY TAPER?

- Tapering corticosteroids gives the adrenal glands time to resume normal function[25]
- Stopping corticosteroids abruptly or tapering too quickly can cause a flare-up of previously observed pneumonitis symptoms

Patients should be routinely evaluated during the course of treatment[19,22]

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How would you proceed if presented with the patient below?

Here's an example patient case

Patient case: Grade 2 pneumonitis

Age: 70 **Weight:** 175 lb (80 kg) **Diagnosis:** Stage IIIC unresectable NSCLC

Treatment history

- Concurrent CRT
- Partial response observed—patient did not progress
- Initiated IMFINZI 4 weeks after completion of concurrent CRT

Experience on IMFINZI

- Patient presents with worsening shortness of breath
  - Infectious workup ordered to rule out infection
- After 2 cycles of IMFINZI, patient presented with Grade 2 pneumonitis

What are the steps you can take to help this patient with their pneumonitis?

Example of managing pneumonitis by dosing and tapering corticosteroids

1. **IMFINZI withheld due to Grade 2 pneumonitis**
2. **Initial prednisone dose determined**

Patient's weight		Recommended prednisone dose[26]*		Prescribed initial dose
80 kg	×	**1-2 mg/kg/day** or equivalent	=	**80-160 mg/day**

3. **Prednisone administered, then tapered**

Administer	Taper
High (160 mg/day) prednisone dose until pneumonitis resolved to ≤Grade 1	Slowly taper prednisone over at least 4 weeks until ≤10 mg/day; monitor patient weekly[1,26†‡]

4. **IMFINZI re-initiated when pneumonitis is ≤Grade 1 and prednisone reached ≤10 mg/day[1]**
   - Permanently discontinue IMFINZI:
     - When pneumonitis does not improve
     - When prednisone (or equivalent) cannot be reduced to ≤10 mg/day within 12 weeks of initiating corticosteroids
5. **Continue with IMFINZI treatment**

*Prednisone or IV methylprednisolone.[26]
†For Grade 2, National Comprehensive Cancer Network® (NCCN®) recommends tapering over 4 to 6 weeks.[26]
‡NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

IMPORTANT SAFETY INFORMATION (continued)

Other Immune-Mediated Adverse Reactions (continued)

- ***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.

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

IMPORTANT SAFETY INFORMATION (continued)

Other Immune-Mediated Adverse Reactions (continued)

- ***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.

IV=intravenous; NCCN=National Comprehensive Cancer Network® (NCCN®).

IMPORTANT SAFETY INFORMATION (continued)

Other Immune-Mediated Adverse Reactions (continued)

- ***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. Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.

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

Lactation

There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for 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 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 pneumonitis/radiation pneumonitis (3.4%) and pneumonia (7%).
- 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.

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

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

You may report side effects related to AstraZeneca products.

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In unresectable Stage III NSCLC following CRT

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Help your patients receiving a full course of IMFINZI actively monitor and identify symptoms suggestive of pneumonitis

Work with your multidisciplinary team to treat pneumonitis by:

1. **Withholding IMFINZI until symptom regression to ≤Grade 1**[1]
   - Permanently discontinue for Grades 3 and 4
2. **Initiating corticosteroids promptly**[1,22,23]
   - Initial recommended minimum corticosteroid dose ranges from 1 mg/kg/day to 2 mg/kg/day
3. **Maintaining corticosteroids until symptoms improve to ≤Grade 1**[1]*
4. **Tapering corticosteroids over at least 4 weeks until ≤10 mg/day**[1]†
   - Permanently discontinue IMFINZI:
     - If Grade 2:
       - When pneumonitis does not improve to ≤Grade 1 within 12 weeks of initiating corticosteroids
       - When prednisone (or equivalent) cannot be reduced to ≤10 mg/day within 12 weeks of initiating corticosteroids
     - If Grade 3 or 4 pneumonitis develops
5. **Resuming IMFINZI once tapering is complete**[1]

You can help your patients receiving the PACIFIC Regimen with prompt management of pneumonitis

Indication:

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 (cCRT).

*Prednisone or IV methylprednisolone.[26]
†For Grade 2, NCCN recommends tapering over 4 to 6 weeks.[26]

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

AstraZeneca