IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

NOW AVAILABLE

FOR THE TREATMENT OF ADULT PATIENTS WITH LS-SCLC WHOSE DISEASE HAS NOT PROGRESSED FOLLOWING CONCURRENT PLATINUM-BASED CHEMOTHERAPY AND RADIATION THERAPY (cCRT)[1]

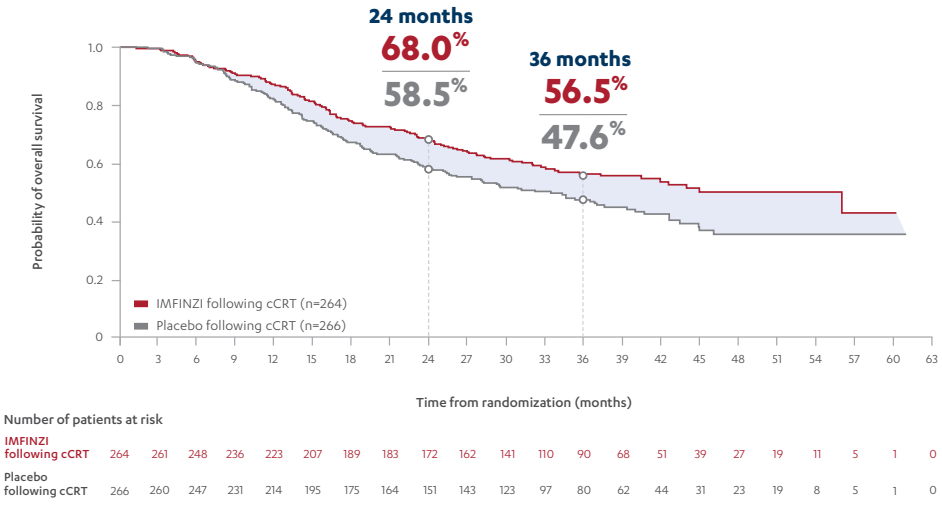
IMFINZI is the FIRST and ONLY immunotherapy in LS-SCLC to demonstrate statistically significant improvement in OS and PFS following cCRT vs placebo following cCRT[1-3]

Median OS was 55.9 months with IMFINZI following cCRT vs 33.4 months with placebo following cCRT (HR=0.73; 95% CI, 0.57-0.93, *P*=0.0104)[1,2*]

Increased mPFS of 16.6 months with IMFINZI following cCRT compared with 9.2 months with placebo following cCRT (HR=0.76; 95% CI, 0.61-0.95, *P*=0.0161).[1,2*]

OVERALL SURVIVAL[1,2*†]

(median duration of follow-up: 37.2 months)



The 24-month and 36-month OS analyses were secondary endpoints and were not tested for statistical significance.[2]

NCCN CATEGORY 1, PREFERRED

National Comprehensive Cancer Network® (NCCN®)—Category 1, Preferred:

Durvalumab (IMFINZI®) following cCRT completion is an NCCN Category 1, preferred treatment option for patients with LS-SCLC who did not experience disease progression following cCRT.[4‡]

*OS and PFS were dual primary endpoints at the time of the planned interim analysis.[1] †The 24-month and 36-month OS rates were 68% (95% CI, 61.9-73.3) and 56.5% (95% CI, 50.0-62.5) in the IMFINZI following cCRT group and 58.5% (95% CI, 52.3-64.3) and 47.6% (95% CI, 41.3-53.7) in the placebo following cCRT group. The 24-month and 36-month OS analyses were secondary endpoints and were not tested for statistical significance.[2] ‡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. To view the most recent and complete version of the guideline, go online to NCCN.org. See the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for detailed recommendations, including other preferred treatment options.[4]

CI=confidence interval; HR=hazard ratio; LS-SCLC=limited-stage small cell lung cancer; mPFS=median progression-free survival; OS=overall survival; PFS=progression-free survival.

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.

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ADRIATIC is an ongoing large, Phase III, double-blind, placebo-controlled, randomized international study that evaluated IMFINZI following cCRT in LS-SCLC[1,2*]

ADRIATIC REGIMEN—STUDY DESIGN[1,2,5]

730 patients (ECOG PS 0-1) with LS-SCLC were assessed:
- cCRT with 3-4 cycles of platinum-based CT†
- RT initiated no later than the second CT cycle
- Medically inoperable

Exclusion criteria included:
- Mixed SCLC and NSCLC histologic features
- Uncontrolled Grade ≥2 AR after cCRT
- History of Grade ≥2 pneumonitis (except resolved infective forms)

RANDOMIZED 1:1:1 (N=730)‡

Treatment was initiated within 42 days of cCRT completion for patients who had not progressed

n=264*
IMFINZI 1500 mg
Q4W for up to 24 months or until disease progression or unacceptable toxicity

n=266*
Placebo§
Q4W for up to 24 months or until disease progression or unacceptable toxicity

IMFINZI was evaluated in patients who had not progressed following cCRT[1,2]
- **Complete response (CR), partial response (PR), or stable disease (SD) without progression**
- **Prophylactic cranial irradiation (PCI) was permitted before randomization**
- **Randomization was stratified according to disease Stage (I or II vs III) and receipt of PCI (yes or no)**

Study endpoints[1,2*]:
- **The dual primary endpoints of the study were OS and PFS with IMFINZI following cCRT vs placebo following cCRT§**
- Key secondary endpoints included:
  - PFS at 18 and 24 months‖
  - OS at 24 and 36 months

Safety and tolerability profile from the ADRIATIC Trial

- Serious ARs occurred in **29.8%** of patients receiving IMFINZI following cCRT and in **24.2%** of patients receiving placebo following cCRT at the interim analysis[2]
- The most frequent serious ARs reported in at least **1%** of patients receiving IMFINZI following cCRT were pneumonitis or radiation pneumonitis **(12%)**, and pneumonia **(5%)**[1]
- The most common ARs occurring in **≥20%** of patients receiving IMFINZI following cCRT were pneumonitis or radiation pneumonitis **(38%)**, and fatigue **(21%)**[1]
- Fatal ARs occurred in **2.7%** of patients receiving IMFINZI following cCRT. These included pneumonia **(1.5%)**, cardiac failure, encephalopathy, and pneumonitis **(0.4% each)**[1]
- Discontinuation occurred in **16.4%** of patients receiving IMFINZI following cCRT and **10.6%** of patients receiving placebo following cCRT[2]

*ADRIATIC investigated consolidation therapy with IMFINZI monotherapy and the combination of IMFINZI and tremelimumab-actl. Tremelimumab-actl is not approved for use in LS-SCLC following cCRT.[2,6] †The radiotherapy component must have been initiated no later than the end of Cycle 2 of chemotherapy and consist of either 60 to 66 Gy over 6 weeks (standard once-daily schedule) or 45 Gy over 3 weeks (hyperfractionated twice-daily schedule).[1,2] ‡730 patients were randomly assigned to receive durvalumab (n=264), durvalumab plus tremelimumab (n=200), or placebo (n=266) following cCRT. A total of 600 patients were enrolled before the protocol amendment, and 130 were enrolled after the protocol amendment. A total of 530 patients in the intention-to-treat population were reported for the first planned interim analysis. Therapy with IMFINZI and tremelimumab-actl was an investigational approach, and the data from that arm are not being presented.[1,2] §Patients received placebo alone as consolidation therapy following cCRT.[1] ‖Assessed using RECIST v1.1 and based on blinded independent central review of scans.[1]

AR=adverse reaction; CT=chemotherapy; ECOG=Eastern Cooperative Oncology Group; Gy=gray; NSCLC=non-small cell lung cancer; PS=performance status; Q4W=every 4 weeks; RECIST v1.1=Response Evaluation Criteria in Solid Tumors version 1.1; RT=radiation therapy; SCLC=small cell lung cancer.

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.

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IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (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. The incidence of pneumonitis (including radiation pneumonitis) in patients with LS-SCLC following chemoradiation within 42 days prior to initiation of IMFINZI in ADRIATIC was 14% (37/262) in patients receiving IMFINZI and 6% (16/265) in patients receiving placebo. Of the patients who received IMFINZI (262), 0.4% had a fatal adverse reaction and 2.7% had Grade 3 adverse reactions.

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.

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.
- ***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.
- ***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.
- ***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.

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 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.

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.

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IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (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 limited-stage SCLC in the ADRIATIC study receiving IMFINZI (n=262), the most common adverse reactions occurring in ≥20% of patients receiving IMFINZI were pneumonitis or radiation pneumonitis (38%), and fatigue (21%). The most common Grade 3 or 4 adverse reactions (≥3%) were pneumonitis or radiation pneumonitis and pneumonia.
- In patients with limited-stage SCLC in the ADRIATIC study receiving IMFINZI (n=262), IMFINZI was permanently discontinued due to adverse reactions in 16% of the patients receiving IMFINZI. Serious adverse reactions occurred in 30% of patients receiving IMFINZI. The most frequent serious adverse reactions reported in ≥1% of patients receiving IMFINZI were pneumonitis or radiation pneumonitis (12%), and pneumonia (5%). Fatal adverse reactions occurred in 2.7% of patients who received IMFINZI including pneumonia (1.5%), cardiac failure, encephalopathy and pneumonitis (0.4% each).

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

Indication:
IMFINZI® (durvalumab), as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).

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

References: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **2.** Cheng Y, Spigel DR, Cho BC, et al. Durvalumab after chemoradiotherapy in limited-stage small-cell lung cancer. *N Engl J Med*. 2024;391(14):1313-1327. **3.** US Food and Drug Administration. FDA approves durvalumab for limited-stage small cell lung cancer. Accessed December 4, 2024. https://www.fda.gov/drugs/resources-information-approveddrugs/fda-approves-durvalumab-limited-stage-small-cell-lung-cancer **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer V.3.2025. ©National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed December 5, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. 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. **5.** Protocol and Supplement: Cheng Y, Spigel DR, Cho BC, et al. Durvalumab after chemoradiotherapy in limited-stage small-cell lung cancer. *N Engl J Med*. 2024;391(14):1313-1327. **6.** IMJUDO® (tremelimumab-actl) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024.

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