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Click here to view IMFINZI (durvalumab) UK Prescribing Information.
Adverse event reporting information can be found at the bottom of this page.

Now licensed across both stages of SCLC

IMFINZI®
durvalumab
Injection for intravenous use 50 mg/mL

IMFINZI is also available and NICE recommended in eligible patients as part of the CASPIAN Regimen.[1]

Approved ES-SCLC indication (CASPIAN Regimen): IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).

Click here to view the CASPIAN Regimen summary document

ADRIATIC REGIMEN

IMFINZI is the FIRST and ONLY immunotherapy in LS-SCLC to demonstrate statistically significant improvement in overall survival (OS) following cCRT (P=0.01) vs placebo following cCRT[1,2]

Approved LS-SCLC indication (ADRIATIC Regimen):
IMFINZI as monotherapy is indicated for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.[1]

IMFINZI IS THE FIRST IMMUNOTHERAPY APPROVED FOR LS-SCLC, LEADING TO ADVANCEMENT IN SYSTEMIC TREATMENT[2]

IMFINZI HAS SHOWN IMPROVED SURVIVAL OUTCOMES (OS AND PFS) VS PLACEBO IN THE TREATMENT OF LS-SCLC THROUGH THE ADRIATIC TRIAL[1,2]

ADRIATIC TRIAL DESIGN

ADRIATIC is a global, Phase III, double-blind, placebo-controlled, randomised trial that evaluated IMFINZI following cCRT in LS-SCLC.[1,2]

730 patients (ECOG PS 0-1) with LS-SCLC were assessed:
- CRT with 3-4 cycles of platinum-based CT*
- RT initiated no later than the second CT cycle
- Prophylactic cranial irradiation (PCI) was permitted before randomisation

Exclusion criteria included:
- Mixed SCLC and NSCLC histologic features
- Uncontrolled Grade ≥2 AR after CRT
- History of Grade ≥2 pneumonitis

R 1:1:1 (n=730)†

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

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

Randomisation occurred within 42 days of CRT completion (platinum-based chemotherapy, concurrent with radiotherapy) or PCI if received.

Patients eligible for randomisation must have not progressed following cCRT; achieved a complete response (CR), partial response (PR), or stable disease (SD)

The dual primary endpoints of this trial are OS and PFS with IMFINZI vs placebo[1,2,§]

- **Key secondary endpoints include:**[2]
  - Objective response rate
  - Progression-free survival at 18 and 24 months
  - Overall survival at 24 and 36 months
  - Tolerability and safety profile
- IMFINZI is being evaluated in patients who had not progressed following 3 to 4 cycles of definitive, platinum-based cCRT completed within 1 to 42 days prior to randomisation.[1]
- PCI could be delivered at the discretion of the investigator after chemoradiation therapy and within 1 to 42 days prior to the first dose of study treatment.[1]

* ADRIATIC is investigating consolidation therapy with IMFINZI monotherapy and the combination of IMFINZI and an unknown combination treatment. The study randomised 730 patients to 1 of 3 treatment groups, of which 200 patients were in the IMFINZI and unknown combination therapy arm.[1]
† Randomisation was stratified by age (<65 years versus ≥65 years), sex, PD-L1 status (TC≥25% versus TC<25% or indeterminate) and stage of cancer (IIA to IIB by Q4 to Q5 by over 6 weeks Standard once-daily schedule) or 42 by over 3 weeks (hyperfractionated twice-daily schedule).[1]
‡ Once 600 patients were randomised, subsequent patients were randomised 1:1 between the IMFINZI monotherapy and placebo arms. Therapy with IMFINZI and the unlicensed combination treatment arm was an investigational approach, and the data from that arm is not being presented.[1]
§ Assessed using RECIST v1.1 and based on blinded independent central review of scans.[1]

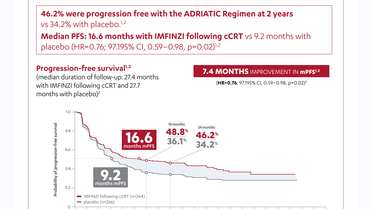
EFFICACY

INTERIM ANALYSIS RESULTS
22.5 MONTHS IMPROVEMENT IN MEDIAN OVERALL SURVIVAL WAS DEMONSTRATED WITH THE ADRIATIC REGIMEN VS PLACEBO[1,2,4]

56.5% were alive with the ADRIATIC Regimen at 3 years vs 47.6% with placebo[1,2]
Median OS: 55.9 months the ADRIATIC Regimen vs 33.4 months with placebo (HR=0.73; 98.321% CI, 0.54-0.98, p=0.01)[1,2]

Overall survival[1,2]
(median duration of follow-up: 37.2 months)[1]

22.5 MONTHS IMPROVEMENT IN mOS[1,2]
(**HR=0.73**; 98.321% CI, 0.54-0.98, p=0.01)[1]



Number of patients at risk

IMFINZI following cCRT	264	261	244	234	223	207	189	180	172	162	144	140	110	93	68	51	39	27	19	11	5	1	1	0	
placebo	266	260	247	231	214	195	175	164	151	143	122	97	80	62	44	31	21	14	9	4	3	1	1	0	

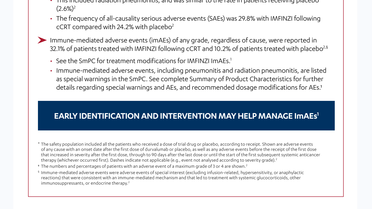
Graph adapted from Cheng Y et al 2024

INTERIM ANALYSIS RESULTS
7.4 MONTHS IMPROVEMENT IN MEDIAN PROGRESSION-FREE SURVIVAL DEMONSTRATED WITH THE ADRIATIC REGIMEN VS PLACEBO[1,2]

46.2% were progression free with the ADRIATIC Regimen at 2 years vs 34.2% with placebo.[1,2]
Median PFS: 16.6 months with IMFINZI following cCRT vs 9.2 months with placebo (HR=0.76; 97.195% CI, 0.59–0.98, p=0.02)[1,2]

Progression-free survival[1,2]
(median duration of follow-up: 27.4 months with IMFINZI following cCRT and 27.7 months with placebo)[1]

7.4 MONTHS IMPROVEMENT IN mPFS[1,2]
(**HR=0.76**; 97.195% CI, 0.59–0.98, p=0.02)[1]



Number of patients at risk

IMFINZI following cCRT	264	252	167	130	113	105	101	98	84	78	51	31	23	21	19	10	10	6	4	2	0	0	0		
placebo	266	208	166	122	100	88	79	76	71	69	47	47	34	23	22	15	14	5	5	1	0	0	0		

Graph adapted from Cheng Y et al 2024

SAFETY PROFILE

The ADRIATIC Regimen was consistent with the established IMFINZI monotherapy safety profile[1,2]

Adverse reactions occurring at any grade in ≥10% or at a maximum severity of grade 3 or 4 in ≥1% of patients in either group[1,2]

	IMFINZI (n=262)		placebo (n=265)	
Adverse reaction	**All grades (%)**	**Grade 3 or 4 (%)***	**All grades (%)**	**Grade 3 or 4 (%)***
Radiation pneumonitis	**22.9**	**1.1**	23.4	1.9
Decreased appetite	**16.8**	**0**	12.8	0
Hypothyroidism	**16.0**	**0**	3.8	0
Cough	**15.3**	**0**	12.1	0
Pruritus	**13.0**	**0**	7.2	0
Nausea	**12.6**	**0**	10.9	0
Dizziness	**12.2**	**0**	7.5	0
Fatigue	**12.2**	**0.4**	12.8	1.5
Diarrhoea	**11.1**	**1.9**	8.3	0
Pneumonia	**11.1**	**2.7**	7.5	3.4
Pneumonitis	**10.7**	**1.1**	6.0	0.8
Rash	**10.7**	**0.4**	6.0	0
Constipation	**10.3**	**0**	9.8	0
Hyperthyroidism	**10.3**	**0**	1.5	0
Headache	**9.2**	**0.4**	13.2	0
Anaemia	**8.8**	**1.1**	6.0	1.1
Arthralgia	**6.9**	**0**	10.9	0.4
Hyperglycaemia	**4.2**	**1.1**	3.8	0
Hypertension	**3.4**	**1.1**	1.5	0
Lipase increased	**3.1**	**1.9**	2.6	1.5
Amylase increased	**2.7**	**1.1**	1.1	0
Chronic obstructive pulmonary disease	**2.3**	**0.4**	2.6	1.5
Pulmonary embolism	**2.3**	**1.9**	1.5	1.1

Table adapted from Cheng Y et al 2024

Please refer to the IMFINZI SmPC for a full list of adverse events.

- Rates of pneumonitis (including radiation pneumonitis) were 38.2% with IMFINZI following cCRT and 30.2% with placebo[1]
- The frequency of all cause Grade 3 to 4 AEs with IMFINZI following cCRT or with placebo was 24.4% and 24.2%, respectively[1]
  - Grade ≥3 pneumonitis was seen in 3.1% of patients taking IMFINZI following cCRT[1,2]
  - This included radiation pneumonitis, and was similar to the rate in patients receiving placebo (2.6%)[2]
  - The frequency of all-causality serious adverse events (SAEs) was 29.8% with IMFINZI following cCRT compared with 24.2% with placebo[1]
- Immune-mediated adverse events (imAEs) of any grade, regardless of cause, were reported in 32.1% of patients treated with IMFINZI following cCRT and 10.2% of patients treated with placebo[1,3]
  - See the SmPC for treatment modifications for IMFINZI imAEs.[1]
  - Immune-mediated adverse events, including pneumonitis and radiation pneumonitis, are listed as special warnings in the SmPC. See complete Summary of Product Characteristics for further details regarding special warnings and AEs, and recommended dosage modifications for AEs.[1]

EARLY IDENTIFICATION AND INTERVENTION MAY HELP MANAGE ImAEs[3]

* The safety population included all the patients who received a dose of trial drug or placebo, according to receipt. Shown are adverse events of any cause with an onset date after the first dose of durvalumab or placebo, as well as any adverse events before the receipt of the first dose of durvalumab or placebo that were Grade 3 or 4 and were thought to be related to the trial treatment, to the chemotherapy regimens, and cancer therapy (whichever occurred first). Dashes indicate not applicable (e.g., event not analysed according to severity grades).
† The numbers and percentages of patients with an adverse event of a maximum grade of 3 or 4 are shown.[1]
‡ Immune-mediated adverse events were adverse events of special interest (excluding infusion-related, hypersensitivity, or anaphylactic reactions) that were consistent with an immune-mediated mechanism and that led to treatment with systemic glucocorticoids, other immunosuppressants, or endocrine therapy.[1]

DOSING & ADMINISTRATION

IMFINZI offers Q4W fixed dosing for LS-SCLC[1,4] and should be initiated as soon as clinically appropriate after the completion of cCRT.[1]

ADRIATIC REGIMEN[1,2]

CONCURRENT PLATINUM-BASED cCRT
Four cycles of platinum/etoposide CT, administered concurrently with a 3- or 6-week RT regimen (starting before end of Cycle 2)*

IMFINZI
Up to 24 months of fixed-dose IMFINZI 1500 mg Q4W (or until disease progression or unacceptable toxicity)†

Initiate IMFINZI within 42 days‡

- 33.5% of patients completed the full 2 years of IMFINZI following cCRT[1]

Maintain immunotherapy with IMFINZI for up to 24 months or until disease progression or unacceptable toxicity following cCRT, during the time when patients are at high risk of progression[1]

- IMFINZI is administered as a 60-minute IV infusion with no premedication required[4]
- Patients with a body weight <30 kg must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg every 4 weeks until weight increases to >30kg[1]
- IMFINZI is supplied as single-dose vials that contain either 120 mg/2.4 mL or 500 mg/10 mL

PREPARE YOUR ELIGIBLE PATIENTS FOR TREATMENT BY COMMUNICATING THE IMPORTANCE OF COMPLETING THE FULL ADRIATIC REGIMEN[1]

* 4 four IMFINZI for up to 24 months or until disease progression or unacceptable toxicity.[1]
† 60 to 66 Gy once daily (QD) over 6 weeks or 45 Gy twice daily (BID) over 3 weeks.[1]
‡ Patients must have achieved CR, PR, or SD, and have not progressed following cCRT.[1]

Abbreviations and references

1. IMFINZI (durvalumab) Summary of Product Characteristics
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 (including Protocol).
3. Yeh - Clinicaltrials.gov. NCT03703297. ADRIATIC study. Available at: https://clinicaltrials.gov/study/NCT03703297 Accessed June 2025

AEs=adverse events; cCRT=concurrent chemoradiation therapy; CT=chemotherapy; ECOG=Eastern Cooperative Oncology Group; Gy=gray; imAEs=immune-mediated adverse events; IV=intravenous; MOA=mechanism of action; NSCLC=non-small cell lung cancer; PS=performance status; Q4W=once every 4 weeks; RECIST=Response Evaluation Criteria in Solid Tumors; RT=radiotherapy

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to AstraZeneca by visiting https://azreporting.astrazeneca.com or by calling 0800 783 0033.

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