RESECTABLE NSCLC

The first NCCN Category 1 recommended perioperative IO option for resectable NSCLC in combination with neoadjuvant platinum-based CT (carboplatin or cisplatin)[1*†‡]

SEE THE DATA Review carboplatin and cisplatin EFS subgroup data on the back cover

The AEGEAN Regimen[§]: Neoadjuvant IMFINZI + platinum-based CT followed by adjuvant IMFINZI after surgery[2]

The AEGEAN Regimen significantly improved EFS for patients with Stage IIA to IIIB (N2) resectable NSCLC vs neoadjuvant CT alone[2,3]

FIRST INTERIM ANALYSIS OF **EFS IN mITT**[2,3‖]

Median EFS not reached with neoadjuvant IMFINZI + CT followed by adjuvant IMFINZI (95% CI, 31.9-NR)

vs

25.9 months with neoadjuvant CT alone (95% CI, 18.9-NR)

Reduction in risk of disease progression, recurrence, or death vs placebo was 32% (**HR=0.68**; 95% CI, 0.53-0.88) with a log-rank test stratified by PD-L1 and disease stage (2-sided *P* value=0.0039)[2,3]

Second interim analysis of EFS in mITT: Median EFS not reached (95% CI, 42.3-NR) with the AEGEAN Regimen and 30.0 months (95% CI, 20.6-NR) with neoadjuvant CT alone (HR=0.69; 95% CI, 0.55-0.88).[4]

At the second interim analysis of EFS, the data maturity rate was 39%. Median duration of follow-up was 25.9 months (range: 0.0-58.6).[4]

- **The second interim EFS analysis was not formally tested for statistical significance**[4]
- A final analysis is planned at ~50% maturity[3]

Updated landmark EFS with the AEGEAN Regimen and neoadjuvant CT alone[4]

1-year: 73.3% and 64.1%

2-year: 65.0% and 54.4%

3-year: 60.1% and 47.9%

- **The 12-month, 24-month, and 36-month EFS analyses were exploratory endpoints and were not tested for statistical significance**[3]

Indication:

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) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

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.

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

Study design: The AEGEAN study was a large, global, Phase III study of 802 patients with Stage IIA to IIIB (N2) resectable NSCLC (tumors ≥4 cm and/or nodal involvement [N1, N2]) based on the 8th edition of the American Joint Committee on Cancer (AJCC) TNM staging system. Randomization at enrollment was stratified according to disease stage and PD-L1 expression. Patients were randomized 1:1 to receive neoadjuvant IMFINZI 1500 mg or placebo in combination with investigator's choice of platinum-based CT Q3W for up to 4 cycles prior to surgery. Following resection, patients received either adjuvant IMFINZI 1500 mg or placebo Q4W for up to 12 cycles. Coprimary endpoints were EFS (assessed by BICR) and pCR (assessed by blinded central pathology review). Secondary endpoints included MPR, DFS, and OS.[2,3]

*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.

†See the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for detailed recommendations, including other treatment options for resectable NSCLC.[1]

‡Neoadjuvant durvalumab (IMFINZI®) in combination with platinum-based CT, followed by durvalumab (IMFINZI®) continued as a single agent as adjuvant treatment after surgery, is a recommended option for patients with resectable (tumors ≥4 cm and/or node positive) NSCLC and no known EGFR mutations or ALK rearrangements.[1]

§The AEGEAN Regimen is defined as neoadjuvant IMFINZI + a choice of platinum-based CT followed by adjuvant IMFINZI after surgery.[2,3]

‖The mITT population excluded patients with documented EGFR or ALK alterations who were enrolled before a protocol amendment.[3]

ALK=anaplastic lymphoma kinase; BICR=blinded independent central review; CI=confidence interval; CT=chemotherapy; DFS=disease-free survival; EFS=event-free survival; EGFR=epidermal growth factor receptor; HR=hazard ratio; IO=immuno-oncology; mITT=modified intent to treat; MPR=major pathological response; NCCN=National Comprehensive Cancer Network® (NCCN®); NR=not reached; NSCLC=non-small cell lung cancer; OS=overall survival; pCR=pathological complete response; PD-L1=programmed death-ligand 1; Q3W=every 3 weeks; Q4W=every 4 weeks; TNM=tumor, node, metastasis.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

The AEGEAN Regimen dosing: Flexibility to choose which platinum-based CT you give your patients[3]

IMFINZI is administered as a 1500-mg fixed dose over 60 minutes Q3W presurgery (neoadjuvant) and continues Q4W after surgery (adjuvant)[2]

RECOMMENDED DOSAGE FOR PATIENTS WITH A BODY WEIGHT OF ≥30 KG[2]

NEOADJUVANT

IMFINZI (1500 mg) concurrently with platinum-based CT
Q3W for up to 4 cycles

Surgical resection

ADJUVANT

IMFINZI (1500 mg)
Q4W for up to 12 cycles

Treat until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery.[2]

For patients with a body weight of <30 kg[2]:

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.

Regimens used in the AEGEAN study included[3]*:

- Carboplatin/paclitaxel
- Carboplatin/pemetrexed
- Carboplatin/gemcitabine
- Cisplatin/gemcitabine
- Cisplatin/pemetrexed
- Cisplatin/paclitaxel

The AEGEAN Regimen offers Q4W dosing and flexibility with a choice of platinum-based chemotherapy[2,3]

Please see Prescribing Information for additional information for dosage modification and management specific to adverse reactions.

*Choice of chemotherapy regimen was determined by histology and at the investigator's discretion. In the event of unfavorable tolerability, patients in the study were able to switch from cisplatin to carboplatin therapy. In patients with comorbidities or unable to tolerate cisplatin per investigator's judgement, carboplatin AUC 5 could be administered from Cycle 1. The platinum-based CT regimen of cisplatin + paclitaxel may also be considered; however, this therapy regimen was used outside the per-protocol choice.[3]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)

Withhold or permanently discontinue IMFINZI depending on severity. See USPI Dosing and Administration for specific details. 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.

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. 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.

AUC=area under the curve.

In resectable Stage IIA to IIIB (tumors ≥4 cm and/or node positive [N1, N2]) NSCLC with no known EGFR mutations or ALK rearrangements

Consistent EFS results demonstrated across a majority of subgroups with the AEGEAN Regimen[4†]

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

EFS SUBGROUP ANALYSIS IN mITT[‡]: SECOND INTERIM ANALYSIS[4]

Subgroup	No. of patients	Median EFS, months (95% CI)		Hazard ratio for disease progression, recurrence, or death (95% CI)
		AEGEAN Regimen	Neoadjuvant CT alone	
All patients	740	NR (42.3-NR)	30.0 (20.6-NR)	0.69 (0.55-0.88)
Age at randomization				
<65 years	358	NR (NR-NR)	34.4 (19.8-NR)	0.69 (0.48-0.97)
≥65 years	382	NR (31.9-NR)	25.9 (15.1-NR)	0.71 (0.52-0.97)
Sex				
Male	530	NR (41.2-NR)	25.9 (19.8-NR)	0.66 (0.50-0.88)
Female	210	NR (33.2-NR)	40.4 (15.1-NR)	0.80 (0.52-1.23)
ECOG PS				
0	506	NR (42.3-NR)	31.1 (19.5-NR)	0.66 (0.50-0.88)
1	234	NR (21.8-NR)	28.6 (18.9-NR)	0.79 (0.52-1.20)
Race[§]				
Asian	307	NR (42.3-NR)	25.9 (19.5-NR)	0.66 (0.45-0.95)
Non-Asian	433	NR (33.2-NR)	31.1 (15.7-NR)	0.73 (0.54-0.99)
Smoking				
Current	190	NR (33.2-NR)	20.4 (8.1-NR)	0.52 (0.32-0.82)
Former	443	NR (41.2-NR)	30.0 (20.7-NR)	0.75 (0.56-1.02)
Never	107	NR (13.0-NR)	34.4 (14.7-NR)	0.88 (0.47-1.61)
Histology				
Squamous	360	NR (41.2-NR)	40.4 (15.1-NR)	0.70 (0.49-0.98)
Nonsquamous	375	NR (36.6-NR)	28.6 (19.8-NR)	0.73 (0.53-1.00)
Disease stage (AJCC 8th ed)				
Stage II	214	NR (41.2-NR)	NR (34.4-NR)	0.82 (0.49-1.34)
Stage IIIA	338	NR (42.3-NR)	25.8 (11.7-45.0)	0.60 (0.42-0.84)
Stage IIIB	186	36.6 (12.7-NR)	19.8 (11.7-42.6)	0.81 (0.53-1.23)
Lymph node station				
N2 single	273	NR (NR-NR)	22.8 (13.9-42.6)	0.58 (0.39-0.85)
N2 multi	74	31.9 (9.3-NR)	12.2 (7.2-NR)	0.78 (0.40-1.49)
PD-L1 expression at baseline				
TC <1%	247	NR (24.7-NR)	20.6 (14.3-NR)	0.69 (0.46-1.02)
TC 1% to 49%	277	NR (31.9-NR)	25.9 (12.3-NR)	0.73 (0.50-1.05)
TC ≥50%	216	36.6 (41.2-NR)	NR (24.5-NR)	0.71 (0.44-1.12)
Planned neoadjuvant platinum agent				
Cisplatin	196	NR (NR-NR)	45.0 (13.9-NR)	0.58 (0.35-0.93)
Carboplatin	544	NR (36.6-NR)	16.2 (20.6-NR)	0.75 (0.57-0.97)

- EFS subgroup analysis was not powered to show differences between or within individual subgroups and was not formally tested for statistical significance[3]

[†]The AEGEAN Regimen included neoadjuvant IMFINZI + platinum-based CT and adjuvant IMFINZI after surgery.[2,3]
[‡]The mITT population excluded patients with documented EGFR or ALK alterations who were enrolled before a protocol amendment.[3]
[§]Race was self-reported per the electronic case report form.[4]

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ECOG=Eastern Cooperative Oncology Group; PS=performance status; TC=tumor cell.

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.

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.
- ***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 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.
- 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 adjuvant 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.

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

You may report side effects related to AstraZeneca products.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer. V.10.2024. ©National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed September 23, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **3.** Heymach JV, Harpole D, Mitsudomi T, et al. Perioperative durvalumab for resectable non–small-cell lung cancer. *N Engl J Med*. 2023;389(18):1672-1684 (Including Supplement and Protocol). **4.** Heymach JV, Harpole D, Mitsudomi T, et al. Perioperative durvalumab for resectable NSCLC: updated outcomes from the phase 3 AEGEAN trial. Presented at: IASLC 2024 World Conference on Lung Cancer; September 7-10, 2024; San Diego, CA. **5.** Data on File, REF-243456, AstraZeneca Pharmaceuticals LP; 2024.

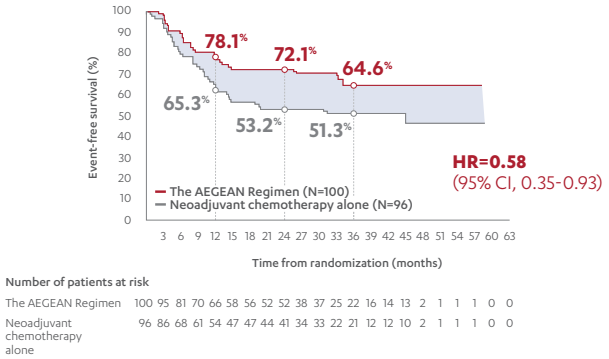
In resectable Stage IIA to IIIB (tumors ≥4 cm and/or node positive [N1, N2]) NSCLC with no known EGFR mutations or ALK rearrangements

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

EFS with neoadjuvant cisplatin or carboplatin and perioperative IMFINZI in the AEGEAN study[4]

At the first interim analysis, median EFS was not reached with the AEGEAN Regimen (95% CI, 31.9-NR) vs 25.9 months with neoadjuvant CT alone (95% CI, 18.9-NR) (HR=0.68; 95% CI, 0.53-0.88; 2-sided *P* value=0.0039)[2]

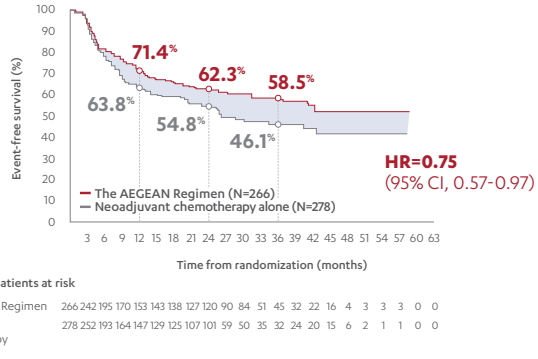
EFS IN CISPLATIN SUBGROUPS: PREDEFINED SUBGROUP SECOND INTERIM ANALYSIS[4]



Number of patients at risk

The AEGEAN Regimen	100	95	81	70	66	58	56	52	52	38	37	25	22	16	14	13	2	1	1	1	0	0
Neoadjuvant chemotherapy alone	96	86	68	61	54	47	47	44	41	34	33	22	21	12	12	10	2	1	1	1	0	0

EFS IN CARBOPLATIN SUBGROUPS: PREDEFINED SUBGROUP SECOND INTERIM ANALYSIS[4]



Number of patients at risk

The AEGEAN Regimen	266	242	195	170	153	143	138	127	120	90	84	51	45	32	22	16	4	3	3	3	0	0
Neoadjuvant chemotherapy alone	278	252	193	164	147	129	125	107	101	59	50	35	32	24	20	15	6	2	1	1	0	0

These prespecified subgroup analyses were not formally tested for statistical significance[3]

SELECT AEGEAN STUDY INFORMATION

Data for both carboplatin and cisplatin subgroups[3]

The second interim EFS analysis in cisplatin and carboplatin subgroups was not formally tested for statistical significance[3]

Option for investigators to switch from cisplatin to carboplatin for tolerability reasons at any time **within the AEGEAN study[2]***

For dosing information and complete efficacy data, visit **IMFINZIhcp.com**

NCCN CATEGORY 1

Perioperative durvalumab (IMFINZI®) in combination with neoadjuvant platinum-based chemotherapy (carboplatin or cisplatin) is an **NCCN Category 1 recommendation** for certain patients with resectable NSCLC[1†‡§]

*Patients were able to switch from cisplatin to carboplatin therapy in the event of unfavorable tolerability at any time during the neoadjuvant period before surgery. In the AEGEAN study, 17 patients switched in the AEGEAN arm, and 7 patients switched in the placebo arm.[2,5]
†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.
‡See the NCCN Guidelines® for detailed recommendations, including other treatment options for resectable NSCLC.[1]
§Neoadjuvant durvalumab (IMFINZI®) in combination with platinum-based CT, followed by durvalumab (IMFINZI®) continued as a single agent as adjuvant treatment after surgery, is a recommended option for patients with resectable (tumors ≥4 cm and/or node positive) NSCLC and no known EGFR mutations or ALK rearrangements.[1]

Indication:

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) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

IMPORTANT SAFETY INFORMATION

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AstraZeneca

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