

A key to more possibilities for treating your appropriate patients with resectable NSCLC

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MSD Oncology

KEYNOTE-671 5-year data update:

KEYTRUDA® (pembrolizumab) in combination with platinum-containing chemotherapy as neoadjuvant therapy and then continued as adjuvant monotherapy for patients with resectable Stage II, IIIA or IIIB (N2) non-small cell lung carcinoma (NSCLC) (AJCC 8th edition) (KEYTRUDA perioperative treatment)

KEYTRUDA in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults.[1]

These slides are provided to UK healthcare professionals as a resource for data for your personal education. To ensure compliance with all relevant codes and regulations these slides must not be amended.

AJCC, American Joint Committee on Cancer; NSCLC, non-small cell lung carcinoma.

1. KEYTRUDA Summary of Product Characteristics. MSD. Available at: https://www.medicines.org.uk/emc/product/2498. Accessed: August 2026.

KEYTRUDA® (pembrolizumab)

MSD

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KEYTRUDA early-stage and advanced NSCLC indications[1]

- **KEYTRUDA, in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung carcinoma (NSCLC) at high risk of recurrence in adults**
- KEYTRUDA as monotherapy is indicated for the adjuvant treatment of adults with NSCLC who are at high risk of recurrence following complete resection and platinum-based chemotherapy
- KEYTRUDA as monotherapy is indicated for the first-line treatment of metastatic NSCLC in adults whose tumours express PD-L1 with a ≥50% TPS with no *EGFR*- or *ALK*-positive tumour mutations
- KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of metastatic non-squamous NSCLC in adults whose tumours have no *EGFR*- or *ALK*-positive mutations
- KEYTRUDA, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of metastatic squamous NSCLC in adults
- KEYTRUDA as monotherapy is indicated for the treatment of locally advanced or metastatic NSCLC in adults whose tumours express PD-L1 with a ≥1% TPS and who have received at least one prior chemotherapy regimen. Patients with *EGFR*- or *ALK*-positive tumour mutations should also have received targeted therapy before receiving KEYTRUDA

Please refer to the Summary of Product Characteristics and Risk Minimisation Materials available on the EMC website before prescribing.

ALK, anaplastic lymphoma kinase; EGFR, epidermal growth factor receptor; EMC, Electronic Medicines Compendium; NSCLC, non-small cell lung carcinoma; PD-L1, programmed death ligand 1; TPS, tumour proportion score.

1. KEYTRUDA Summary of Product Characteristics. MSD. Available at: https://www.medicines.org.uk/emc/product/2498. Accessed: August 2026.

NSCLC DFS rates by stage[1]

In a retrospective observational study of patients with early-stage NSCLC (Stage IB-IIIA, AJCC 7th edition), two-thirds experienced disease recurrence during 4.5 years of follow-up, even after curative resection.*[1]

Real-world disease-free survival (rwDFS) by stage:[1]

Stage	Median rwDFS	5-year rwDFS
IB	40.9 months	38.9%
II	24.4 months	29.1%
IIIA	13.8 months	21.5%

*Based on 1761 patients from the SEER-Medicare database (2007–2019) with early-stage resected NSCLC.
AJCC, American Joint Committee on Cancer; DFS, disease-free survival; NSCLC, non-small cell lung carcinoma; rwDFS, real-world disease-free survival; SEER, Surveillance, Epidemiology, and End Results.

1. West H, *et al. Clin Lung Cancer* 2023;24:260–268.

KEYNOTE-671 indication:

KEYTRUDA in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults[1]

1. KEYTRUDA Summary of Product Characteristics. MSD. Available at: https://www.medicines.org.uk/emc/product/2498. Accessed: August 2026.

KEYNOTE-671 study design: Randomised, double-blind, Phase III[1]

Resectable Stage II, IIIA or IIIB (N2) NSCLC (AJCC 8th edition)
- ECOG PS 0–1
- Tumour tissue for PD-L1 evaluation at central lab
- Biopsy of suspicious hilar or mediastinal lymph node(s)
- Untreated, pathologically confirmed (PET scan may be used as surrogate for N1 lymph nodes)*
- No ILD or pneumonitis requiring steroids
- *EGFR/ALKm* permitted

R 1:1
(N=797)

Neoadjuvant phase

IV KEYTRUDA 200 mg Q3W **+ cisplatin** 75 mg/m^2
combined with either
pemetrexed† 500 mg/m^2 OR **gemcitabine**‡ 1000 mg/m^2
for up to 4 cycles

→ Surgery → 4–12w → Adjuvant phase§

KEYTRUDA¶ 200 mg Q3W
≤13 cycles
(approx. 9 months)

IV placebo Q3W **+ cisplatin** 75 mg/m^2
combined with either
pemetrexed† 500 mg/m^2 OR **gemcitabine**‡ 1000 mg/m^2
for up to 4 cycles

→ Surgery → 4–12w

Placebo¶ Q3W
≤13 cycles
(approx. 9 months)

Stratification factors:
- Stage (II vs III)
- PD-L1 by 22C3 (TPS <50% vs ≥50%)
- Histology (SQ vs NSQ)
- Region (East Asia vs other)

Dual primary endpoints:
- EFS per investigator review‖ and OS

Key secondary endpoints:
- mPR and pCR per blinded, independent pathology review, and safety

Adapted from Wakelee H, *et al*. N Engl J Med 2023.[1]

*For participants with T2b and T4 tumours.[1] †Permitted for non-squamous disease only.[1] ‡Administered on Days 1 and 8 of cycle; squamous histology only.[1] §For the adjuvant phase of this indication, KEYTRUDA is to be administered every 3 weeks for up to 13 cycles, taking approximately 9 months.[1] ¶Postoperative radiation therapy could be administered for patients with R1-2 resection, extracapsular nodal disease after surgery, and those who do not undergo surgery (followed by adjuvant KEYTRUDA/placebo).[1] ‖EFS defined as time from randomisation to first occurrence of: (i) local PD precluding surgery, (ii) unresectable tumour, (iii) progression or recurrence per RECIST v1.1 by investigator, (iv) death from any cause.[1]
AJCC, American Joint Committee on Cancer; *ALKm*, anaplastic lymphoma kinase mutation; DFS, disease-free survival; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EFS, event-free survival; *EGFR*, epidermal growth factor receptor; ILD, interstitial lung disease; IV, intravenous; mPR, major pathological response; N1, involvement of ipsilateral peribronchial and/or ipsilateral hilar lymph nodes (includes direct extension to intrapulmonary nodes);[1] N2, involvement of the ipsilateral mediastinal and/or subcarinal lymph nodes;[1]
NSCLC, non-small cell lung carcinoma; NSQ, non-squamous cell carcinoma; OS, overall survival; pCR, pathological complete response; PET, positron emission tomography; PD, progressive disease; PD-L1, programmed death ligand 1; Q3W, every 3 weeks; R, randomised; RECIST, Response Evaluation Criteria in Solid Tumours; SQ, squamous cell carcinoma; TPS, tumour proportion score; w, weeks.
1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (including protocol).

KEYNOTE-671: Patient characteristics[1]

Stage II disease

Characteristic, n (%)		KEYTRUDA	Placebo
Median age, years (range)		63 (26–83)	64 (35–81)
Sex	Male	279 (70.3)	284 (71.0)
Race	American Indian or Alaska Native	1 (0.3)	0
	Asian	124 (31.2)	125 (31.3)
	Black or African American	6 (1.5)	10 (2.5)
	Multiple	3 (0.8)	10 (2.5)
	White	250 (63.0)	239 (59.8)
	Missing data	13 (3.3)	16 (4.0)
Geographic region	East Asia	123 (31.0)	121 (30.3)
	Not East Asia	274 (69.0)	279 (69.8)
ECOG PS	0	253 (63.7)	246 (61.5)
	1	144 (36.3)	154 (38.5)
Histology	Non-squamous	226 (59.6)	227 (56.8)
	Squamous	171 (43.1)	173 (43.3)

Characteristic, n (%)		KEYTRUDA	Placebo
Smoking status	Current	96 (24.2)	103 (25.8)
	Former	247 (62.2)	250 (62.5)
	Never	54 (13.6)	47 (11.8)
Clinical stage	II	118 (29.7)	121 (30.3)
	IIIA	217 (54.7)	225 (56.3)
	IIIB	62 (15.6)	54 (13.5)
N status*	N0	148 (37.3)	142 (35.5)
	N1	81 (20.4)	71 (17.8)
	N2	168 (42.3)	187 (46.8)
PD-L1 TPS	≥50%	132 (33.2)	134 (33.5)
	1–49%	127 (32.0)	115 (28.8)
	<1%	138 (34.8)	151 (37.8)
Known *EGFR* mutation†		14 (3.5)	19 (4.8)
Known *ALK* translocation†		12 (3.0)	9 (2.3)

Adapted from Wakelee H, *et al*. ASCO 2023.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1]
*As determined by imaging and biopsy.[1] †*EGFR* and *ALK* status were tested locally per investigator discretion. *EGFR* status was unknown in 68.5% in the KEYTRUDA group and 63.5% in the placebo group; *ALK* status was unknown in 70.8% and 64.5%, respectively.[1]
ALK, anaplastic lymphoma kinase; ECOG PS, Eastern Cooperative Oncology Group Performance Status; *EGFR*, epidermal growth factor receptor; IA, interim analysis; PD-L1, programmed death ligand 1; N, nodal involvement; TPS, tumour proportion score.
1. Wakelee H, *et al.* ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100.

KEYNOTE-671: Patient characteristics (IA3 Stage II disease)*[1]

Prespecified subgroup of patients with Stage II disease at baseline[1]

Characteristic, n (%)		KEYTRUDA (n = 118)	Placebo (n = 121)
Median age, years (range)		63 (26–79)	63 (45–79)
Male		88 (74.6)	89 (73.6)
Race	Asian	52 (44.1)	54 (44.6)
	Black or African American	1 (0.8)	3 (2.5)
	Multiple	2 (1.7)	3 (2.5)
	White	58 (49.2)	57 (47.1)
	Missing data	5 (4.2)	4 (3.3)
ECOG PS 0		80 (67.8)	76 (62.8)
Histology	Squamous	66 (55.9)	64 (52.9)
	Non-squamous	52 (44.1)	57 (47.1)
Smoking status	Current	30 (25.4)	34 (28.1)
	Former	71 (60.2)	74 (61.2)
	Never	17 (14.4)	13 (10.7)

Characteristic, n (%)		KEYTRUDA (n = 118)	Placebo (n = 121)
Clinical stage	IIA	22 (18.6)	19 (15.7)
	IIB	96 (81.4)	102 (84.3)
Clinical tumor stare	T1	9 (7.6)	11 (9.1)
	T2	46 (39.0)	44 (36.4)
	T3	63 (53.4)	66 (54.5)
Clinical node status	N0	85 (72.0)	85 (70.2)
	N1	33 (28.0)	36 (29.8)
PD-L1 TPS	≥50%	36 (30.5)	34 (28.1)
	1–49%	39 (33.1)	36 (29.8)
	<1%	43 (36.4)	51 (42.1)

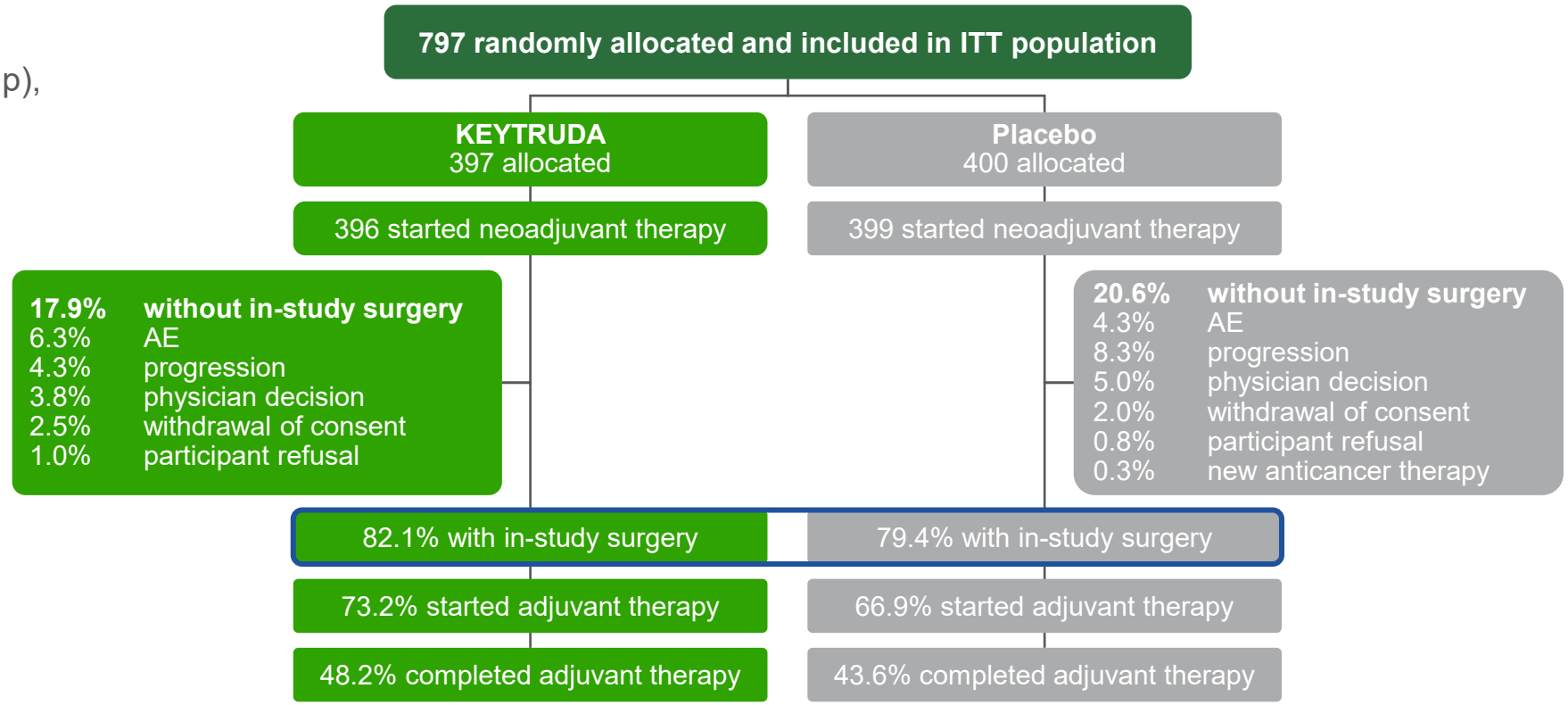
Adapted from Weksler B, *et al*. STS 2026.[1]

Data cut-off date for IA3: 3 July 2025. Median follow-up: 58.7 [range, 43.0–85.7] months.[1]
*Per AJCC 8.1.[1]
AJCC, American Joint Committee on Cancer; ECOG PS, Eastern Cooperative Oncology Group Performance Status; IA, interim analysis; PD-L1, programmed death ligand 1; N, nodal involvement; TPS, tumour proportion score.
1. Weksler B, *et al*. Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation.

KEYNOTE-671: Treatment disposition[1]

Stage II disease

- Most patients underwent in-study surgery (82.1% in the KEYTRUDA group vs 79.4% in the placebo group), **similar to other perioperative IO trials**[1]



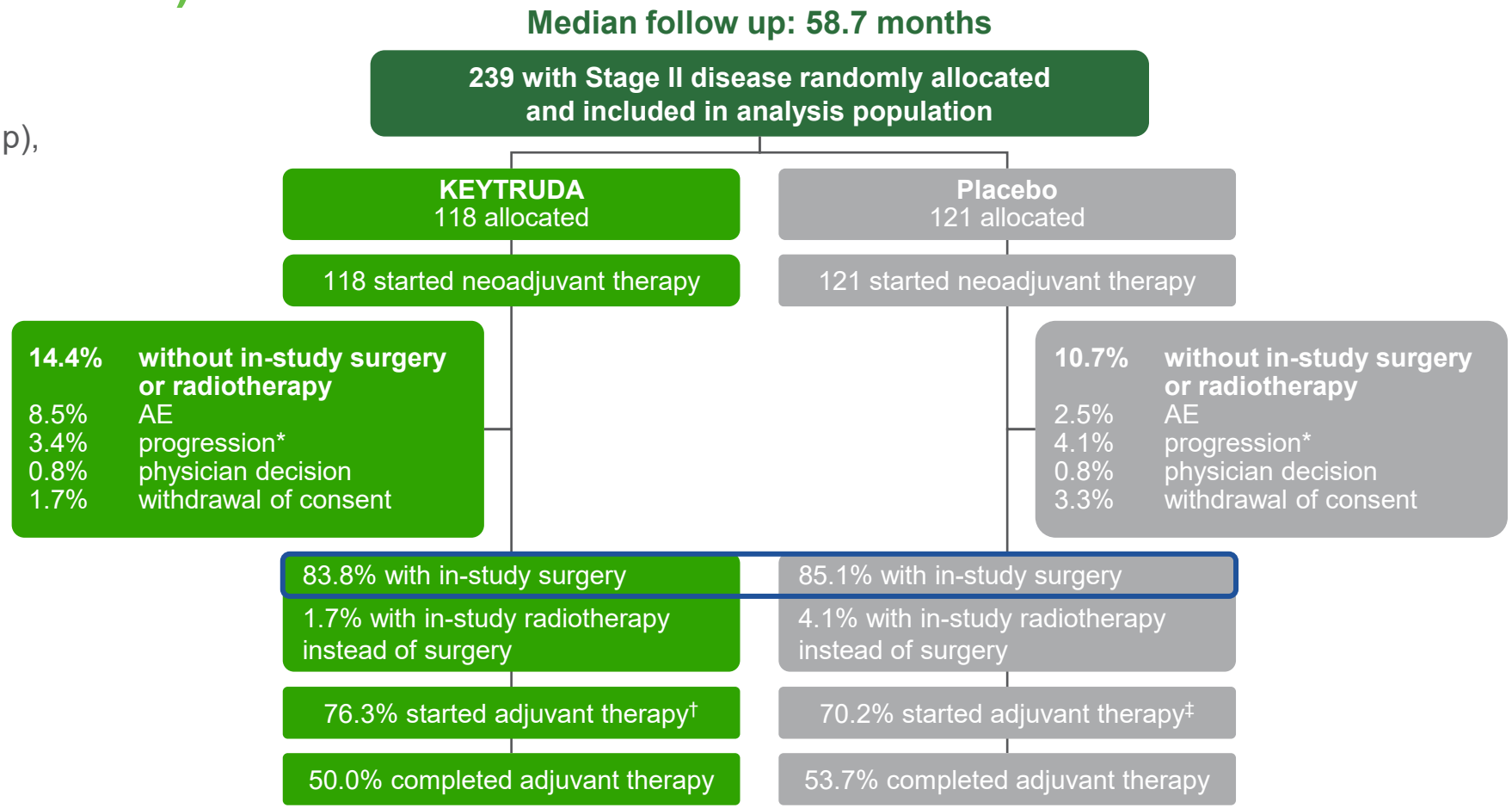
Adapted from Spicer J, *et al.* STS 2024.[1]

Data cut-off date for IA2: 10 July 2023. Median follow-up: 36.6 months.[1]
*In the KEYTRUDA group, 307 participants underwent surgery alone, 18 underwent in-study surgery and radiotherapy, and 17 underwent in-study radiotherapy alone. In the placebo group, 282 participants underwent in-study surgery alone, 35 underwent in-study surgery and radiotherapy, and 18 underwent in-study radiotherapy alone. All percentages are based on the number who received ≥1 dose of neoadjuvant treatment.[1]
AE, adverse event IA, interim analysis; IO, immunotherapy; ITT, intention-to-treat; R0, complete resection defined as no invasive cancer at bronchial margin or soft tissue surrounding bronchus, no invasive cancer at pulmonary artery or pulmonary vein margins or surrounding soft tissue, no invasive cancer at medial, lateral, superior and inferior margins of chest wall resection, no minimal margin distance, bronchial dysplasia is considered a negative margin.[1]

1. Spicer J, *et al.* Presented at STS 2024.

KEYNOTE-671: Treatment disposition (5-year exploratory analysis in Stage II disease)[1]

- Most patients underwent in-study surgery (83.8% in the KEYTRUDA group vs 85.1% in the placebo group), **similar to other perioperative IO trials**[1,2]



Adapted from Weksler B, *et al.* STS 2026.[1]

Data cut-off date for IA3: 3 July 2025. Median follow-up: 58.7 [range, 43.0–85.7] months.[1]
All percentages are based on the number who received ≥1 dose of neoadjuvant treatment.[1] *Includes clinical progression, local progression preventing surgery, and radiographic progression.[1] †Includes 1 patient who received in-study radiotherapy instead of surgery.[1]
‡Includes 3 patients who received in-study radiotherapy instead of surgery.[1]
AE, adverse event IA, interim analysis.
1. Weksler B, et al. Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation. **2.** Spicer J, *et al.* Presented at STS 2024.

KEYNOTE-671: Background[1–4]

In the Phase III KEYNOTE-671 study, neoadjuvant KEYTRUDA + chemotherapy followed by surgery and adjuvant KEYTRUDA **significantly improved OS and EFS** compared with neoadjuvant placebo + chemotherapy and surgery alone in resectable, early-stage NSCLC.

Summary of IA1, IA2, IA3 and 5-year analyses

	IA1[1,2] (KEYTRUDA vs placebo)	IA2[3] (KEYTRUDA vs placebo)	IA3[4] (KEYTRUDA vs placebo)	5-year[5] (KEYTRUDA vs placebo)
Median follow-up	25.2 months	36.6 months	41.1 months	60.4 months
OS, HR (95% CI)	0.73 (0.54–0.99), p=0.02124 (significance boundary not met)	**0.72 (0.56–0.93), p=0.0052 (significance boundary met)**	0.73 (0.58–0.92) (significance boundary met at IA2)	0.74 (0.59–0.92) (significance boundary met at IA2)
mOS, months (95% CI)	KEYTRUDA NR (NR–NR) vs PLACEBO 45.5 (42.0–NR)	KEYTRUDA NR (NR–NR) vs PLACEBO 52.4 (45.7–NR)	KEYTRUDA NR (NR–NR) vs PLACEBO NR (50.3–NR)	KEYTRUDA NR (NR–NR) vs PLACEBO 70.7 (53.7–NR)
EFS, HR (95% CI)	**0.58 (0.46–0.72), p<0.001 (significance boundary met)**	0.59 (0.48–0.72) (significance boundary met at IA1)	0.57 (0.47–0.69) (significance boundary met at IA1)	0.58 (0.48–0.69) (significance boundary met at IA1)
mEFS, months (95% CI)	KEYTRUDA NR (34.1–NR) vs PLACEBO 17.0 (14.3–22.0)	KEYTRUDA 47.2 (32.9–NR) vs PLACEBO 18.3 (14.8–22.1)	KEYTRUDA 57.1 (38.0–69.1) Vs PLACEBO 18.4 (14.8–22.1)	KEYTRUDA 57.1 (38.0–NR) vs PLACEBO 18.4 (14.8–22.1)

CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; m, median; NSCLC; non-small cell lung cancer; OS, overall survival.

1. Wakelee H, *et al.* Presented at ASCO. 2–6 June 2023. Chicago, Illinois, USA. Abstract: LBA100. **2.** Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (plus supplementary appendix).
3. Spicer JD, *et al. Lancet* 2024;404:1240–1252. **4.** Majem M, *et al.* Presented at ESMO I-O 2024. 11–13 December 2024. Geneva, Switzerland. Abstract LBA3. **5.** Wakelee H, *et al.* Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation.

KEYNOTE-671: Exploratory 5-year EFS in the ITT population*[1]

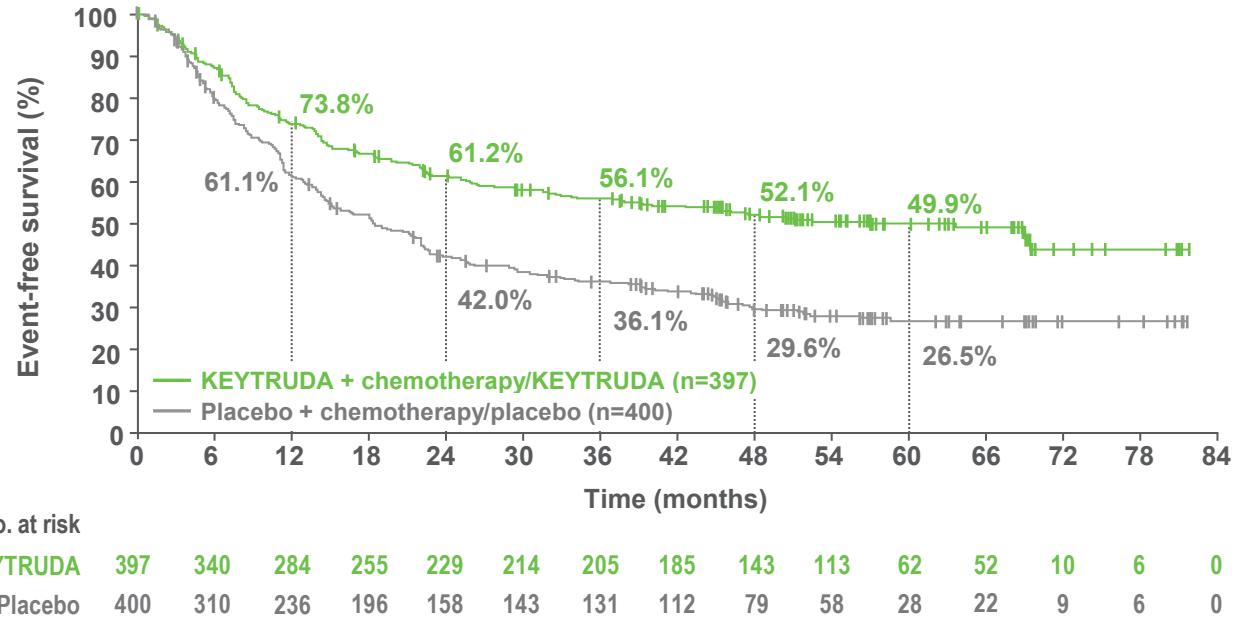
Stage II disease

Exploratory analysis

Median follow-up: 60.4 months

Data cut-off date: 3 July 2025

5-year analysis: EFS in the ITT population



Adapted from Wakelee H, *et al*. ESMO 2025.[1]

	Pts w/ Event, % (n/N)	Median (95% CI), mo	HR (95% CI)
KEYTRUDA group	48.1 (191/397)	57.1 (38.0–NR)	0.58 (0.48–0.69)
Placebo group	68.3 (273/400)	18.4 (14.8–22.1)	

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

No conclusions can be drawn from exploratory analyses. *Event-free survival defined as time from randomisation to first occurrence of local progression precluding planned surgery, unresectable tumour, progression or recurrence per RECIST version 1.1 by investigator assessment, or death from any cause.[1,2]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; ITT, intention-to-treat; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.
1. Wakelee H, *et al*. Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation. **2.** Wakelee H, *et al*. *N Engl J Med* 2023;389:491–503.

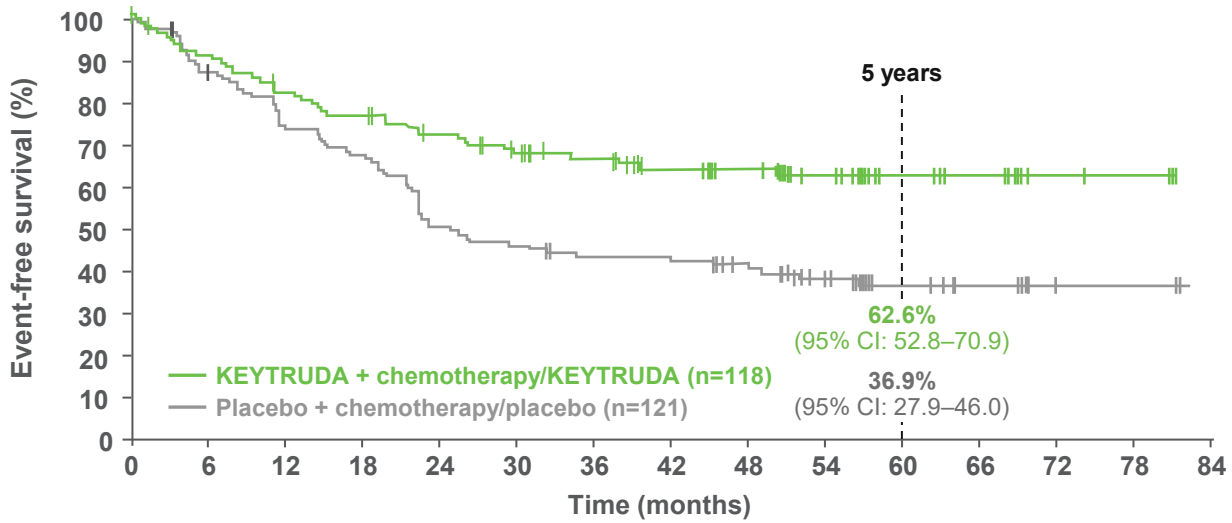
KEYNOTE-671: EFS (5-year exploratory analysis) in Stage II disease*[1]

Exploratory analysis

Median follow-up: 58.7 [range, 43.0–85.7] months

Data cut-off date: 3 July 2025

EFS in the ITT population (Stage II disease)



No. at risk

KEYTRUDA	118	105	94	88	81	75	72	62	45	33	16	13	4	3	0
Placebo	121	102	86	78	59	54	49	45	38	27	13	8	3	2	0

	Pts w/ Event, % (n/N)	Median (95% CI), mo	HR (95% CI)
KEYTRUDA group	35.6 (42/118)	NR (NR–NR)	0.52 (0.35–0.76)
Placebo group	59.5 (72/121)	24.4 (21.7–47.8)	

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

Adapted from Weksler B, *et al.* STS 2026.[1]

No conclusions can be drawn from exploratory analyses. *Event-free survival defined as time from randomisation to first occurrence of local progression precluding planned surgery, unresectable tumour, progression or recurrence per RECIST version 1.1 by investigator assessment, or death from any cause.[1,2]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; ITT, intention-to-treat; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.
1. Weksler B, *et al.* Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation. **2.** Wakelee H, *et al. N Engl J Med* 2023;389:491–503.

KEYNOTE-671: EFS in key subgroups (5-year exploratory analysis)*[1]

Stage II disease

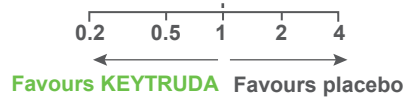
Exploratory analysis

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

5-year data

EFS within the ITT population

Subgroup	KEYTRUDA (Events/patients)	Placebo (Events/patients)	Hazard ratio (95% CI)
Overall	191/397	273/400	0.58 (0.48–0.69)
Disease Stage			
II	42/118	72/121	0.52 (0.35–0.76)
III	149/279	201/279	0.58 (0.47–0.72)
Nodal Status†			
N0	62/148	89/142	0.55 (0.40–0.77)
N1	31/82	48/73	0.48 (0.30–0.75)
N2	97/166	136/185	0.64 (0.49-0.83)
Histology			
Nonsquamous	114/226	147/227	0.66 (0.51–0.84)
Squamous	77/171	126/173	0.49 (0.37–0.65)
PD-L1 TPS†			
≥50%	45/132	81/134	0.44 (0.31–0.64)
1%–49%	63/127	83/115	0.54 (0.39–0.75)
<1%	83/138	109/151	0.74 (0.55–0.98)



Adapted from Wakelee H, *et al*. ESMO 2025.[1]

Data cut-off: 3 July 2025. Median follow-up: 60.4 months.[1]
No conclusions can be drawn from exploratory analyses. *EFS is defined as the time from randomisation to the first occurrence of local progression that precluded the planned surgery, unresectable tumour, progression or recurrence according to RECIST v1.1, or death from any cause.[1,2] †The subgroup for PD-L1 TPS (<1% and 1–49%) and nodal status (N0, N1, and N2) were not prespecified in the Statistical Analysis Plan.[3]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; ITT, intention to treat; PD-L1, programmed death-ligand 1; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; TPS, tumour proportion score.
1. Wakelee H, *et al*. Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation. **2.** Wakelee H, *et al. N Engl J Med* 2023;389(6):491–503. **3.** ClinicalTrials.gov.. Protocol amendment 671-11. Approval date November 29, 2022. Available at: https://cdn.clinicaltrials.gov/large-docs/43/NCT03425643/Prot_SAP_000.pdf. Accessed: August 2026.

KEYNOTE-671: EFS in key subgroups (5-year exploratory analysis) in Stage II disease*[1]

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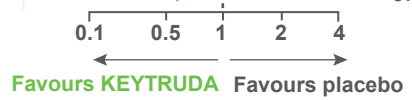
Exploratory analysis

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

5-year data

EFS in patients with Stage II disease

Subgroup	KEYTRUDA (Events/patients)	Placebo (Events/patients)	Hazard ratio (95% CI)
Overall	42/118	72/21	0.52 (0.35–0.76)
Disease Stage			
IIA	8/22	11/19	0.56 (0.23–1.39)
IIB	34/96	61/102	0.51 (0.34–0.78)
Nodal Status†			
N0	31/85	48/85	0.57 (0.36–0.89)
N1	11/33	24/36	0.42 (0.21–0.86)
Histology			
Nonsquamous	18/52	32/57	0.52 (0.29–0.93)
Squamous	24/66	40/64	0.52 (0.31–0.86)
PD-L1 TPS			
≥50%	6/36	15/34	0.32 (0.12–0.82)
1%–49%	15/39	21/36	0.63 (0.32–1.21)
<1%	21/43	36/51	0.57 (0.33–0.99)



Adapted from Weksler B, et al. STS 2026.[1]

Data cut-off: 3 July 2025. Median follow-up: 60.4 months.[1]
No conclusions can be drawn from exploratory analyses. *EFS is defined as the time from randomisation to the first occurrence of local progression that precluded the planned surgery, unresectable tumour, progression or recurrence according to RECIST v1.1, or death from any cause.[1,2] †The subgroup for PD-L1 TPS (<1% and 1–49%) and nodal status (N0, N1, and N2) were not prespecified in the Statistical Analysis Plan.[2]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; ITT, intention to treat; PD-L1, programmed death-ligand 1; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; TPS, tumour proportion score.
1. Weksler B, et al. Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation. **2.** ClinicalTrials.gov.. Protocol amendment 671-11. Approval date November 29, 2022.
Available at: https://cdn.clinicaltrials.gov/large-docs/43/NCT03425643/Prot_SAP_000.pdf. Accessed: August 2026.

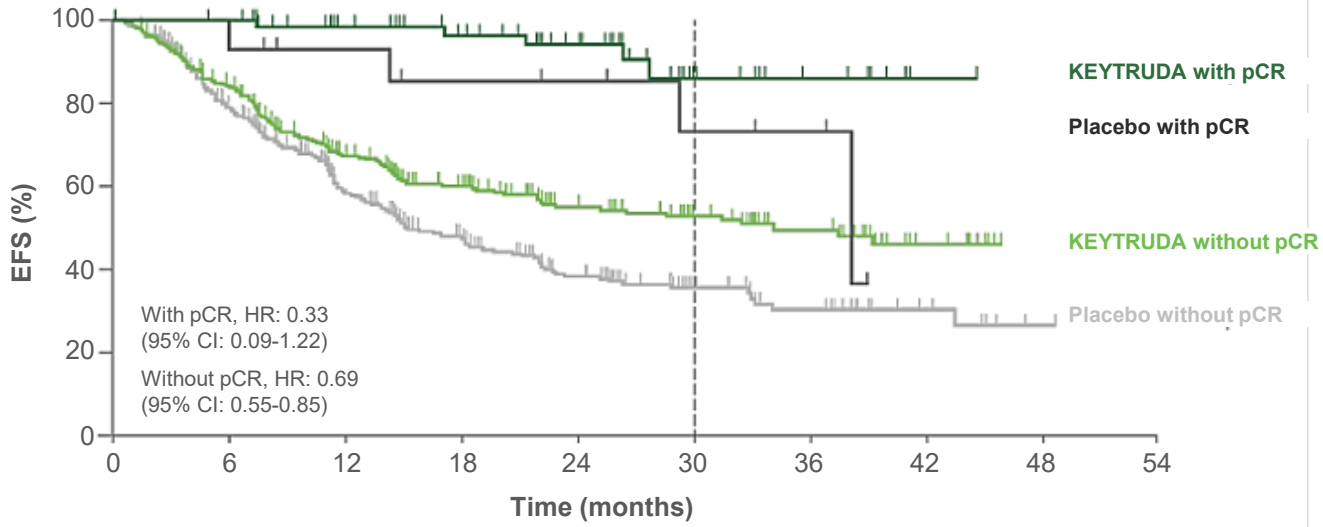
KEYNOTE-671: EFS by pCR[1,2]

Exploratory analysis

- Exploratory data from IA1* showed EFS benefit in the perioperative KEYTRUDA group **regardless of whether participants had a complete pathologic response or not**[1,2]
  - With pCR, HR: 0.33; without pCR, HR: 0.69[1]
- The EFS benefit in those without pCR is particularly important as it suggests a specific benefit from adjuvant KEYTRUDA

As seen in other trials there is evidence to support pCR as a surrogate endpoint for survival[3]
- However, the majority of patients do not achieve a pCR or mPR and a high unmet medical need exists for this group[1,2]

IA1 data



Number at risk

KEYTRUDA with pCR	72	72	59	46	33	15	8	1	0	0
Placebo with pCR	16	14	12	10	9	5	4	0	0	0
KEYTRUDA without pCR	325	258	177	126	84	57	34	10	0	0
Placebo without pCR	384	280	171	114	65	33	20	9	1	0

Adapted from Wakelee H, *et al. N Engl J Med* 2023.[2]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[2]
*Exploratory analysis from IA1 was not updated at IA2 as the updated EFS in the ITT was consistent with IA1.[1,2]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; pCR, pathological complete response.
1. Wakelee H, *et al.* KEYNOTE-671: Randomised, double-blind, Phase 3 study of pembrolizumab or placebo plus platinum-based chemotherapy followed by resection and pembrolizumab or placebo for early-stage NSCLC. ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100.
2. Wakelee H, *et al. N Engl J Med* 2023;389:491–503. **3.** Deutsch JS, *et al. Nat Med* 2024;30:218–228.

KEYNOTE-671: EFS by pCR at 5-year follow-up[1,2]

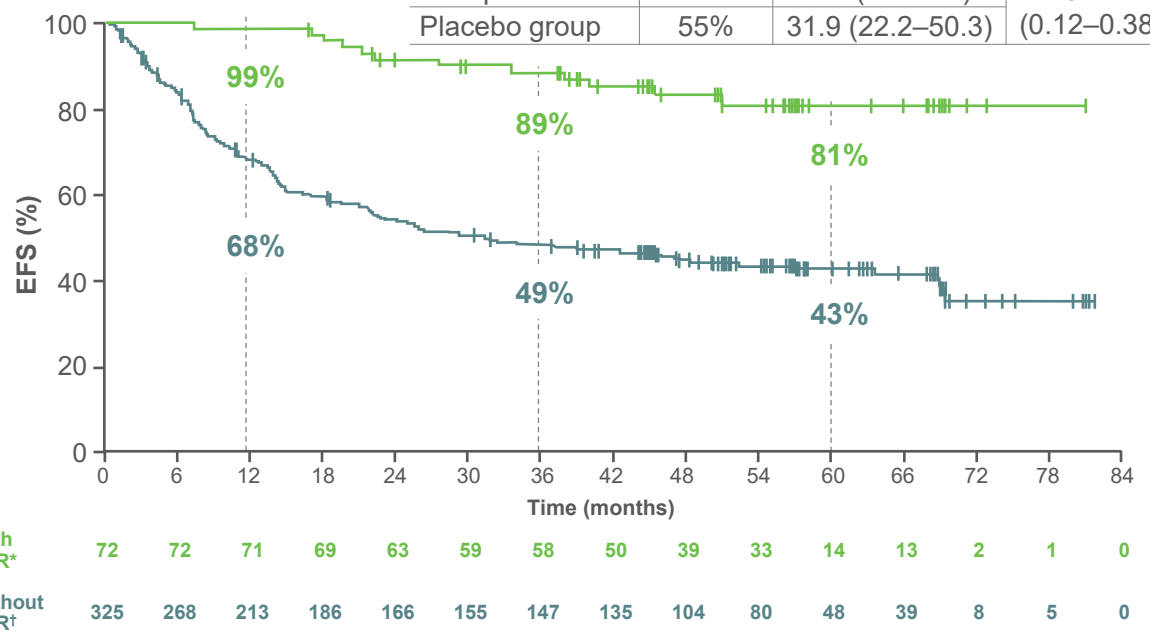
Exploratory analysis

No statistical conclusions can be drawn from exploratory analyses.

- In the perioperative KEYTRUDA group, 5-year EFS rates were 81% for those with pCR vs 43% for those without pCR (HR=0.21; 95% CI: 0.12–0.38)[2]
- In patients with pCR, 5-year EFS rates demonstrated a 63% relative reduction in the risk of an event vs placebo (HR=0.37; 95% CI: 0.14–1.00)[1]
- In patients without pCR, 5-year EFS rates demonstrated a 31% relative reduction in the risk of an event vs placebo (HR=0.69; 95% CI: 0.57–0.83)[2]

5-year data **EFS in patients in the KEYTRUDA group, with vs without pCR**

Treatment group	Pts w/ Event	Median (95% CI), mo	HR (95% CI)
With pCR	17%	NR (NR–NR)	0.21 (0.12–0.38)
Placebo group	55%	31.9 (22.2–50.3)	



Adapted from Reck M, et al. ELCC 2026.

Data cut-off: 3 July 2025; With pCR median follow-up: 62.3 months; without pCR median follow-up: 60.2 months.[1] *Percentage of participants with pCR are based on the ITT population, all other percentages are based on the number of participants who achieved pCR. †Percentage of participants without pCR are based on the ITT population, all other percentages are based on the number of participants who started neoadjuvant therapy. CI, confidence interval; EFS, event-free survival; HR, hazard ratio; mo, months; NR, not reached; pCR, pathological complete response.[1]

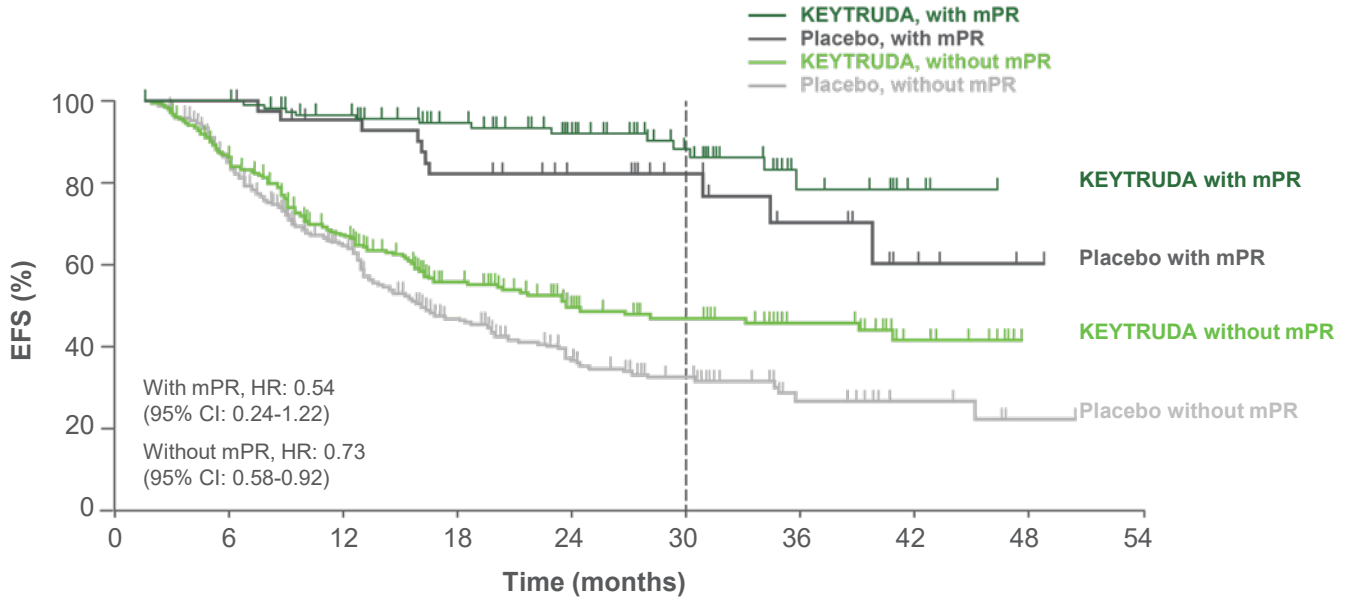
1. Majem M, *et al.* Presentation 223MO. Presented at ELCC 2026. 25–28 March, Copenhagen, Denmark. **2.** Reck M, *et al.* Presentation 222MO. Presented at ELCC 2026. 25–28 March, Copenhagen, Denmark.

KEYNOTE-671: EFS by mPR[1,2]

Exploratory analysis

- Exploratory data from IA1* showed EFS benefit in the perioperative KEYTRUDA group **regardless of whether participants had a major pathological response or not**[1,2]
  - With mPR, HR: 0.54; without mPR, HR: 0.73[1]

IA1 data



Number at risk

KEYTRUDA with mPR	120	117	99	79	60	30	15	1	0	0
Placebo with mPR	44	42	36	28	22	12	10	2	0	0
KEYTRUDA without mPR	277	213	137	93	57	42	27	10	0	0
Placebo without mPR	356	252	147	96	52	26	14	7	1	0

Adapted from Wakelee H, *et al. N Engl J Med* 2023.[2]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[2]
*Exploratory analysis from IA1 was not updated at IA2 as the updated EFS in the ITT was consistent with IA1.[1,2]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; mPR, major pathologic response.
1. Wakelee H, *et al.* ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100. **2.** Wakelee H, *et al. N Engl J Med* 2023;389:491–503.

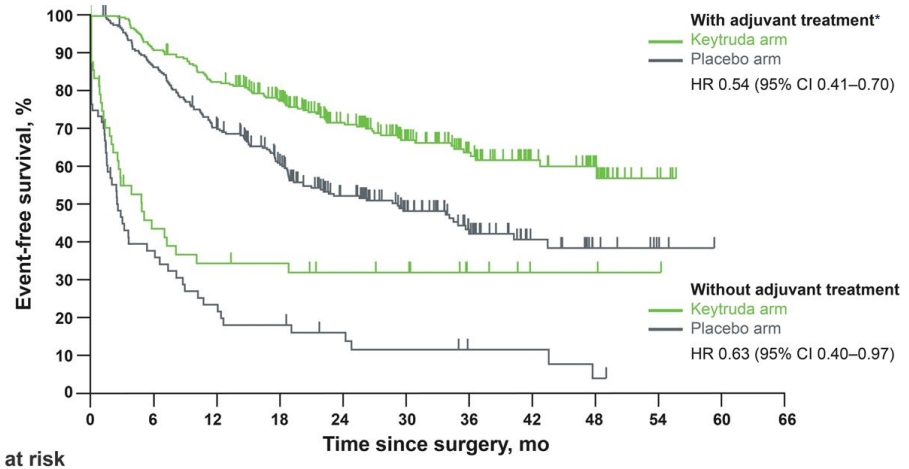
KEYNOTE-671: EFS benefit of adjuvant treatment[1–3]

Exploratory analysis

No statistical conclusions can be drawn from exploratory analyses. The possibility that both the neoadjuvant and adjuvant treatment phases contributed to the overall benefit cannot be eliminated.

- 73.2% (290/396) of participants in the neoadjuvant KEYTRUDA + chemotherapy group started adjuvant therapy vs 66.9% (267/399) of participants in the placebo + chemotherapy group[1]
- 48.2% (191/396) of participants in the neoadjuvant KEYTRUDA + chemotherapy group completed adjuvant treatment vs 43.6% (n=174/399) of participants in the placebo + chemotherapy/ placebo group completed adjuvant treatment[2]
- Exploratory data suggests that KEYTRUDA demonstrated a 46% relative reduction in the risk of an event vs placebo (HR: 0.54; 95% CI: 0.41–0.70) in patients who received adjuvant treatment*[3]
- Exploratory data suggests that KEYTRUDA + chemotherapy demonstrated a 37% relative reduction in the risk of an event vs placebo + chemotherapy (HR: 0.63; 95% CI: 0.40–0.97) in patients who did not receive adjuvant treatment*[3]

IA2 data **EFS in patients who received or did not receive adjuvant therapy**



Number at risk (number censored)

With adjuvant treatment	Keytruda arm	276 (0)	250 (1)	225 (3)	191 (24)	139 (63)	99 (95)	64 (126)	38 (150)	24 (163)	4 (182)	0 (186)	0 (186)
	Placebo arm	253 (0)	216 (3)	173 (5)	136 (21)	91 (48)	64 (69)	39 (89)	18 (108)	8 (117)	3 (122)	0 (125)	0 (125)
Without adjuvant treatment	Keytruda arm	49 (0)	19 (4)	15 (4)	14 (5)	11 (7)	10 (8)	5 (13)	2 (16)	2 (16)	1 (17)	0 (18)	0 (18)
	Placebo arm	64 (0)	21 (5)	13 (5)	10 (5)	7 (7)	5 (7)	3 (9)	3 (9)	1 (9)	0 (10)	0 (10)	0 (10)

Adapted from Garassino M, *et al.* Presented at ESMO 2024.[3]

IA1: Data cut-off: Jul 29, 2022; Median follow-up: 25.2 months;[1] IA2: Data cut-off: Jul 10, 2023; Median follow-up: 36.6 months.[2]
*Among patients who started adjuvant treatment, HRs for EFS and OS from the start of adjuvant therapy were 0.55 (95% CI: 0.42–0.72; N=548) and 0.71 (95% CI: 0.49–1.03; N=557), respectively.[3]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; mo, months; OS, overall survival; rNSCLC, resectable non-small cell lung cancer.

1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503. **2.** Spicer JD, *et al. Lancet* 2024;404:P1240–1252.
3. Garassino M, *et al.* Presented at ESMO 2024.13–17 September 2024. Barcelona, Spain. Abstract OP121.

KEYNOTE-671: Exploratory 5-year OS in the ITT population*[1]

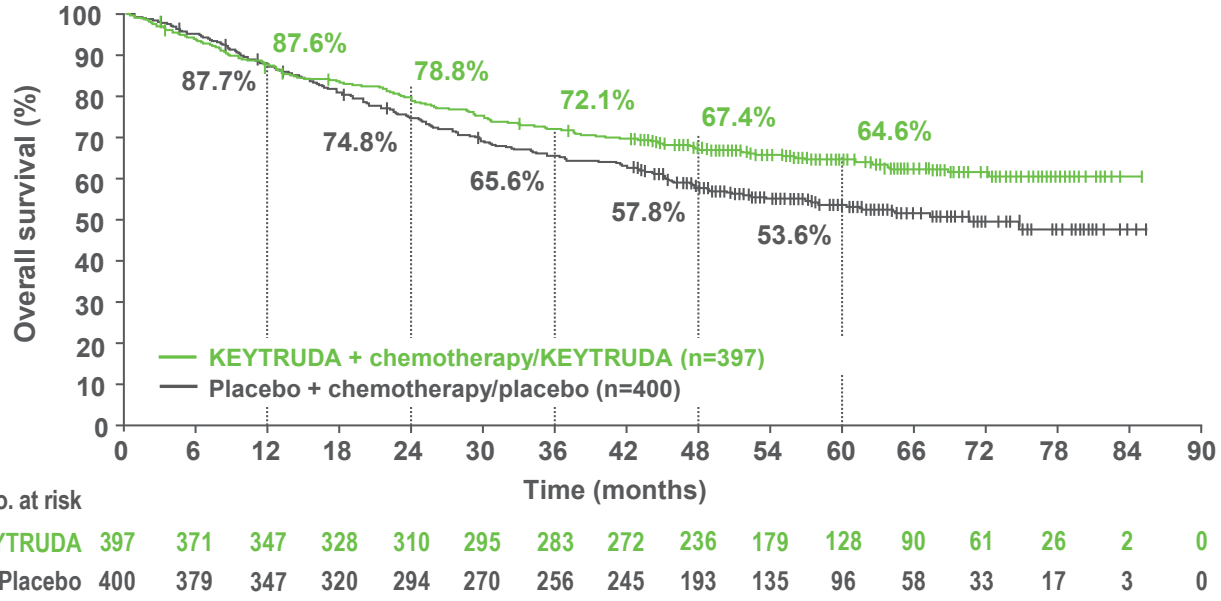
Exploratory analysis

Median follow-up: 60.4 months

Data cut-off date: 3 July 2025

5-year analysis: OS in the ITT population

Stage II disease



	Pts w/ Event, % (n/N)	Median (95% CI), mo	HR (95% CI)
KEYTRUDA group	35.8 (142/397)	NR (NR–NR)	0.74 (0.59–0.92)
Placebo group	45.5 (182/400)	70.7 (53.7–NR)	

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

Adapted from Wakelee H, *et al*. ESMO 2025.[1]

No conclusions can be drawn from exploratory analyses. *OS was defined as time from randomisation to death from any cause.[2]
CI, confidence interval; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; mo, months; NR, not reached; OS, overall survival.
1. Wakelee H, *et al*. Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation. **2.** Spicer JD, *et al*. *Lancet* 2024;404:P1240–1252.

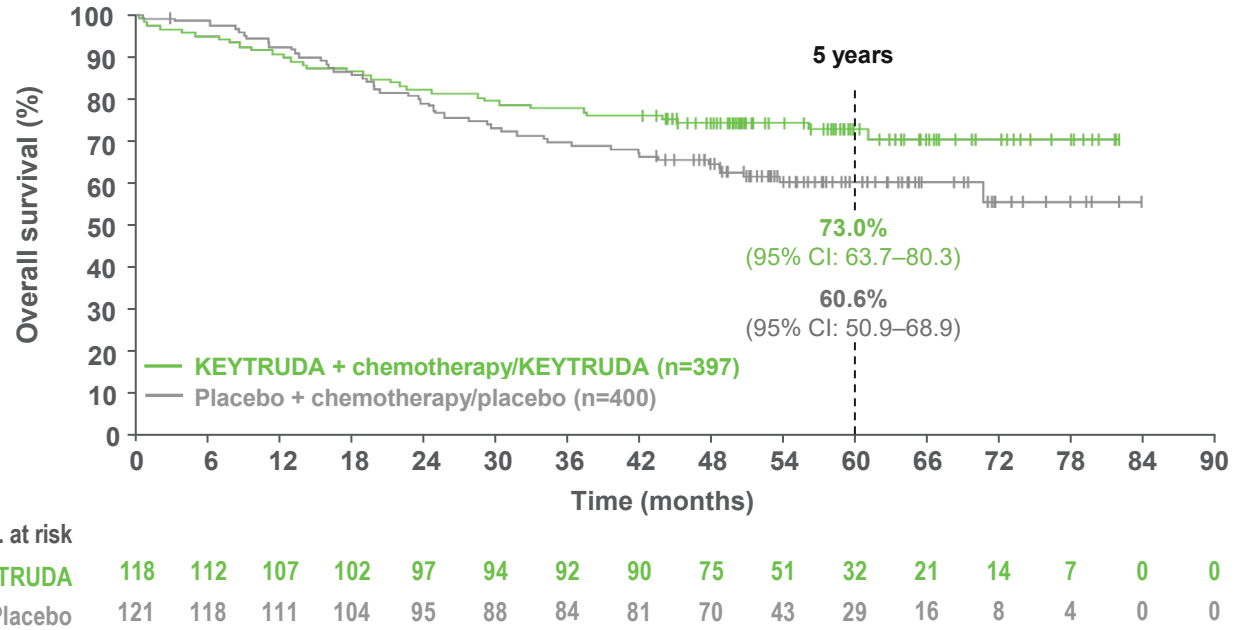
KEYNOTE-671: OS (5-year exploratory analysis) in Stage II disease*[1]

Exploratory analysis

Median follow-up: 58.7 [range, 43.0–85.7] months

Data cut-off date: 3 July 2025

OS in the ITT population (Stage II disease)



	Pts w/ Event, % (n/N)	Median (95% CI), mo	HR (95% CI)
KEYTRUDA group	27.1 (32/118)	NR (NR–NR)	0.67 (0.43–1.05)
Placebo group	38.8 (47/121)	NR (70.7–NR)	

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

Adapted from Weksler B, *et al*. STS 2026 .[1]

No conclusions can be drawn from exploratory analyses. *OS was defined as time from randomisation to death from any cause.[2]
CI, confidence interval; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; mo, months; NR, not reached; OS, overall survival.
1. Weksler B, *et al.* Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation. **2.** Spicer JD, *et al. Lancet* 2024;404:P1240–1252.

KEYNOTE-671: OS in key subgroups (5-year exploratory analysis)*[1]

Exploratory analysis

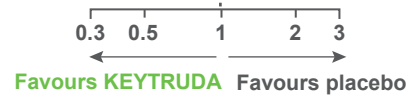
- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

5-year data

Stage II disease

OS within the ITT population

Subgroup	KEYTRUDA (Events/patients)	Placebo (Events/patients)	Hazard ratio (95% CI)
Overall	142/397	182/400	0.74 (0.59–0.92)
Disease Stage			
II	32/118	47/121	0.67 (0.43–1.05)
III	110/279	135/279	0.75 (0.58–0.96)
Nodal Status†			
N0	46/148	61/142	0.68 (0.46–0.99)
N1	24/82	32/73	0.64 (0.38–1.08)
N2	71/166	89/185	0.82 (0.60–1.12)
Histology			
Non-squamous	72/226	86/227	0.79 (0.58–1.08)
Squamous	70/171	96/173	0.68 (0.50–0.92)
PD-L1 TPS†			
≥50%	34/132	48/134	0.65 (0.42–1.00)
1%–49%	45/127	56/115	0.67 (0.45–0.99)
<1%	63/138	78/151	0.87 (0.62–1.21)



Adapted from Wakelee H, *et al*. ESMO 2025.[1]

Data cut-off: 3 July 2025. Median follow-up: 60.4 months.[1]
No conclusions can be drawn from exploratory analyses. *OS was defined as time from randomisation to death from any cause.[2] †The subgroup for PD-L1 TPS (<1% and 1–49%) and nodal status (N0, N1, and N2) were not prespecified in the Statistical Analysis Plan.[3]
ALK, anaplastic lymphoma kinase; CI, confidence interval; HR, hazard ratio; ITT, intention to treat; OS, overall survival; PD-L1, programmed death-ligand 1; TPS, tumour proportion score.
1. Wakelee H, *et al*. Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation. **2.** Spicer JD, *et al. Lancet* 2024;404:P1240–1252. **3.** ClinicalTrials.gov.. Protocol amendment 671-11. Approval date November 29, 2022. Available at: https://cdn.clinicaltrials.gov/large-docs/43/NCT03425643/Prot_SAP_000.pdf. Accessed August 2026.

KEYNOTE-671: OS in key subgroups (5-year exploratory analysis) in Stage II disease*[1]

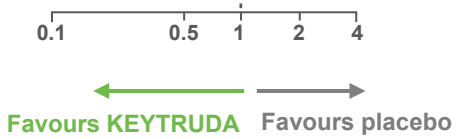
Exploratory analysis

- No statistical conclusions can be drawn from exploratory analyses. KEYNOTE-671 was not powered to detect differences in the treatment effect in these subgroups; therefore, no conclusions can be drawn

5-year data

OS in patients with Stage II disease

Subgroup	KEYTRUDA (Events/patients)	Placebo (Events/patients)	Hazard ratio (95% CI)
Overall	32/118	47/121	0.67 (0.43–1.05)
Disease Stage			
IIA	6/22	7/19	0.73 (0.24–2.16)
IIB	29/96	40/102	0.66 (0.40–1.08)
Nodal Status†			
N0	25/85	33/85	0.74 (0.44–1.24)
N1	7/33	14/36	0.50 (0.20–1.24)
Histology			
Nonsquamous	10/52	15/57	0.71 (0.32–1.58)
Squamous	22/66	32/64	0.63 (0.37–1.08)
PD-L1 TPS			
≥50%	5/36	6/34	0.72 (0.22–2.35)
1%–49%	12/39	17/36	0.64 (0.31–1.34)
<1%	15/43	24/51	0.72 (0.38–1.37)



Adapted from Weksler B, et al. STS 2026.[1]

No conclusions can be drawn from exploratory analyses. Data cut-off: 3 July 2025. Median follow-up: 58.7 months. *OS was defined as time from randomisation to death from any cause.[2]
CI, confidence interval; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; mo, months; NR, not reached; OS, overall survival.
1. Weksler B, *et al.* Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation. **2.** Spicer JD, *et al. Lancet* 2024;404:P1240–1252.

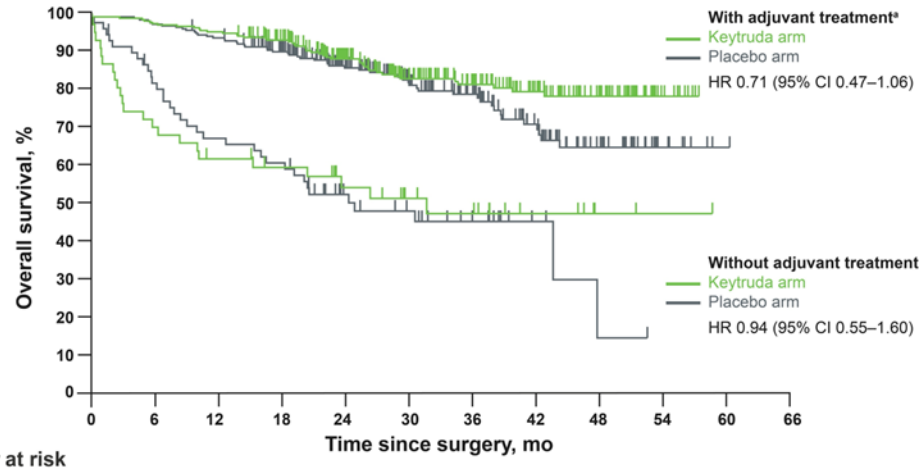
KEYNOTE-671: OS benefit of adjuvant treatment[1–3]

Exploratory analysis

No statistical conclusions can be drawn from exploratory analyses. The possibility that both the neoadjuvant and adjuvant treatment phases contributed to the overall benefit cannot be eliminated.

- 73.2% (290/396) of participants in the neoadjuvant KEYTRUDA + chemotherapy group started adjuvant therapy vs 66.9% (267/399) of participants in the placebo + chemotherapy group[1]
- 48.2% (191/396) of participants in the neoadjuvant KEYTRUDA + chemotherapy group completed adjuvant treatment vs 43.6% (n=174/399) of participants in the placebo + chemotherapy/placebo group completed adjuvant treatment[2]
- Exploratory data suggests that KEYTRUDA demonstrated a 29% relative reduction in the risk of death vs placebo (HR: 0.71; 95% CI: 0.47–1.06) in patients who received adjuvant treatment*[3]
- Exploratory data suggests that KEYTRUDA + chemotherapy demonstrated a 6% relative reduction in the risk of death vs placebo + chemotherapy (HR: 0.94; 95% CI: 0.55–1.60) in patients who did not receive adjuvant treatment*[3]

IA2 data **OS in patients who received or did not receive adjuvant therapy**



Number at risk (number censored)

With adjuvant treatment	Keytruda arm	276 (0)	271 (0)	265 (0)	245 (14)	183 (64)	139 (98)	102 (133)	71 (162)	45 (187)	10 (222)	0 (232)	0 (232)
	Placebo arm	253 (0)	248 (0)	238 (1)	212 (18)	158 (63)	112 (102)	85 (126)	52 (152)	26 (174)	8 (192)	1 (199)	0 (200)
Without adjuvant treatment	Keytruda arm	49 (0)	34 (1)	29 (2)	25 (5)	19 (9)	14 (13)	12 (14)	6 (20)	2 (24)	1 (25)	0 (26)	0 (26)
	Placebo arm	64 (0)	51 (2)	42 (2)	38 (2)	24 (11)	18 (15)	11 (21)	4 (28)	1 (29)	0 (30)	0 (30)	0 (30)

Adapted from Garassino M, *et al.* Presented at ESMO 2024.[3]

IA1: Data cut-off: Jul 29, 2022; Median follow-up: 25.2 months;[1] IA2: Data cut-off: Jul 10, 2023; Median follow-up: 36.6 months.[2]
*Among patients who started adjuvant treatment, HRs for EFS and OS from the start of adjuvant therapy were 0.55 (95% CI: 0.42–0.72; N=548) and 0.71 (95% CI: 0.49–1.03; N=557), respectively.[3]
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; mo, months; OS, overall survival; rNSCLC, resectable non-small cell lung cancer.
1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503. **2.** Spicer JD, *et al. Lancet* 2024;404:P1240–1252. **3.** Garassino M, *et al.* Presented at ESMO 2024.13–17 September 2024. Barcelona, Spain. Abstract OP121.

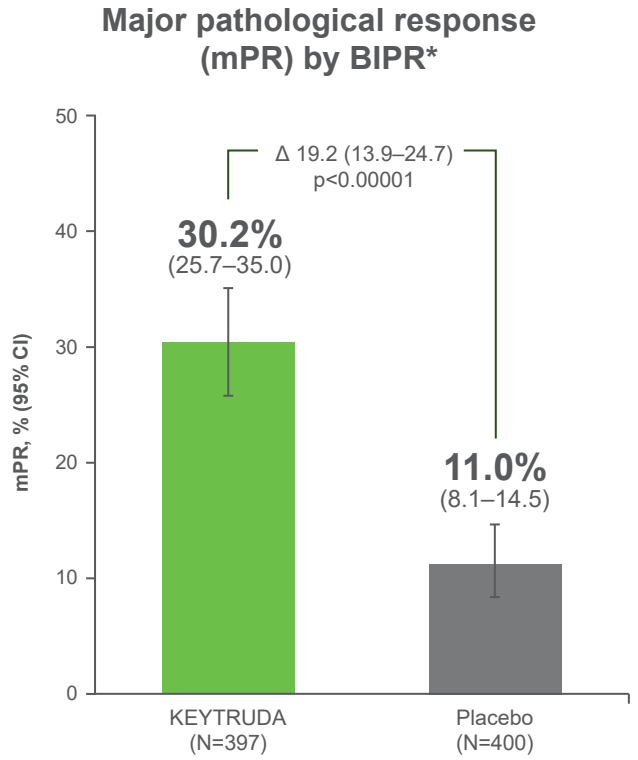
KEYNOTE-671: pCR and mPR (IA1 exploratory analysis)[1,2]

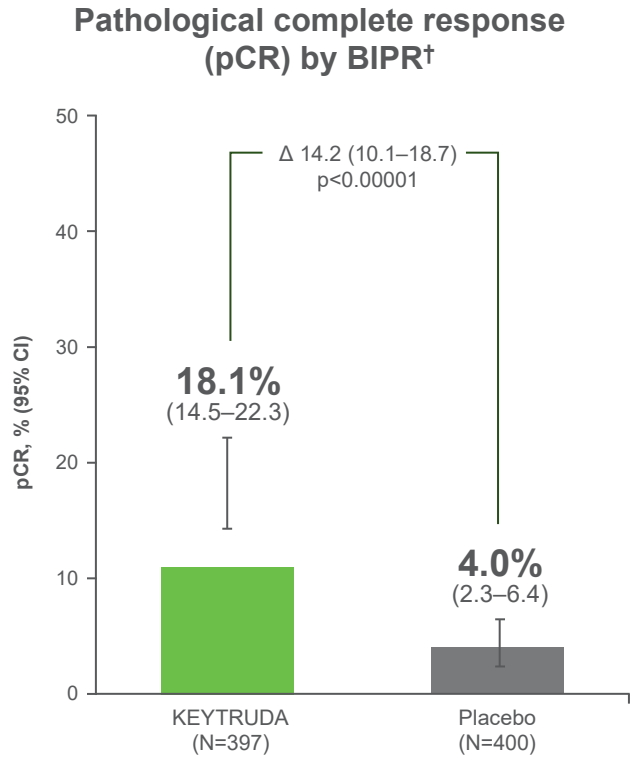
Stage II disease

Secondary analysis

- **Higher rates of pathologic response** were seen in the KEYTRUDA group[1,2]
  - pCR and mPR were assessed by blinded review and defined by IASLC criteria*†[1,2]

IA1 data





Adapted from Wakelee H, *et al.* ASCO 2023.[1]

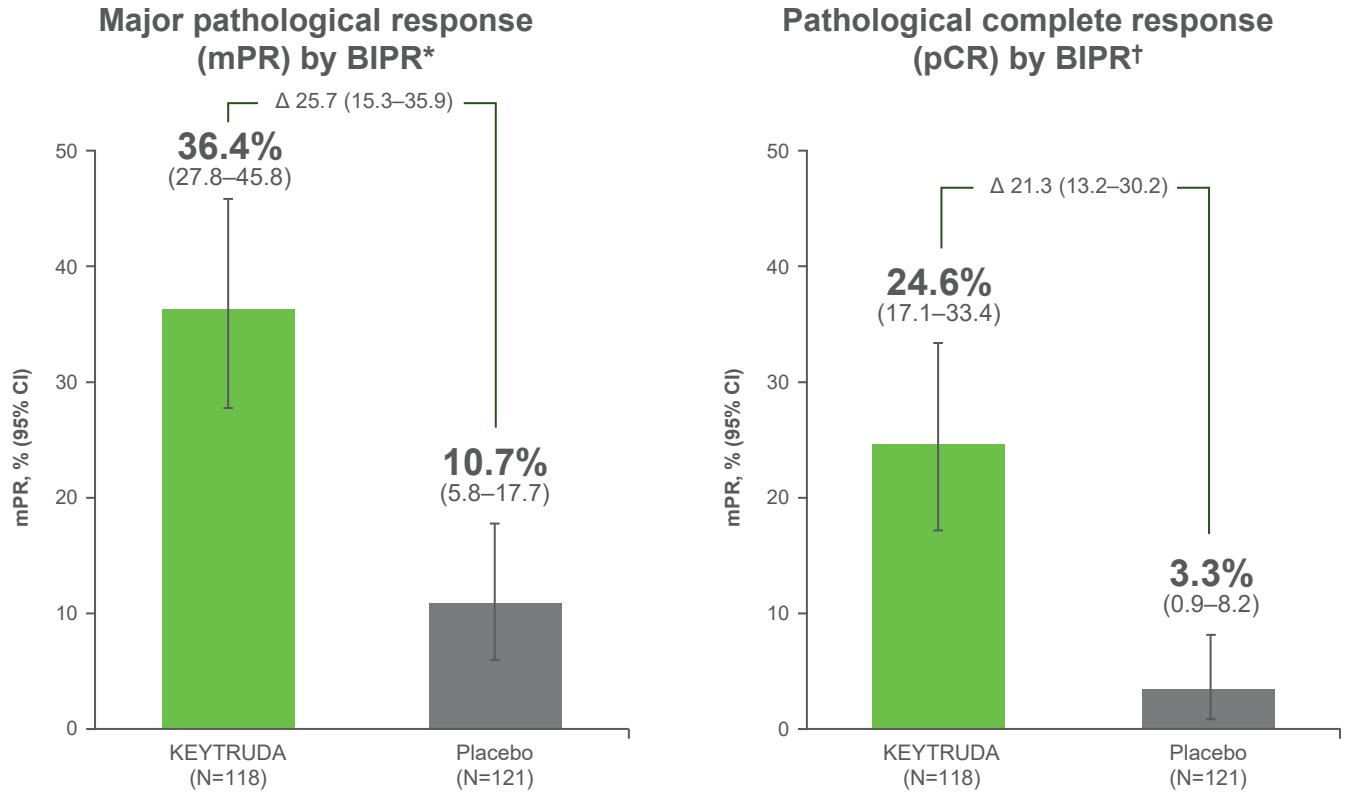
Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[2]
No conclusions can be drawn from exploratory analyses. *Per IASLC criteria, mPR was defined as ≤10% viable tumour cells in resected primary tumour and lymph nodes.[1] †Per IASLC criteria, pCR was defined as ≤10% viable tumour cells in resected primary tumour and lymph nodes.[1]
BIPR, blinded independent pathological review; CI, confidence interval; IASLC, International Association for the Study of Lung Cancer; IA, interim analysis; irPRC, immune-related pathologic response criteria; mPR, major pathologic response; pCR, pathological complete response.
1. Wakelee H, *et al.* ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100. **2.** Wakelee H, *et al. N Engl J Med* 2023;389:491–503.

KEYNOTE-671: pCR and mPR in Stage II disease (IA3)[1]

Exploratory analysis

- **Higher rates of pathologic response** were seen in the KEYTRUDA group[1,2]
  - pCR and mPR were assessed by blinded review and defined by IASLC criteria*†[1,2]

IA3 data (Stage II)



Adapted from Tsuboi M, *et al.* ESTS 2025.[1]

Data cut-off date for IA3: 19 August 2024. Median follow-up: 41.1 months.[1]
*mPR was defined as ≤10% viable tumour cells in resected primary tumour and lymph nodes.[1] †Per IASLC criteria, pCR was defined as ≤10% viable tumour cells in resected primary tumour and lymph nodes.[2]
BIPR, blinded independent pathological review; CI, confidence interval; IASLC, International Association for the Study of Lung Cancer; IA, interim analysis; mPR, major pathologic response; pCR, pathological complete response.
1. Tsuboi M, *et al.* Presented at ESTS. 25–27 May 2025. Budapest, Hungary. Oral presentation. **2.** Wakelee H, *et al.* ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100.

KEYNOTE-671: Surgical outcomes[1,2]

Stage II disease

- Most patients who received at least one dose of neoadjuvant therapy underwent in-trial surgery (82.1% in the KEYTRUDA group vs 79.4% in the placebo group)[1,2]
- Among those who underwent surgery, the most common surgical procedure was lobectomy (78.8% vs 75.1%), and the **majority of patients had complete (R0) resection (92.0% vs 84.2%)[1,2]**

IA1 data

Summary of surgical outcomes, n (%)		KEYTRUDA (n=325)	Placebo (n=317)
In-study surgery*	Resected	320 (98.5)	302 (95.3)
	Complete – R0	299 (92.0)	267 (84.2)
	Incomplete – R1	17 (5.2)	31 (9.8)
	Incomplete – R2	4 (1.2)	4 (1.3)
	Unresected	5 (1.5)	15 (4.7)
Surgical procedure	Lobectomy	256 (78.8)	238 (75.1)
	Pneumonectomy	37 (11.4)	39 (12.3)
	Bilobectomy	26 (8.0)	26 (8.2)
	Exploratory thoracotomy	4 (1.2)	13 (4.1)
	Other	2 (0.6)†	1 (0.3)‡
30-day mortality		6 (1.8)§	2 (0.6)¶

Adapted from Wakelee H, *et al.* ASCO 2023.[2]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1]
*An additional 8 participants in the KEYTRUDA group and 7 participants in the placebo group underwent off-study surgery.[1] †Lung segmentectomy (n=1), lung wedge resection (n=1).[1] ‡Lymph node dissection only (planned surgery was lung lobectomy; need for more extensive surgery discovered during surgery, but consent was not granted).[1] §Pulmonary embolism (n=2), pulmonary haemorrhage due to arterial injury during surgery (n=1), pulmonary sepsis (n=1), respiratory failure (n=1) and septic shock (n=1).[1] ¶Respiratory failure (n=1) and pneumonia (n=1).[1]
AE, adverse event; IA, interim analysis; R0, complete resection defined as no invasive cancer at bronchial margin or soft tissue surrounding bronchus, no invasive cancer at pulmonary artery or pulmonary vein margins or surrounding soft tissue, no invasive cancer at medial, lateral, superior and inferior margins of chest wall resection, no minimal margin distance, bronchial dysplasia is considered a negative margin.[1] R1, microscopic invasive cancer at bronchial, pulmonary vein or pulmonary arterial margins or surrounding soft tissue, carcinoma *in situ* at bronchial margin; R2, gross residual disease.
1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (and supplementary appendix). **2.** Wakelee H, *et al.* ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100.

KEYNOTE-671: Surgical outcomes in Stage II disease (5-year exploratory analysis)[1]

- Most patients who received at least one dose of neoadjuvant therapy underwent in-trial surgery (83.9% in the KEYTRUDA group vs 85.1% in the placebo group)[1]
- Among those who underwent surgery, the most common surgical procedure was lobectomy (73.7% vs 72.8%), and the **majority of patients had complete (R0) resection (94.9% vs 86.4%)**[1]

5-year data (Stage II)

Summary of surgical outcomes, n (%)		KEYTRUDA (n=118)	Placebo (n=121)
Participants who underwent surgery		99 (83.9)	103 (85.1)
Weeks from randomisation to surgery, median (range)		15.3 (6.7–26.3)	15.6 (4.6–20.6)
Procedure*	Bilobectomy	11 (11.1)	13 (12.6)
	Lobectomy	73 (73.7)	75 (72.8)†
	Pneumonectomy	15 (15.2)	12 (11.7)
	Thoracotomy	0 (0.0)	3 (2.9)†
Surgical Completeness*	R0 resection	94 (94.9)	89 (86.4)
	R1 resection	4 (4.0)	10 (9.7)
	R2 resection	1 (1.0)	0 (0.0)
	Unresectable	0 (0.0)	4 (3.9)†
Participants with surgical delay*‡		6 (6.1)	5 (4.9)

Adapted from Weksler B, *et al*. STS 2026.[1]

Data cut-off date for IA3: 3 July 2025. Median follow-up: 58.7 [range, 43.0–85.7] months.[1]
*Percentage calculated out of the number of patients who underwent surgery.[1] †In the placebo group, 1 participant who underwent lobotomy and 3 who underwent thoracotomy has unresectable tumours due to PD and pleural metastases (n=1), PD (n=1) and aortic involvement (n=1).[1]
‡Surgical delay was defined as surgery >20 weeks between the first neoadjuvant dose and surgery in patients who received 4 cycles of neoadjuvant therapy or >8 weeks between the last neoadjuvant dose and surgery in patients who received 1–3 cycles of neoadjuvant therapy.[1]
AE, adverse event; IA, interim analysis; R0, complete resection defined as no invasive cancer at bronchial margin or soft tissue surrounding bronchus, no invasive cancer at pulmonary artery or pulmonary vein margins or surrounding soft tissue, no invasive cancer at medial, lateral, superior and inferior margins of chest wall resection, no minimal margin distance, bronchial dysplasia is considered a negative margin.[1] R1, microscopic invasive cancer at bronchial, pulmonary vein or pulmonary arterial margins or surrounding soft tissue, carcinoma *in situ* at bronchial margin; R2, gross residual disease.

1. Weksler B, *et al*. Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation.

KEYNOTE-671: Safety[1]

- **Most TRAEs occurred in the neoadjuvant phase,** consistent with neoadjuvant chemotherapy being the main contributor[1]
  - Addition of KEYTRUDA did not substantially increase the rate of any-grade TRAEs (Δ+2.0%), high-grade TRAEs (Δ+4.1%), or discontinuation due to AEs (Δ+1.7%)[1]
- The rate of TRAEs in the adjuvant phase was lower than in the neoadjuvant phase, indicating that **adjuvant KEYTRUDA is generally well-tolerated**[1]
  - Adjuvant KEYTRUDA was associated with an increase in any TRAEs (Δ+22.7%) and high-grade TRAEs (Δ+4.4%)[1]
  - At IA1, more patients received and completed adjuvant therapy with KEYTRUDA than placebo (Δ+5.1%)[1]
  - Only a small proportion discontinued adjuvant therapy due to AEs (9.3% vs 3.3%)[1]

IA1 data

Completion/discontinuation by treatment phase[1]		KEYTRUDA (n=396)	Placebo (n=399)
Neoadjuvant phase, n (%)	Completed 4 cycles	295 (74.5)	297 (74.4)
	Discontinued due to AEs	8 (2.0)	1 (0.3)
Surgery phase, n (%)	Underwent surgery	325 (82.1)	317 (79.4)
	Did not proceed to adjuvant due to AEs	19 (4.8)	10 (2.5)
Adjuvant phase, n (%)	Received adjuvant	290 (73.2)	267 (66.9)
	Completed adjuvant	160 (40.4)	141 (35.3)
	Discontinued due to AEs	37 (9.3)	13 (3.3)

Adapted from Wakelee H, *et al. N Engl J Med* 2023. Supplementary appendix.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1]
AE, adverse event; IA, interim analysis; TRAE, treatment-related adverse event.
1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (and supplementary appendix).

KEYNOTE-671: TRAEs in the as-treated population*

- **KEYTRUDA did not substantially increase the rate of TRAEs vs placebo:**[1]
  - 96.7% (383/396) in the KEYTRUDA group vs 95.0% (379/399) in the placebo group[1]
  - Treatment-related deaths were low and balanced (1.0% in the KEYTRUDA group vs 0.8% in the placebo group)[1]
- The most frequent TRAEs **were consistent with expected chemotherapy-related events** (e.g., anaemia, decrease in neutrophil count and nausea)[1]

IA1 data	KEYTRUDA (n=396)		Placebo (n=399)	
Any treatment-related adverse event, n (%)	**383 (96.7)**		**379 (95.0)**	
Grade 3–5	178 (44.9)		149 (37.3)	
Serious	70 (17.7)		57 (14.3)	
Led to death	4 (1.0)†		3 (0.8)‡	
Treatment-related adverse events with incidence ≥10% in either group, n (%)	**Any Grade**	**Grade 3–4**	**Any Grade**	**Grade 3–4**
Nausea	215 (54.3)	8 (2.0)	204 (51.1)	6 (1.5)
Neutrophil count decreased	167 (42.2)	82 (20.7)	167 (41.9)	78 (19.5)
Anaemia	143 (36.1)	29 (7.3)	135 (33.8)	22 (5.5)
White blood cell count decreased	111 (28.0)	21 (5.3)	98 (24.6)	22 (5.5)
Fatigue	108 (27.3)	6 (1.5)	94 (23.6)	3 (0.8)
Constipation	106 (26.8)	3 (0.8)	100 (25.1)	0
Decreased appetite	91 (23.0)	6 (1.5)	88 (22.1)	0
Vomiting	75 (18.9)	4 (1.0)	58 (14.5)	1 (0.3)
Platelet count decreased	74 (18.7)	20 (5.1)	74 (18.5)	24 (6.0)
Blood creatinine increased	56 (14.1)	3 (0.8)	48 (12.0)	0
Diarrhoea	52 (13.1)	6 (1.5)	56 (14.0)	3 (0.8)
Alanine aminotransferase increased	51 (12.9)	7 (1.8)	31 (7.8)	4 (1.0)
Asthenia	45 (11.4)	4 (1.0)	55 (13.8)	2 (0.5)
Rash	45 (11.4)	3 (0.8)	26 (6.5)	0
Alopecia	40 (10.1)	0	40 (10.0)	1 (0.3)

Adapted from Wakelee H, *et al. N Engl J Med* 2023.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1] *The as-treated population included all the participants who underwent randomisation and received at least one dose of KEYTRUDA or placebo plus chemotherapy. TRAEs were AEs considered to be related to chemotherapy, KEYTRUDA, or placebo by the investigator. †One participant each due to immune-mediated lung disease, pneumonia, and sudden cardiac death. ‡One participant each due to acute coronary syndrome, pneumonia, and pulmonary haemorrhage. †Due to atrial fibrillation.
AE, adverse event; IA, interim analysis; TRAE, treatment-related adverse event.

1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503.

KEYNOTE-671: ImAEs and infusion reactions in the as-treated population*

- **KEYTRUDA was associated with a higher overall incidence of imAEs vs placebo,** including any-grade (Δ+14.8%) and high-grade (Δ+4.3%)[1]
  - Despite higher overall AE rates with KEYTRUDA, treatment discontinuation due to AEs remained low (5.1% vs 0.8%), supporting a manageable safety profile[1]
- Most imAEs were low-grade, with **Grade 3–5 events remaining uncommon across both treatment groups[1]**
  - ImAEs were more frequent with KEYTRUDA, including hypothyroidism (11.1% vs 1.8%), pneumonitis (5.6% vs 1.8%), and hyperthyroidism (5.6% vs 3.3%), consistent with the established immunotherapy safety profile[1]

	KEYTRUDA (n=396)		Placebo (n=399)	
Any adverse event of interest, n (%)	**100 (25.3)**		**42 (10.5)**	
Grade 3–5	23 (5.8)		6 (1.5)	
Serious	21 (5.3)		6 (1.5)	
Led to death	1 (0.3)†		0	
Led to discontinuation of all study treatment	20 (5.1)		3 (0.8)	
Specific adverse events of interest	**Any Grade**	**Grade 3–5**	**Any Grade**	**Grade 3–5**
Hypothyroidism	44 (11.1)	0	7 (1.8)	0
Hyperthyroidism	22 (5.6)	0	13 (3.3)	0
Pneumonitis	22 (5.6)	8 (2.0)	7 (1.8)	1 (0.3)
Severe skin reactions	9 (2.3)	6 (1.5)	0	0
Colitis	5 (1.3)	3 (0.8)	0	0
Infusion reactions	5 (1.3)	0	6 (1.5)	0
Thyroiditis	4 (1.0)	0	1 (0.3)	0
Hepatitis	3 (0.8)	1 (0.3)	2 (0.5)	2 (0.5)
Hypophysitis	2 (0.5)	1 (0.3)	0	0
Adrenal insufficiency	1 (0.3)	1 (0.3)	0	0
Myasthenic syndrome	1 (0.3)	1 (0.3)	0	0
Myocarditis	1 (0.3)	1 (0.3)	0	0
Myositis	1 (0.3)	1 (0.3)	0	0
Guillain-Barré syndrome	0	0	1 (0.3)	1 (0.3)
Pancreatitis	0	0	2 (0.5)	1 (0.3)
Uveitis	0	0	1 (0.3)	0
Vasculitis	0	0	2 (0.5)	1 (0.3)

Adapted from Wakelee H, *et al. N Engl J Med* 2023. Supplementary appendix.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1] *The as-treated population included all the participants who underwent randomisation and received at least one dose of KEYTRUDA or placebo plus chemotherapy. Potential imAEs and infusion reactions were based on a list of preferred terms prepared by the sponsor and considered regardless of attribution to study treatment by the investigator. †Pneumonitis (reported as immune-mediated lung disease).[1]

AE, adverse event; IA, interim analysis; ImAE, immune-mediated adverse event.

1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (and supplementary appendix).

KEYNOTE-671: TRAEs that occurred during the neoadjuvant/surgery treatment phase (as-treated population)*

- **KEYTRUDA did not substantially increase the rate of TRAEs vs placebo during the neoadjuvant/surgery treatment phase:**[1]
  - 95.7% (379/396) in the KEYTRUDA group vs 93.7% (374/399) in the placebo group
  - Treatment-related deaths were low and balanced (0.8% in both groups)
- The most frequent TRAEs **were consistent with expected chemotherapy-related events** (e.g., anaemia and nausea)

IA1 data	KEYTRUDA (n=396)		Placebo (n=399)	
Any treatment-related adverse event, n (%)	**379 (95.7)**		**374 (93.7)**	
Grade 3–5	161 (40.7)		146 (36.6)	
Serious	56 (14.1)		52 (13.0)	
Led to death	3 (0.8)†		3 (0.8)‡	
Treatment-related adverse events with incidence ≥10% in either group, n (%)	**Any Grade**	**Grade 3–4**	**Any Grade**	**Grade 3–4**
Nausea	213 (53.8)	7 (1.8)	202 (50.6)	6 (1.5)
Neutrophil count decreased	167 (42.2)	82 (20.7)	166 (41.6)	78 (19.5)
Anaemia	140 (35.4)	29 (7.3)	134 (33.6)	22 (5.5)
White blood cell count decreased	111 (28.0)	21 (5.3)	98 (24.6)	22 (5.5)
Fatigue	106 (26.8)	4 (1.0)	93 (23.3)	3 (0.8)
Constipation	105 (26.5)	3 (0.8)	99 (24.8)	0
Decreased appetite	86 (21.7)	5 (1.3)	86 (21.6)	0
Vomiting	74 (18.7)	4 (1.0)	57 (14.3)	1 (0.3)
Platelet count decreased	72 (18.2)	20 (5.1)	74 (18.5)	23 (5.8)
Blood creatinine increased	53 (13.4)	3 (0.8)	44 (11.0)	0
Alanine aminotransferase increased	44 (11.1)	5 (1.3)	27 (6.8)	2 (0.5)
Asthenia	43 (10.9)	4 (1.0)	55 (13.8)	2 (0.5)
Diarrhoea	39 (9.8)	3 (0.8)	46 (11.5)	3 (0.8)
Alopecia	36 (9.1)	0	40 (10.0)	1 (0.3)

Adapted from Wakelee H, *et al. N Engl J Med* 2023. Supplementary appendix.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1] *The neoadjuvant/surgery phase began with the first dose of neoadjuvant therapy and ended with the first dose of adjuvant KEYTRUDA or placebo. The adjuvant phase began with the first dose of adjuvant therapy. TRAEs were AEs considered to be related to chemotherapy, KEYTRUDA, or placebo by the investigator.[1] †One participant each due to immune-mediated lung disease, pneumonia, and sudden cardiac death. ‡One participant each due to acute coronary syndrome, pneumonia, and pulmonary haemorrhage.[1]

AE, adverse event; IA, interim analysis; ImAE, immune-mediated adverse event; TRAE, treatment-related adverse event.

1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (and supplementary appendix).

KEYNOTE-671: TRAEs that occurred during the adjuvant treatment phase (as-treated population)*

- **During the adjuvant treatment phase, KEYTRUDA did slightly increased the the rate of TRAEs vs placebo:[1]**
  - 54.5% (158/290) in the KEYTRUDA group vs 31.8% (85/267) in the placebo group
  - Treatment-related deaths were low balanced (0.3% in the KEYTRUDA group vs 0.8% in the placebo group groups)
- The most frequent TRAEs included pruritus, rash, diarrhoea and hypothyroidism

	KEYTRUDA (n=290)		Placebo (n=267)	
Any treatment-related adverse event, n (%)	**158 (54.5)**		**85 (31.8)**	
Grade 3–5	29 (10.0)		15 (5.6)	
Serious	16 (5.5)		7 (2.6)	
Led to death	1 (0.3)†		0	
Treatment-related adverse events with incidence ≥5% in either group, n (%)	**Any Grade**	**Grade 3–4**	**Any Grade**	**Grade 3–4**
Pruritus	24 (8.3)	2 (0.7)	6 (2.2)	0
Rash	18 (6.2)	1 (0.3)	8 (3.0)	0
Diarrhoea	15 (5.2)	3 (1.0)	12 (4.5)	0
Hypothyroidism	15 (5.2)	0	2 (0.7)	0

Adapted from Wakelee H, *et al. N Engl J Med* 2023. Supplementary appendix.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.[1] *The adjuvant phase began with the first dose of adjuvant therapy. TRAEs were AEs considered to be related to chemotherapy, KEYTRUDA, or placebo by the investigator. †Due to atrial fibrillation.
AE, adverse event; IA, interim analysis; ImAE, immune-mediated adverse event; TRAE, treatment-related adverse event.
1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (and supplementary appendix).

KEYNOTE-671: Summary of AEs that occurred during the surgical treatment phase (participants who underwent in-study surgery)

- **During the surgical treatment phase, KEYTRUDA was associated with similar levels of overall AEs vs placebo,** including any-grade (Δ+0.2%) and high-grade (Δ+4.3%)[1]
- **KEYTRUDA, treatment discontinuation due to AEs remained low** (5.8% vs 2.2%), supporting a manageable safety profile[1]

IA1 data	KEYTRUDA (n=325)	Placebo (n=317)
Any adverse event of interest, n (%)	**231 (71.1)**	**226 (71.3)**
Grade 3–5	84 (25.8)	68 (21.5)
Serious	59 (18.2)	54 (17.0)
Led to death	9 (2.8)	5 (1.6)
Led to discontinuation of all study treatment	19 (5.8)	7 (2.2)

Adapted from Wakelee H, *et al. N Engl J Med* 2023. Supplementary appendix.[1]

Data cut-off date for IA1: 29 July 2022. Median follow-up: 25.2 months.
AE, adverse event; IA, interim analysis
1. Wakelee H, *et al. N Engl J Med* 2023;389:491–503 (and supplementary appendix).

KEYNOTE-671: 5-year AE summary in the as-treated population[1]

Stage II disease

5-year data

AE summary across treatment phases, n (%)	KEYTRUDA (n=396)	Placebo (n=399)
Treatment-related AEs	383 (96.7)	381 (95.5)
Grade 3–5	179 (45.2)	151 (37.8)
Serious	73 (18.4)	59 (14.8)
Led to death	4 (1.0)	3 (0.8)
Led to discontinuation of all study treatments	55 (19.4)	21 (5.3)
Immune-mediated AEs and infusion reactions*	103 (26.0)	37 (9.3)
Grade 3–5	25 (6.3)	7 (1.8)
Serious	24 (6.1)	7 (1.8)
Led to death	1 (0.3)	0
Led to discontinuation of all study treatments	22 (5.6)	3 (0.8)

Adapted from Wakelee H, *et al*. ESMO 2025.[1]

- Profile of the perioperative KEYTRUDA regimen (plus chemotherapy) was **consistent with safety profiles of the individual components**, and no new safety signals were seen[2]
- At the 5-year analysis, the addition of KEYTRUDA did not substantially increase the rate of any-grade TRAEs vs placebo[1]
  - Grade 3–5 TRAEs occurred in 45.2% (179/396) of the perioperative KEYTRUDA participants and 37.8% (151/399) of the placebo participants[1]
  - TRAEs led to discontinuation of all treatments in 19.4% (55/396) of participants in the perioperative KEYTRUDA group and 5.3% (21/399) in the placebo group[1]
  - There were 5 TRAE- or imAE-related deaths in the perioperative KEYTRUDA group and 3 in the placebo group[1]

Data cut-off: 3 July 2025. Median follow-up: 60.4 months.[1]
*Immune-mediated AEs and infusion reactions were based on a list of preferred terms intended to capture known risks of KEYTRUDA and were considered regardless of attribution to study treatment by the investigator.[1]
AE, adverse event; imAE, immune-mediated adverse event; TRAE, treatment-related adverse event.
1. Wakelee H, *et al.* Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation. **2.** Spicer J, *et al.* Presented at ESMO 2023; abstract LBA56.

KEYNOTE-671: AE summary in Stage II disease (5-year exploratory analysis)[1]

X

5-year data (Stage II)

AE summary across treatment phases, n (%)	KEYTRUDA (n=118)	Placebo (n=121)
Treatment-related AEs	116 (98.3)	116 (95.9)
Grade 3 or 4	59 (50.0)	49 (40.5)
Serious	23 (19.5)	19 (15.7)
Led to death	0 (0.0)	0 (0.0)
Led to discontinuation of any study treatment	29 (24.6)	19 (15.7)
Immune-mediated AEs and infusion reactions*	34 (28.8)	13 (10.7)
Grade 3 or 4	10 (8.5)	5 (4.1)
Serious	7 (5.9)	5 (4.1)
Led to death	0 (0.0)	0 (0.0)
Led to discontinuation of any study treatment	8 (6.8)	3 (2.5)

Adapted from Weksler B, *et al.* STS 2026.[1]

- In patients with Stage II disease, the addition of KEYTRUDA did not substantially increase the rate of any-grade TRAEs vs placebo[1]
  - Grade 3–5 TRAEs occurred in 50.0% (59/118) of the perioperative KEYTRUDA participants and 40.5% (49/121) of the placebo participants[1]
  - TRAEs led to discontinuation of any study treatment in 24.6% (29/118) of participants in the perioperative KEYTRUDA group and 15.7% (19/121) in the placebo group[1]
  - There were no TRAE- or imAE-related deaths in either group[1]

Data cut-off date for IA3: 3 July 2025. Median follow-up: 58.7 [range, 43.0–85.7] months.[1]
*Immune-mediated AEs and infusion reactions were based on a list of preferred terms intended to capture known risks of KEYTRUDA and were considered regardless of attribution to study treatment by the investigator.[1]
AE, adverse event; imAE, immune-mediated adverse event; TRAE, treatment-related adverse event.
1. Weksler B, *et al.* Presented at STS. 29 January–1 February 2026. New Orleans, USA. Oral presentation.

KEYNOTE-671: AE summary during surgical treatment period in the as-treated population[1]

- **The incidence of all-cause AEs during the surgical treatment phase was the same between treatment groups ~72%:** 71.7% in the KEYTRUDA group vs 72.2% in the placebo group[1]
  - Addition of KEYTRUDA did not substantially increase the rate of high-grade AEs (Δ+4%), serious AEs (Δ+1.5%) or discontinuation due to AEs (Δ+3.3%)[1]
- Overall surgical-phase safety was broadly comparable between treatment groups, with a slight increase in grade 3–5 events in the KEYTRUDA group, **but no new safety signals[1]**

IA2 data	KEYTRUDA (n=325)		Placebo (n=317)	
All AE during the surgical phase, n (%)*	**233 (71.7)**		**229 (72.2)**	
Grade 3–5	83 (25.5)		68 (21.5)	
Serious	60 (18.5)		54 (17.0)	
Led to discontinuation	18 (5.5)		7 (2.2)	
AEs occurring in ≥5% of participants in any treatment group during the surgical phase	**Any Grade**	**Grade 3–5**	**Any Grade**	**Grade 3–5**
Procedural pain	58 (17.8)	5 (1.5)	57 (18.0)	2 (0.6)
Anaemia	48 (14.8))	16 (4.9)	54 (17.0)	16 (5.0)
Dyspnoea	33 (10.2)	3 (0.9)	20 (6.3)	1 (0.3)
Cough	32 (9.8)	0	29 (9.1)	0
Pneumothorax	26 (8.0)	4 (1.2)	28 (8.8)	3 (0.9)
Constipation	21 (6.5)	0	28 (8.8)	1 (0.3)
Incision site pain	21 (6.5)	1 (0.3)	18 (5.7)	0
Chest pain	20 (6.2)	1 (0.3)	12 (3.8)	0
Wound complication	18 (5.5)	0	18 (5.7)	0
Diarrhoea	17 (5.2)	2 (0.6)	4 (1.3)	1 (0.3)
Pleural effusion	16 (4.9)	1 (0.3)	20 (6.3)	5 (1.6)
Pneumonia	15 (4.6)	8 (2.5)	20 (6.3)	8 (2.5)
Productive cough	12 (3.7)	0	18 (5.7)	0
Hypokalaemia	11 (3.4)	3 (0.9)	16 (5.0)	0
Subcutaneous emphysema	8 (2.5)	0	17 (5.4)	1 (0.3)
Atrial fibrillation	6 (1.8)	1 (0.3)	17 (5.4)	3 (0.9)

Adapted from Liberman M, *et al. Ann Thorac Surg* 2026. Supplementary appendix.[1]

Data cut-off: 10 July 2023. Median time from randomisation to surgery: 15.4 weeks.
*Includes all AEs that occurred beginning with the day of in-study surgery until the first dose of in-study radiotherapy or adjuvant KEYTRUDA or placebo, whichever was earlier. In the absence of in-study radiotherapy or adjuvant KEYTRUDA or placebo, AEs were captured for up to 90 days following in-study surgery.
AEs, adverse events; IA2, interim-analyses 2.
1. Liberman M, *et al. Ann Thorac Surg*. 2026;121:281-9 (plus supplementary appendix).

KEYNOTE-671: All-cause mortality within 30 and 90 days of surgery in the surgical population[1]

- **In the overall surgical population, mortality was slightly higher in the KEYTRUDA group at both 30 and 90 days after surgery[1]**
  - 1.8% (6/325) of patients in the KEYTRUDA group vs 0.6% in the placebo group (2/317) within 30 days
  - 4% (13/325) of patients in the KEYTRUDA group vs 1.6% in the placebo group (5/317) within 90 days
- Additionally, participants who underwent pneumonectomy had a higher mortality within 90 days of surgery than participants who underwent lobectomy or bilobectomy:[1]
  - 8.1% for pneumonectomy and 3.5% for lobectomy/bilobectomy with KEYTRUDA vs 2.6% and 1.5%, respectively with placebo
  - Similar mortality rates have been reported in retrospective studies of patients with lung cancer

	KEYTRUDA	Placebo
All participants who underwent surgery	**n=325**	**n=317**
Within 30 days	6 (1.8%)*	2 (0.6%)†
Within 90 days	13 (4.0%)‡	5 (1.6%)§
Participants who underwent lobectomy or bilobectomy	**n=282**	**n=264**
Within 30 days	4 (1.4%)	2 (0.8%)
Within 90 days	10 (3.5%)	4 (1.5%)
Participants who underwent pneumonectomy	**n=37**	**n=39**
Within 30 days	2 (5.4%)‖	0
Within 90 days	3 (8.1%)‖	1 (2.6%)¶

Adapted from Liberman M, *et al. Ann Thorac Surg* 2026. Supplementary appendix.[1]

Data cut-off: 10 July 2023. Median time from randomisation to surgery: 15.4 weeks.[1] *Pulmonary embolism (n=2) and pulmonary haemorrhage due to arterial injury during surgery, pulmonary sepsis, respiratory failure, and septic shock (n=1 each); all attributed to surgery. †Pneumonia and respiratory failure (n=1 each); both attributed to surgery. ‡Additional deaths that occurred from days 31-90: malignant neoplasm progression (n=3) and cardiac arrest, pulmonary haemorrhage, immune-mediated lung disease, and unexplained death (n=1 each); non attributed to surgery; immune-mediated lung disease attributed to study drug. §Additional deaths that occurred from days 31-90: acute respiratory failure, malignant neoplasm progression, and septic shock (n=1 each); non attributed to surgery or study drug. ‖Deaths within 30 days occurred in 1 or 23 participants with a left-sided tumour and 1 of 14 patients with a right-sided tumour; within 90 days, 1 additional participant with a right-sided tumour died. ¶Death occurred in 1 of 24 participants with a right-sided tumour.

1. Liberman M, *et al. Ann Thorac Surg*. 2026;121:281–289 (plus supplementary appendix).

KEYNOTE-671: Summary[1–5]

A key to more possibilities for appropriate patients with resectable NSCLC

Efficacy of KEYTRUDA in KEYNOTE-671[1–4]

- **EFS benefit** in the perioperative KEYTRUDA group was sustained over 3 years.[1–4] KEYTRUDA reduced the relative risk of an event vs placebo by:
  - **43%** in the ITT population (HR: 0.57; 95% CI: 0.41–0.69)[4]
  - **56%** in participants with PD-L1 TPS ≥50% (HR: 0.44; 95% CI: 0.30–0.63)[4]
- The **reduction in relative risk** with KEYTRUDA was also observed regardless of whether participants had a major or complete pathologic response:*[1,2]
  - With pCR HR: 0.33; without pCR HR: 0.69
  - With mPR HR: 0.54; without mPR HR: 0.73
- An **OS benefit** in the perioperative KEYTRUDA group was observed.[3] KEYTRUDA reduced the relative risk of death vs placebo by:
  - **28%** in the ITT population (HR: 0.72; 95% CI: 0.56–0.93)[3]
- Positive trends in the data suggest that this benefit was sustained over 3 years[3]

At the 5-year exploratory analysis[5]

- **Median follow-up time: 60.4 months**
  - **OS r**ates were 64.6% with KEYTRUDA vs 53.6% with placebo (HR=0.74; 95% CI, 0.59–0.92)
  - **EFS** rates were 49.9% with KEYTRUDA vs 26.5% with placebo (HR=0.58; 95% CI, 0.48–0.69)

No conclusions can be drawn from exploratory analyses. *Exploratory analysis from IA1 was not updated at IA2, as the updated EFS in the ITT was consistent with IA1.[2,3] The possibility that both the neoadjuvant and adjuvant treatment phases contributed to the overall benefit cannot be eliminated.

CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; OS, overall survival; mPR, major pathologic response; pCR, pathological complete response.

1. Wakelee H, *et al*. ASCO. 2–6 June 2023. Chicago, IL, USA. Abstract: LBA100. **2.** Wakelee H, *et al. N Engl J Med* 2023;389:491–503. **3.** Spicer JB, *et al.* ESMO. 20–24 October 2023. Madrid, Spain. Abstract: LBA56. **4.** Majem M, *et al.* Presented at ESMO I-O 2024. 11–13 December 2024. Geneva, Switzerland. Abstract LBA3. **5.** Wakelee H, *et al.* Presented at ESMO. 17–21 October 2025. Berlin, Germany. Oral presentation.

KEYNOTE-671: Summary[1–5]

A key to more possibilities for appropriate patients with resectable NSCLC

Safety profile of KEYTRUDA in KEYNOTE-671

After 60.4 months median follow-up, no new safety signals were identified[1–4]

- Grade 3–5 treatment-related adverse events were seen in 45.2% of those treated with KEYTRUDA vs 37.8% who received placebo[4]
- The safety of KEYTRUDA as monotherapy has been evaluated in 7631 patients across tumour types in clinical studies. The most frequent adverse reactions with KEYTRUDA were fatigue (31%), diarrhoea (22%) and nausea (20%)[5]

No conclusions can be drawn from exploratory analyses. *Exploratory analysis from IA1 was not updated at IA2, as the updated EFS in the ITT was consistent with IA1.[2,3] The possibility that both the neoadjuvant and adjuvant treatment phases contributed to the overall benefit cannot be eliminated.

CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; OS, overall survival; mPR, major pathologic response; pCR, pathological complete response.

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KEYTRUDA offers flexibility of dosing[1]



Administered as an IV infusion



Over 30 minutes



200 mg Q3W or 400 mg Q6W

Assessment of regimens

The 200 mg Q3W (once every 3 weeks) regimen has been assessed in Phase II and III registration studies across a multitude of indications of KEYTRUDA. An exposure-response evaluation, using modelling and simulation, led to the approval of the 400 mg Q6W (once every 6 weeks) dosing for monotherapy and combination therapy.[1]

IV, intravenous; Q3W, every 3 weeks; Q6W, every 6 weeks.

1. KEYTRUDA Summary of Product Characteristics. MSD. Available at: https://www.medicines.org.uk/emc/product/2498. Accessed: August 2026.