

NSCLC CLINICAL TRIAL SUMMARIES

KEYTRUDA[®] (pembrolizumab) is a Prescription Medicine and is available as a 100 mg/4 mL concentrate for solution for infusion.

Please review the KEYTRUDA Data Sheet before prescribing. The Data Sheet is available at www.medsafe.govt.nz.

INDICATIONS: In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic non-squamous non-small cell lung carcinoma (NSCLC), with no EGFR or ALK genomic tumour aberrations. In combination with carboplatin and either paclitaxel or nab-paclitaxel for first-line treatment of metastatic squamous NSCLC. As monotherapy for first-line treatment of patients with NSCLC whose tumours express PD-L1 [tumour proportion score (TPS) $\geq 1\%$] as determined by a validated test, with no EGFR or ALK genomic tumour aberrations and are either; metastatic, or stage III where patients are not candidates for surgical resection or definitive chemoradiation. As monotherapy for the treatment of patients with advanced NSCLC with a PD-L1 TPS level $\geq 1\%$ as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA. As monotherapy for the adjuvant treatment of patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC who have undergone complete resection. See Data Sheet for other indications.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the Data Sheet. See Data Sheet for further information.

PRECAUTIONS: Severe and fatal cases of immune-mediated adverse reactions have occurred. Immune-related adverse reactions have occurred after discontinuation of treatment with KEYTRUDA and can affect more than one body system simultaneously. For management of immune-mediated adverse reactions, see Data Sheet. Immune-mediated adverse reactions have occurred as follows: pneumonitis (including fatal cases), colitis, hepatitis, nephritis, adrenal insufficiency, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis, severe skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis [including fatal cases], bullous pemphigoid), uveitis, myositis, Guillain-Barre syndrome, pancreatitis, encephalitis, sarcoidosis, myasthenic syndrome/myasthenia gravis (including exacerbation), myelitis, vasculitis, hypoparathyroidism, gastritis, haemolytic anaemia, pericarditis, myocarditis, sclerosing cholangitis, exocrine pancreatic insufficiency, solid organ transplant rejection, acute graft-versus-host-disease (GVHD) including fatal GVHD with a history of allogeneic hematopoietic stem cell transplantation, higher than expected frequencies of Grades 3 and 4 ALT and AST elevations in advanced RCC when used in combination with axitinib, increased mortality when in combination with dexamethasone and a thalidomide analogue in multiple myeloma (not indicated), severe infusion reactions including hypersensitivity and anaphylaxis. Monitor thyroid and liver function. Limited data in patients with active infections and with history of severe adverse reaction to ipilimumab – use caution. No data in severe renal impairment, or moderate or severe hepatic impairment. Pregnancy (Category D). See Data Sheet for further information.

INTERACTIONS: None expected. Avoid systemic corticosteroids or immunosuppressants prior to treatment (except as premedication in combination with chemotherapy).

ADVERSE EVENTS: Monotherapy: pneumonitis, colitis, diarrhoea, pyrexia, fatigue, pruritus, rash, nausea, hypothyroidism, hyperthyroidism, adrenal insufficiency, hepatitis, hypophysitis, nephritis, type 1 diabetes mellitus, arthralgia, cough, back pain, vitiligo, lymphopenia, hypertriglyceridemia, abdominal pain, hyponatremia, hyperglycaemia, hypoalbuminemia, increased AST and ALP, anaemia, dyspnoea, constipation, increased lipase; Combination (where not already listed under Monotherapy) with chemotherapy: alopecia, asthenia, decreased neutrophil count, neutropenia, thrombocytopenia, mucosal inflammation, stomatitis, vomiting, decreased white blood cell count, decreased appetite, decreased platelet count. See Data Sheet for further information.

DOSAGE AND ADMINISTRATION: Adults: 200 mg every 3 weeks or 400 mg every 6 weeks. Paediatrics (see Indications): 2 mg/kg (up to 200 mg) every 3 weeks. Administered as an intravenous infusion over 30 minutes. For use in combination, please review the Data Sheets for KEYTRUDA and the relevant concomitant therapies. KEYTRUDA should be administered first when given in combination with intravenous chemotherapy. Treat with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e. an initial transient increase in tumour size or small new lesions followed by shrinkage) have been observed. Clinically stable patients (i.e. asymptomatic and not requiring urgent intervention) with initial evidence of progression can remain on treatment until confirmed. For the adjuvant treatment of NSCLC, treat with KEYTRUDA for up to one year or until disease recurrence or unacceptable toxicity. See Data Sheet for further information. (v54.02)

KEYTRUDA is funded for the first-line treatment of patients with advanced or metastatic NSCLC. Further restrictions apply, see pharmac.govt.nz.¹

KEYTRUDA is unfunded for the other NSCLC indications - a charge will apply.



KEYTRUDA evidence and experience in advanced and mNSCLC

KEYTRUDA has been available in Aotearoa New Zealand for patients with certain types of advanced and metastatic NSCLC for >8 years, and has been extensively studied in four Phase 3, first-line trials.^{2,3}

Each of these trials has outcome data at **~5 years of median follow-up** (see following pages for details).^{2,4-11}

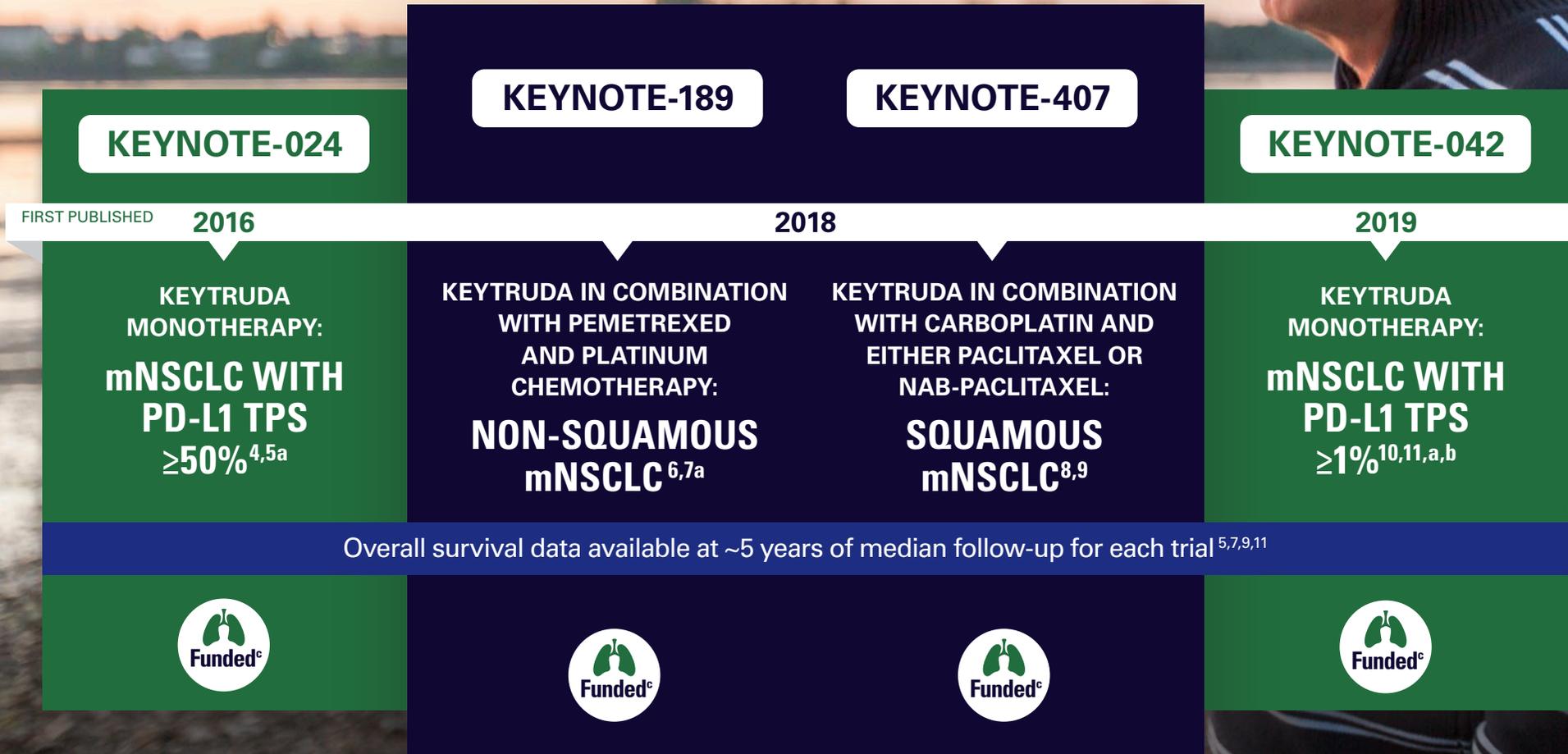


**5-YEAR
FOLLOW-UP
DATA**



A legacy of evidence and experience in advanced and metastatic NSCLC

KEYTRUDA has been available in Aotearoa New Zealand for patients with certain types of advanced or metastatic NSCLC for >8 years, and has been extensively studied in four Phase 3, first-line trials.^{2,3}



a. In patients with tumours with no EGFR or ALK genomic tumour aberrations.

b. KEYNOTE-042 also included Stage III patients who were not candidates for surgical resection or definitive chemoradiation.

c. Restrictions apply.¹

KEYNOTE-024^{2,4,5}



Study Design

KEYNOTE-024 was a multicentre, randomised, controlled trial of previously untreated patients with metastatic NSCLC whose tumours expressed PD-L1 with TPS $\geq 50\%$.²

Patients were randomised (1:1) to one of the following regimens:

- i) KEYTRUDA 200 mg every 3 weeks (n=154).²
- ii) investigator's choice platinum-containing chemotherapy (n=151; including pemetrexed + carboplatin, pemetrexed + cisplatin, gemcitabine + cisplatin, gemcitabine + carboplatin, or paclitaxel + carboplatin).²

Treatment with KEYTRUDA continued until disease progression or unacceptable toxicity.⁴

The primary efficacy outcome measure was progression-free survival (PFS) as assessed by blinded independent central review (BICR) using RECIST v1.1. The secondary efficacy outcome measures were overall survival (OS) and objective response rate (ORR) as assessed by BICR using RECIST v1.1.²



Selected Baseline Characteristics²

Characteristics	N=305
Median age, years	65
Age ≥ 65 years	54%
Male	61%
Ethnicity	
White	82%
Asian	15%
ECOG PS	
0	35%
1	65%
Disease subtype	
Squamous	18%
Non-squamous	82%
M1	99%
Brain metastases	9%

KEYNOTE-024

mNSCLC WITH PD-L1 TPS \geq 50% IN PATIENTS WITH NO EGFR OR ALK GENOMIC TUMOUR ABERRATIONS
Overall survival data available at ~5 years of median follow-up^{2,4,5}

Results	KEYTRUDA (n=154)	Platinum-containing chemotherapy (n=151)
PFS		
Primary analysis (median follow-up of 11.2 months)^{2,4}		
Number of events (%)	73 (47%)	116 (77%)
Median PFS (95% CI)	10.3 months (6.7–NA)	6.0 months (4.2–6.2)
HR (95% CI), p-value	0.50 (0.37–0.68), p<0.001	
OS (secondary endpoint)		
Primary analysis (median follow-up of 11.2 months)^{2,4}		
Number of events (%)	44 (29%)	64 (42%)
Median OS (95% CI)	Not reached (NA–NA)	Not reached (9.4 months–NA)
HR (95% CI), p-value	0.60 (0.41–0.89), p=0.005	
Post hoc exploratory analysis (median follow-up of 59.9 months)⁵		
LIMITATION: No formal statistical testing was planned for this analysis, therefore no statistical conclusions can be made.		
Number of events (%)	103 (67%)	123 (82%)
HR (95% CI)	0.62 (0.48–0.81)	

Safety Profile

Treatment-related adverse events (TRAEs) at exploratory analysis (median follow-up of 59.9 months)⁵		
TRAEs (any Grade) (%)	118 (77%)	135/150 (90%)
TRAEs (Grades 3-5) (%)	48 (31%)	80/150 (53%)
Immune-mediated adverse events (imAEs) at exploratory analysis (median follow-up of 59.9 months)⁵		
imAEs and infusion reactions (any Grade) (%)	53 (34%)	8 (5%)
imAEs and infusion reactions (Grade 3-5) (%)	21 (14%)	1 (<1%)

TRAEs led to death in 2 patients (1.3%) in the KEYTRUDA group (pneumonitis, n=1; sudden death, n=1).⁵

imAEs and infusion reactions (>1%, any grade) in the KEYTRUDA group included: hypothyroidism, pneumonitis, hyperthyroidism, infusion reactions, colitis, severe skin toxicity, thyroiditis, myositis and hepatitis.⁵ **Grade 3–5 imAEs and infusion reactions (>1%)** included severe skin toxicity, pneumonitis, colitis and hepatitis.⁵

KEYNOTE-189^{2,6,7}



Study Design

KEYNOTE-189 was a multicentre, randomised, active-controlled, double-blind trial of KEYTRUDA in combination with pemetrexed and platinum chemotherapy. Key eligibility criteria were metastatic non-squamous NSCLC, no prior systemic treatment for metastatic NSCLC, and no EGFR or ALK genomic tumour aberrations.²

Patients with autoimmune disease that required systemic therapy within 2 years of treatment; a medical condition that required immunosuppression; or who had received more than 30 Gy of thoracic radiation within the prior 26 weeks were ineligible.²

Patients were randomised (2:1) to receive one of the following regimens:

- i) KEYTRUDA 200 mg with pemetrexed 500 mg/m² and investigator's choice of cisplatin 75 mg/m² or carboplatin AUC 5 mg/mL/min intravenously every 3 weeks for 4 cycles followed by KEYTRUDA 200 mg and pemetrexed 500 mg/m² intravenously every 3 weeks (n=410).²
- ii) Placebo with pemetrexed 500 mg/m² and investigator's choice of cisplatin 75 mg/m² or carboplatin AUC 5 mg/mL/min intravenously every 3 weeks for 4 cycles followed by placebo and pemetrexed 500 mg/m² intravenously every 3 weeks (n=206).²

Treatment with KEYTRUDA continued until RECIST 1.1-defined progression of disease as determined by the investigator, unacceptable toxicity, or a maximum of 24 months. The primary efficacy outcome measures were OS and PFS (as assessed by BICR using RECIST v1.1).²



Selected Baseline Characteristics²

Characteristics	N=616
Median age, years	64
Age ≥65 years	49%
Male	59%
Ethnicity	
White	94%
Asian	3%
ECOG PS	
0	43%
1	56%
PD-L1 expression status ⁶	
TPS <1%	31%
Brain metastases	18%

KEYNOTE-189

FIRST-LINE NON-SQUAMOUS mNSCLC WITH NO EGFR OR ALK GENOMIC TUMOUR ABERRATIONS WITH OR WITHOUT PD-L1 EXPRESSION

Overall survival data available at ~5 years of median follow-up^{2,6,7}

Results	KEYTRUDA + plat-pem (n=410)	Placebo + plat-pem (n=206)
PFS		
Primary analysis (median follow-up of 10.5 months)^{2,6}		
Number of events (%)	245 (60%)	166 (81%)
Median PFS (95% CI)	8.8 months (7.6–9.2)	4.9 months (4.7–5.5)
HR (95% CI), p-value	0.52 (0.43–0.64), p<0.00001	
OS		
Primary analysis (median follow-up of 10.5 months)^{2,6}		
Number of events (%)	127 (31%)	108 (52%)
Median OS (95% CI)	Not reached (NA–NA)	11.3 months (8.7–15.1)
HR (95% CI), p-value	0.49 (0.38–0.64), p<0.00001	
Exploratory analysis (median follow-up of 64.6 months)⁷		
LIMITATION: No formal statistical testing was planned for this analysis, therefore no statistical conclusions can be made.		
Number of events (%)	329 (80%)	183 (89%)
Median OS (95% CI)	22.0 months (19.5–24.5)	10.6 months (8.7–13.6)
HR (95% CI)	0.60 (0.50–0.72)	

Safety Profile

Treatment-related adverse events (TRAEs) at exploratory analysis (median follow-up of 64.6 months)⁷

TRAEs (any Grade) (%)	377/405 (93%)	183/202 (91%)
TRAEs (Grades 3-5) (%)	212/405 (52%)	85/202 (42%)

Immune-mediated adverse events (imAEs) at exploratory analysis (median follow-up of 64.6 months)⁷

imAEs and infusion reactions (any Grade) (%)	113/405 (28%)	27/202 (13%)
imAEs and infusion reactions (Grade 3-5) (%)	52/405 (13%)	9/202 (5%)

TRAEs led to death in 8 patients (2.0%) in the KEYTRUDA + plat-pem group (acute kidney injury, n=2; pneumonitis, n=2; death (unknown cause), encephalopathy, neutropenic sepsis, and pneumonia, n=1 each).^{7,12}

imAEs and infusion reactions (>1%, any grade) in the KEYTRUDA + plat-pem group included: hypothyroidism, pneumonitis, hyperthyroidism, colitis, infusion reactions, severe skin reactions, nephritis, and hepatitis.⁷ Grade 3–5 imAEs and infusion reactions (>1%) included pneumonitis, severe skin reactions, colitis, nephritis, and hepatitis.⁷

KEYNOTE-407^{2,8,9}

Study Design



KEYNOTE-407 was a randomised, double-blind, multicentre, placebo-controlled study of KEYTRUDA in combination with carboplatin and either paclitaxel or nab-paclitaxel. The key eligibility criteria for this study were metastatic squamous NSCLC, regardless of tumour PD-L1 expression status, and no prior systemic treatment for metastatic disease. Patients with autoimmune disease that required systemic therapy within 2 years of treatment; a medical condition that required immunosuppression; or who had received more than 30 Gy of thoracic radiation within the prior 26 weeks were ineligible.²

Patients were randomised (1:1) to one of the following regimens:

- i) KEYTRUDA 200 mg and carboplatin AUC 6 mg/mL/min on Day 1 of each 21-day cycle for 4 cycles, and paclitaxel 200 mg/m² on Day 1 of each 21-day cycle for 4 cycles or nab-paclitaxel 100 mg/m² on Days 1, 8 and 15 of each 21-day cycle for 4 cycles, followed by KEYTRUDA 200 mg every 3 weeks. KEYTRUDA was administered prior to chemotherapy on Day 1 (n=278).²
- ii) Placebo and carboplatin AUC 6 mg/mL/min on Day 1 of each 21-day cycle for 4 cycles and paclitaxel 200 mg/m² on Day 1 of each 21-day cycle for 4 cycles or nab-paclitaxel 100 mg/m² on Days 1, 8 and 15 of each 21-day cycle for 4 cycles, followed by placebo every 3 weeks (n=281).²

Treatment with KEYTRUDA or placebo continued until RECIST 1.1-defined progression of disease as determined by BICR, unacceptable toxicity, or a maximum of 24 months. The major efficacy outcome measures were PFS and ORR as assessed by BICR using RECIST v1.1 and OS.²

Selected Baseline Characteristics²



Characteristics	N=559
Median age, years	65
Age ≥65 years	55%
Male	81%
White	77%
ECOG PS	
0	29%
1	71%
Brain metastases	8%
PD-L1 expression status ⁸	
TPS <1%	35%
Location ⁸	
East Asia	19%
Rest of world	81%
Received paclitaxel	60%

KEYNOTE-407

FIRST-LINE SQUAMOUS mNSCLC WITH OR WITHOUT PD-L1 EXPRESSION

Overall survival data available at ~5 years of median follow-up^{2,8,9}

Results	KEYTRUDA + carbo + pac/nab-pac (n=278)	Placebo + carbo + pac/nab-pac (n=281)
PFS		
Primary analysis (median follow-up of 7.8 months) ^{2,8}		
Number of events (%)	152 (55%)	197 (70%)
Median PFS (95% CI)	6.4 months (6.2–8.3)	4.8 months (4.2–5.7)
HR (95% CI), p-value	0.56 (0.45–0.70), p<0.0001	
OS		
Primary analysis (median follow-up of 7.8 months) ^{2,8}		
Number of events (%)	85 (31%)	120 (43%)
Median OS (95% CI)	15.9 months (13.2–NA)	11.3 months (9.5–14.8)
HR (95% CI), p-value	0.64 (0.49–0.85), p=0.0008	
Exploratory analysis (median follow-up of 56.9 months) ⁹		
LIMITATION: No formal statistical testing was planned for this analysis, therefore no statistical conclusions can be made.		
Number of events (%)	225 (81%)	248 (88%)
Median OS (95% CI)	17.2 months (14.4–19.7)	11.6 months (10.1–13.7)
HR (95% CI)	0.71 (0.59–0.85)	

Safety Profile

Treatment-related adverse events (TRAEs) at exploratory analysis (median follow-up of 56.9 months) ⁹		
TRAEs (any Grade) (%)	266 (96%)	252/280 (90%)
TRAEs (Grades 3-5) (%)	159 (57%)	156/280 (56%)
Immune-mediated adverse events (imAEs) at exploratory analysis (median follow-up of 56.9 months) ⁹		
imAEs and infusion reactions (any Grade) (%)	99 (36%)	26/280 (9%)
imAEs and infusion reactions (Grade 3-5) (%)	37 (13%)	9/280 (3%)

TRAEs led to death in 12 patients (4.3%) in the KEYTRUDA + carbo + pac/nab-pac group (sepsis, n=3; death (cause not specified), n=2; cardiac arrest, cardiac failure, hepatic failure, necrotising fasciitis, pneumonitis, pulmonary haemorrhage, and respiratory failure, n=1 each).⁹

imAEs and infusion reactions (>1%, any grade) with KEYTRUDA + carbo + pac/nab-pac included: hypothyroidism, pneumonitis, hyperthyroidism, infusion reactions, colitis, hepatitis, severe skin reactions, hypophysitis, and thyroiditis.⁹

KEYNOTE-042^{2,10,11}



Study Design

KEYNOTE-042 was a multicentre, randomised, controlled trial conducted in 1274 patients with Stage III NSCLC who were not candidates for surgical resection or definitive chemoradiation, or patients with metastatic NSCLC. Only patients whose tumours expressed PD-L1 TPS $\geq 1\%$ and who had not received prior systemic treatment for metastatic NSCLC were eligible. Patients with EGFR or ALK genomic tumour aberrations; autoimmune disease that required systemic therapy within 2 years of treatment; a medical condition that required immunosuppression; or who had received more than 30 Gy of thoracic radiation within the prior 26 weeks were ineligible.²

Patients were randomised (1:1) to one of the following regimens:

- i) KEYTRUDA 200 mg every 3 weeks (n=637).²
- ii) Investigator's choice platinum-containing chemotherapy (n=637; including pemetrexed + carboplatin^a or paclitaxel + carboplatin.^a Patients with non-squamous NSCLC could receive pemetrexed maintenance).²

Patients were treated with KEYTRUDA until unacceptable toxicity or disease progression. Patients without disease progression could be treated for up to 24 months.²

The primary efficacy outcome measure was OS.²

a. Dosing of chemotherapy agents may not be consistent with the New Zealand Data Sheet. Please consult each Data Sheet before prescribing.



Selected Baseline Characteristics²

Characteristics	N=1,274
Median age, years	63
Age ≥ 65 years	45%
Male	71%
Ethnicity	
White	64%
Asian	30%
Hispanic/Latino	19%
ECOG PS	
0	31%
1	69%
Disease subtype	
Squamous	39%
Non-squamous	61%
Metastatic status	
M0	13%
M1	87%
Brain metastases	6%
PD-L1 expression status	
TPS 1–49%	53%
TPS $\geq 50\%$	47%

KEYNOTE-042

IN PATIENTS WITH STAGE III NSCLC WHO WERE NOT CANDIDATES FOR SURGICAL RESECTION OR DEFINITIVE CHEMORADIATION, OR mNSCLC, WITH PD-L1 TPS $\geq 1\%$ AND NO EGFR OR ALK GENOMIC TUMOUR ABERRATIONS
Overall survival data available at ~5 years of median follow-up^{2,10,11}

Results (PD-L1 TPS $\geq 1\%$)	KEYTRUDA (n=637)	Platinum-based chemotherapy (n=637)
OS		
Primary analysis (median follow-up of 12.8 months)^{2,10}		
Number of events (%)	371 (58%)	438 (69%)
HR (95% CI), p-value	0.81 (0.71–0.93), p=0.002	
Exploratory analysis (median follow-up of 61.1 months)¹¹		
LIMITATION: No formal statistical testing was planned for this analysis, therefore no statistical conclusions can be made.		
Number of events (%)	530 (83%)	575 (90%)
HR (95% CI)	0.79 (0.70–0.89)	

Safety Profile

Treatment-related adverse events (TRAEs) at exploratory analysis (median follow-up of 61.1 months)¹¹		
TRAEs (any Grade) (%)	406/636 (64%)	555/615 (90%)
TRAEs (Grades 3-5) (%)	120/636 (19%)	257/615 (42%)
Immune-mediated adverse events (imAEs) at exploratory analysis (median follow-up of 61.1 months)^{11,a}		
imAEs and infusion reactions (any Grade) (%)	175/636 (28%)	47/615 (8%)
imAEs and infusion reactions (Grade 3-5) (%)	52/636 (8%)	9/615 (2%)

TRAEs led to death in 13 patients (2.0%) in the KEYTRUDA group (cardiac failure acute, death not otherwise specified, encephalopathy, haemoptysis, hypovolaemic shock, ileus, klebsiella infection, malignant neoplasm progression, pneumonitis, pulmonary embolism, respiratory failure, sepsis, and sudden death (all n=1)).^{10,11}

imAEs and infusion reactions (>1%, any Grade) in the KEYTRUDA group included: hypothyroidism, pneumonitis, hyperthyroidism, severe skin reactions, thyroiditis, hepatitis, infusion reactions, colitis.¹¹

Grade 3–5 imAEs and infusion reactions (>1%) in the KEYTRUDA group included pneumonitis, severe skin reactions and hepatitis.¹¹

DOSING AND SPECIAL POPULATIONS

KEYTRUDA RECOMMENDED DOSING IN ADVANCED AND mNSCLC²



OR



As an IV infusion over 30 minutes²

- For use in combination, see the Data Sheet for the concomitant therapies. When administering KEYTRUDA as part of a combination with intravenous chemotherapy, KEYTRUDA should be administered first.²
- Patients with NSCLC should be treated with KEYTRUDA until disease progression or unacceptable toxicity, or for up to 24 months.²
- Atypical responses (i.e. an initial transient increase in tumour size or small new lesions followed by shrinkage) have been observed. Clinically stable patients (i.e. asymptomatic and not requiring urgent intervention) with initial evidence of progression can remain on treatment until confirmed. **See Data Sheet for further information.²**

SPECIAL POPULATIONS

Renal insufficiency

No dose adjustment is needed for patients with mild or moderate renal impairment. KEYTRUDA has not been studied in patients with severe renal impairment.²

Hepatic insufficiency

No dose adjustment is needed for patients with mild hepatic impairment. KEYTRUDA has not been studied in patients with moderate or severe hepatic impairment.²

Elderly

No overall differences in safety or efficacy were reported between elderly patients (65 years and over) and younger patients (less than 65 years). No dose adjustment is necessary in this population.²

Withhold or discontinue KEYTRUDA to manage adverse reactions as described in the Data Sheet.²

ALK: anaplastic lymphoma kinase; **AUC:** area under the curve; **BICR:** blinded independent central review; **carbo:** carboplatin; **CI:** confidence interval; **ECOG PS:** Eastern Cooperative Oncology Group Performance Status; **EGFR:** epidermal growth factor receptor; **HR:** hazard ratio; **imAEs:** immune-mediated adverse events; **mNSCLC:** metastatic non-small cell lung cancer; **nab-pac:** nab-paclitaxel; **NSCLC:** non-small cell lung cancer; **ORR:** objective response rate; **OS:** overall survival; **pac:** paclitaxel; **PD-L1:** programmed death ligand 1; **pem:** pemetrexed; **PFS:** progression-free survival; **PK:** pharmacokinetic; **plat:** platinum therapy (carboplatin or cisplatin); **Q3W:** every 3 weeks; **Q6W:** every 6 weeks; **RECIST:** response evaluation criteria in solid tumours; **TPS:** tumour proportion score; **TRAEs:** treatment-related adverse events.

References: **1.** PHARMAC. Pharmaceutical Schedule. Available at: <https://schedule.pharmac.govt.nz/ScheduleOnline.php?edition=&osq=pembrolizumab> Accessed: 27 May 2025. **2.** KEYTRUDA Data Sheet. **3.** Data on file. **4.** Reck M *et al.* *N Engl J Med* 2016;375(19):1823–1833. **5.** Reck M *et al.* *J Clin Oncol* 2021;39(21):2339–2349. **6.** Gandhi L *et al.* *N Engl J Med* 2018;378(22):2078–2092. **7.** Garassino MC *et al.* *J Clin Oncol* 2023;41(11):1992–1998. **8.** Paz-Ares L *et al.* *N Engl J Med* 2018;379:2040–2051. **9.** Novello S *et al.* *J Clin Oncol* 2023;41(11):1999–2006. **10.** Mok TSK *et al.* *Lancet* 2019;393(10183):1819–1830. **11.** de Castro G Jr *et al.* *J Clin Oncol* 2023;41(11):1986–1991 and Data Supplement. **12.** Rodríguez-Abreu D *et al.* *Ann Oncol* 2021;32(7):881–895.