18 April 2025

The Secretary
Expert Committee on the Selection and Use of
Essential Medicines

Letter to the 2025 WHO Expert Committee on the Selection and Use of essential medicines regarding Application 22: PD-1/PD-L1 immune checkpoint inhibitors – multiple cancers

Dear WHO Expert Committee on the Selection & Use of Essential Medicines:

BeOne is a global oncology company that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide. As part of this mission, BeOne supports global health organisations, who strive to achieve the highest possible level of health for everyone.

Tislelizumab (Tevimbra®) is a PD-1 inhibitor and is in the same ATC category (L01FF PD/PD-L1 inhibitors) as nivolumab and pembrolizumab. It is given as an intravenous infusion and has now received regulatory approval in various countries across a range of indications (refer to Table 1 for a summary of approvals in 1L NSCLC). It is in this capacity that we provide commentary on Application A.22 PD-1/PD-L1 for the 25th Expert Committee review of the Model List of Essential Medicines with a focus on two indications in which Tislelizumab has been studied: Non-Small Cell Lung Cancer (NSCLC) and Oesophageal Squamous Cell Carcinoma (OSCC).

BeOne appreciates the opportunity to provide commentary on this submission and the committee's consideration of including tislelizumab as a relevant immune checkpoint inhibitor (ICI) for the first-line treatment of palliative NSCLC.

Rationale for Consideration of Tislelizumab

The original searches conducted for the A.22 application were conducted in July 2024 with updated searches conducted in January 2025.

According to the prioritisation framework developed by the authors of A.22, the following factors were required for inclusion as an intervention in A.22:

- European Medicines Agency (EMA) approval as a first-line palliative treatment, with evidence from RCTs, and

- ESMO Magnitude of Clinical Benefit Score (ESMO-MCBS) of 4 or 5.

Tislelizumab for NSCLC

Tislelizumab received EMA approval for the first-line palliative treatment of non-squamous and squamous NSCLC in April 2024.[1] ESMO-MCBS scores of 4 were assigned to these indications based on RCT data from the trial RATIONALE-304 and RATIONALE-307 (in combination with carboplatin + paclitaxel, noting the Tislelizumab + Carboplatin + nab-paclitaxel arm received an ESMO MCBS score of 3) in March 2024 and July 2024 respectively.[2] [3] However, the ESMO-MCBS was only updated with this information in November 2024, which was after the initial search date for the A.22 review.

According to the authors, the updated search results in January 2025 noted the following:

"Since our initial search of the EMA register, three additional ICI-based combination regimens were approved and, according to our predefined criteria, would have qualified for further review, considering an ESMO-MCBS of 4 or higher. These include approvals for tislelizumab together with a platinum-based doublet in squamous and non-squamous cell NSCLC …" (p.37).

Based on these recent updates, tislelizumab meets the requirements for consideration as an intervention for 1L NSCLC alongside the other technologies included in A.22. Notably, tislelizumab as a monotherapy treatment also has data to support its clinical efficacy and safety compared to chemotherapy (docetaxel) in the second-line NSCLC setting.[4]

Global Regulatory Approvals of Tislelizumab

The global TEVIMBRA clinical development program includes almost 14,000 patients enrolled to date in 35 counties and regions across 70 trials, including 21 registration-enabling studies. Tislelizumab has now received regulatory approvals in 45 countries worldwide, with funded access expanding across multiple markets and more than 1.3 million patients have been treated globally.

Below is an updated summary of regulatory approvals from key agencies in the first-line NSCLC setting.

Table 1: Approval from key regulatory agencies in 1L NSCLC

Regulatory Agency	Approved Indications	Approval Date
European Medicines Agency (EMA, Europe)	Tevimbra in combination with pemetrexed and platinum-containing chemotherapy is indicated for the first-line treatment of adult patients with non-squamous NSCLC whose tumours have PD-L1 expression on ≥50% of tumour cells with no EGFR or ALK positive mutations and who have:	22-Apr-24

[1] Tevimbra (tislelizumab). European Medicines Agency.
[2] Tislelizumab. RATIONALE-304. ESMO-MCBS Scorecards
[3] Tislelizumab. RATIONALE-307. ESMO-MCBS Scorecards
[4] Tislelizumab. RATIONALE-303. ESMO-MCBS Scorecards

	• locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC. Tevimbra in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of adult patients with squamous NSCLC who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC.	
Medicines & Healthcare products Regulatory Agency (MHRA, United Kingdom)	Tevimbra in combination with pemetrexed and platinum-containing chemotherapy is indicated for the first-line treatment of adult patients with non-squamous NSCLC whose tumours have PD-L1 expression on ≥ 50% of tumour cells with no EGFR or ALK positive mutations and who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC. Tevimbra in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of adult patients with squamous NSCLC who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC.	28-Oct-24
Therapeutic Good Administration (TGA, Australia)	Tevimbra in combination with pemetrexed and platinum containing chemotherapy is indicated for the first-line treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC), with PD-L1 expression ≥ 50% but no epidermal growth factor	30-May-24

	receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations. Tevimbra in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of patients with locally advanced or metastatic squamous NSCLC.	

1L: first-line, 2L: second-line, sq: squamous, nsq: non-squamous

We have presented a summary of the evidence since the previous application for tislelizumab in NSCLC for the 24th Expert Committee review in 2023 in the Appendix, Table 2, along with the references for key trial publications. We would also like to highlight that tislelizumab has been recommended in the January 2025 ESMO Non-Oncogene-Addicted Metastatic NSCLC Living Guideline as a first-line palliative treatment for both squamous and non-squamous NSCLC.[1,2]

Tislelizumab for OSCC

A separate application was made by BeOne for the use of tislelizumab for the first- and second-line palliative treatment of OSCC (A.27 Tislelizumab for the first- and second-line treatment of adults with unresectable, locally advanced, recurrent or metastatic OSCC). Tislelizumab has been recommended in the February 2025 ESMO Clinical Practice Guideline interim update on the treatment of locally advanced oesophageal and oesophagogastric junction adenocarcinoma and metastatic squamous cell carcinoma.[3]

Conclusion

With a geographically diverse, state-of-the-art supply chain and manufacturing facilities operating under GMP standards from the U.S. FDA, China's NMPA, and Europe's EMA, BeOne is positioned to provide broad access for middle- and low-income countries, ensuring that more patients worldwide benefit from our high-quality, life-changing treatments. Furthermore, BeOne remains committed to advancing equitable access to cancer care through strategic collaborations, such as the Access to Oncology Medicines (ATOM) Coalition and the City Cancer Challenge. These initiatives are instrumental in addressing critical gaps in the foundational elements of cancer care and immuno-oncology.

We appreciate your consideration of BeOne's submissions to the EML, as well as our insights into submissions from other organisations. We look forward to continued engagement in support of our shared mission to improve outcomes for cancer patients worldwide.

Sincerely,

Dr Megan Bohensky, MPH PhD
Head of Market Access, JAPAC Region
Global Value Access & Pricing
BeOne Medicines

Appendix

Table 2. Updated evidence of tislelizumab as 1L treatment for NSCLC since 2023

Article Title (year)	Brief Summary of Findings
RATIONALE-307 – Trial Evidence by End Point (Risk of Bias Assessment in Table 3)	
Overall survival	
Randomized phase III study of tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for advanced squamous non-small cell lung cancer (sq-NSCLC): RATIONALE-307 updated analysis[29] (2024) RATIONALE-307 long-term outcomes: First-line tislelizumab (TIS) plus chemotherapy (chemo) vs chemo alone for advanced squamous (sq) NSCLC[30] (2024)	• Tislelizumab-carboplatin-paclitaxel demonstrated a statistically significant improvement in median OS compared to the chemotherapy arm as of the July 15, 2022 cut-off date in the RATIONALE-307 trial (26.1 vs 19.4 months, HR: 0.69 [95% CI, 0.5-0.95], p=NR).[29] • The same outcome was observed as of the latest cut-off date, April 18, 2023, with a HR of 0.67 (95% CI, 0.49-0.92), p=NR.[30]
Progression-free survival	
Randomized phase III study of tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for advanced squamous non-small cell lung cancer (sq-NSCLC): RATIONALE-307 updated analysis[29] (2022) RATIONALE-307 Long-term Outcomes: First-line Tislelizumab (TIS) Plus Chemotherapy (chemo) vs Chemo Alone for Advanced Squamous (sq) NSCLC[30] (2024)	• In an updated data cut-off (30 September 2020), Independent review committee (IRC) assessed median PFS showed significant improvement in the intervention arms compared to the chemotherapy arm with HR of 0.45 and 0.43, respectively.[29] • On the most recent cut-off date of April 18, 2023, the RATIONALE 307 trial showed a slight change in the median PFS and HR. However, the results remained statistically significant, consistent with previous cut-off dates (tislelizumab-carboplatin-paclitaxel: 7.7 months, HR: 0.45 [95% CI, 0.33-0.62], p=NR and tislelizumab-carboplatin-nab paclitaxel: 9.5 months, HR: 0.45 [95% CI, 0.33-0.62],p=NR).[30]

Response rate	
Randomized phase III study of tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for advanced squamous non-small cell lung cancer (sq-NSCLC): RATIONALE-307 updated analysis[29] (2022)	• Consistent improvements in ORR in Arms A (74.2% [95%CI: 65.4, 81.7]) and B (73.9% [95%CI: 65.1, 81.6]) vs C (47.9% [95%CI: 38.8, 57.2]) were observed. Median DoR in Arms A and B was 8.4 (95%CI: 5.0, 15.8) mos and 8.6 (95%CI: 7.1, 12.5) mos, respectively vs 4.3 (95%CI: 2.9, 5.4) mos in Arm C.[29]
HRQoL endpoints	
The effects of tislelizumab plus chemotherapy as first-line treatment on health-related quality of life of patients with advanced squamous non-small cell lung cancer: Results from a phase 3 randomized clinical trial.[8] (2022)	• The addition of tislelizumab to platinum-based chemotherapy is associated with improvements in sq-NSCLC patients' HRQoL, especially in GHS/QoL and most importantly in lung cancer-specific symptoms including coughing, dyspnea, and hemoptysis. • Patients in the open-label, multicenter, phase 3 RATIONALE 307 trial were randomized to one of the three arms: tislelizumab plus carboplatin and paclitaxel (Arm A), tislelizumab plus carboplatin and nab-paclitaxel (Arm B), or paclitaxel plus carboplatin (Arm C). A total of 355 sq-NSCLC patients received at least one dose of study drug and completed at least one HRQoL assessment. The GHS/QoL scores improved in Arms A and B relative to Arm C at Weeks 6 and 12. Arms A and B also experienced a reduction in most lung cancer-specific symptoms relative to Arm C. Time to deterioration of GHS/QoL was not reached by any of the three arms.
Safety and discontinuation outcomes	
Treatment emergent serious adverse events (TE-SAEs)	
Tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for advanced squamous non-small-cell lung cancer: final analysis of the randomized, phase III RATIONALE-307 trial[6] (2024)	• In RATIONALE 307 at new cut-off date, TE-SAEs were reported as 43.3% in the tislelizumab-carboplatin-paclitaxel arm, 42.4% in the tislelizumab-carboplatin-nab-paclitaxel arm and 24.8% in the carboplatin-paclitaxel arm.[6]

	• Tislelizumab + carboplatin + paclitaxel (120 patients) was associated with Grade ≥3 TEAEs: 89.2%; Grade ≥3 TRAEs: 86.7%; imAEs: All grade: 44.2%, Grade ≥3: 9.2% • Tislelizumab + carboplatin + nab-paclitaxel (118 patients): Grade ≥3 TEAEs: 87.3%; Grade ≥3 TRAEs: 83.9%; imAEs: All grade: 50.8%, Grade ≥3: 6.8% Carboplatin + paclitaxel (117 patients): Grade ≥3 TEAEs: 84.6%; Grade ≥3 TRAEs: 80.3%; imAEs: All grade: 7.7%, Grade ≥3: 0%
RATIONALE-307: Safety analysis of patients (pts) receiving tislelizumab (TIS) plus chemotherapy (chemo) vs chemo alone in advanced squamous (sq) NSCLC[31] (2022)	• Results from a post-hoc safety analysis of Tislelizumab + chemo vs chemo alone from the phase 3 RATIONALE-307 study showed that Tislelizumab + chemo had a tolerable safety profile. Tislelizumab did not add toxicity or impact treatment when added to chemo. Specifically, there were no notable differences in safety results for pts receiving Tislelizumab + chemo vs chemo alone. P-values between Arms A vs C, and Arms B vs C were > 0.01. Confidence intervals (CIs) of the differences between Arms A vs C and Arms B vs C all included 0, except between Arms B vs C for TEAEs leading to discontinuation. There was a numerical difference between Arms B vs C for TEAEs leading to discontinuation during the chemo co-administrated period, but this was not clinically meaningful.
RATIONALE-304 – Trial Evidence by End Point (Risk of Bias assessment in Table 3)	
Overall survival	
Tislelizumab plus chemotherapy as first-line treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (final analysis of RATIONALE-304: a randomized phase III trial) (2024) [9]	• The final analysis showed that OS stratified HR for tislelizumab plus chemotherapy versus chemotherapy was 0.90 (95% CI 0.63-1.28), with median OS of 21.4 months (95% CI 17.7 months-not estimable) versus 21.3 months (95% CI 15.6 months-not estimable), respectively. At a subsequent *ad hoc* analysis (median follow-up 19.3 months), OS HR between arms was 0.85 (95% CI 0.63-1.14); when adjusted for crossover using the two-stage method, the OS HR was 0.68 (95% CI 0.48-0.96).
Tislelizumab combined with chemotherapy as first-line therapy for locally advanced or	• In patients with PD-L1 ≥50%, tislelizumab plus chemotherapy significantly prolonged overall survival compared to chemotherapy alone, with a median

metastatic non-squamous non-small Cell Lung Cancer (nsq-NSCLC): Programmed Death-Ligand 1 (PD-L1) expression ≥50% subgroup analysis of the randomized, Phase 3 RATIONALE-304 Trial (2025)[35]	OS of 41.9 months versus 13.1 months, corresponding to a hazard ratio (HR) of 0.38 (95% CI: 0.24–0.63) in the updated analysis with 23.4 months median follow-up.
Progression-free survival	
Tislelizumab plus chemotherapy as first-line treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (final analysis of RATIONALE-304: a randomized phase III trial)[9] (2024)	• Tislelizumab plus chemotherapy continued to demonstrate prolongation of PFS_{IRC} versus chemotherapy alone {stratified hazard ratio (HR) 0.63 [95% confidence interval (CI) 0.47-0.86]; median PFS_{IRC} 9.8 months (95% CI 8.9-11.7 months) versus 7.6 months (95% CI 5.6-8.0 months), respectively.
Randomized phase III study of tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for advanced non-squamous non-small cell lung cancer (nsq-NSCLC): RATIONALE-304 updated analysis[32] (2022) Tislelizumab plus chemotherapy as first-line treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (final analysis of RATIONALE-304: a randomized phase III trial)[9] (2024)	• At October 26, 2020 cut-off date also showed significant improvement in median PFS compared to chemotherapy (9.8 month follow-up [IA]: 8.5 [n=223] vs 5.6 months [n=111], HR: 0.561 [95% CI, 0.411-0.767], p=0.0001.[32] • The IA median PFS results remained consistent at the 16.1 month follow-up, similar to the 9.8-month follow-up (16.1 month follow-up [IA]: 9.7 [n=223] vs 5.6 months [n=111], HR: 0.55 [95% CI, 0.42-0.73], p=NR).[9]
Tislelizumab combined with chemotherapy as first-line therapy for locally advanced or metastatic non-squamous non-small Cell Lung Cancer (nsq-NSCLC): Programmed Death-Ligand 1 (PD-L1) expression ≥50% subgroup analysis of the randomized, Phase 3 RATIONALE-304 Trial (2025)[35]	• In patients with PD-L1 ≥50%, tislelizumab plus chemotherapy significantly improved progression-free survival with a median PFS of 14.6 months versus 4.6 months for chemotherapy alone (stratified HR = 0.31; 95% CI: 0.18–0.55), indicating a 69% reduction in the risk of progression or death

Response rate	
Randomized phase III study of tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for advanced non-squamous non-small cell lung cancer (nsq-NSCLC): RATIONALE-304 updated analysis[32] (2022)	• At July 15, 2022 data cut-off, the ORR was greater in Arm A (51.6% [95% CI: 44.8, 58.3]) vs Arm B (27.9% [95% CI: 19.8, 37.2]) and median DoR was longer (14.5 [95% CI: 10.1, 24.4] vs 8.4 [95% CI: 6.0, 15.5] mos, respectively).[32]
Tislelizumab combined with chemotherapy as first-line therapy for locally advanced or metastatic non-squamous non-small Cell Lung Cancer (nsq-NSCLC): Programmed Death-Ligand 1 (PD-L1) expression ≥50% subgroup analysis of the randomized, Phase 3 RATIONALE-304 Trial (2025)[35]	• In the PD-L1 ≥50% subgroup, tislelizumab plus chemotherapy achieved a significantly higher confirmed objective response rate compared to chemotherapy alone: 70.3% (95% CI: 58.5–80.3) vs 30.6% (95% CI: 16.3–48.1), reflecting a substantial improvement in tumour response with the immunotherapy-based combination treatment.
HRQoL endpoints	
Examining the Impact of Tislelizumab Added to Chemotherapy on Health-Related Quality-of-Life Outcomes in Previously Untreated Patients With Non-squamous Non–Small Cell Lung Cancer[33] (2022)	• Tislelizumab showed significantly better GHS/QoL score compared to chemotherapy in RATIONALE 304 with LS mean of 5.7 (95% CI: 1.0 to 10.5); p=0.0183 at week 18.
Safety and discontinuation outcomes	
Treatment emergent serious adverse events (TE-SAEs)	
Tislelizumab plus chemotherapy as first-line treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (final analysis of RATIONALE-304: a randomized phase III trial)[9] (2024)	• All patients in the tislelizumab plus chemotherapy arm and 109 patients (99.1%) in the chemotherapy alone arm experienced one or more TEAE, and safety results were consistent with those at the interim analysis. • Event rates appeared to be similar after exposure adjustment [exposure-adjusted event rate (EAER) for ≥grade 3 TEAEs: 25.8 versus 26.5 events/100 person-months with tislelizumab plus chemotherapy versus chemotherapy alone, respectively.

	• Discontinuation of any treatment component due to TEAEs occurred in 30.6% and 10.0% of patients in the tislelizumab plus chemotherapy arm and the chemotherapy alone arm, respectively, with the difference mainly driven through discontinuation of chemotherapy components (26.1% versus 10.0%, respectively). TEAEs leading to permanent discontinuation and dose modifications or treatment delays of tislelizumab occurred in 14.4% and 64.0% of patients in the tislelizumab plus chemotherapy arm, respectively. • EAERs per 100 person-months were lower in the tislelizumab plus chemotherapy arm versus the chemotherapy alone arm for any TEAE (287.9 versus 329.0, respectively) and for treatment-related TEAEs (234.2 versus 261.0, respectively). • ImAEs of all grades occurred in 45.0% (100/222) of patients in the tislelizumab plus chemotherapy arm and 10.9% (12/110) of patients in the chemotherapy alone arm.
Tislelizumab combined with chemotherapy as first-line therapy for locally advanced or metastatic non-squamous non-small Cell Lung Cancer (nsq-NSCLC): Programmed Death-Ligand 1 (PD-L1) expression ≥50% subgroup analysis of the randomized, Phase 3 RATIONALE-304 Trial (2025)[35]	• In the PD-L1 ≥50% subgroup of patients with advanced nsq-NSCLC, serious treatment-emergent adverse events (TE-SAEs) occurred in 43.2% of patients receiving tislelizumab plus chemotherapy, compared to 28.6% in those receiving chemotherapy alone, indicating a higher but manageable incidence of serious toxicity in the immunotherapy-combination arm.
Subgroup analysis	
Tislelizumab (TIS) plus chemotherapy (chemo) vs chemo alone as first-line (1L) treatment for non-squamous (non-sq) non-small cell lung cancer (NSCLC) in patients (pts) who are smokers vs non-smokers[34] (2021)	• Results based on smoking status showed that clinically meaningful improvements in PFS were observed with TIS plus chemo in pts with advanced non-sq NSCLC who were smokers. The safety and efficacy profile of TIS was consistent with the overall population of this phase III study. PFS was longer with TIS plus chemo vs chemo alone for pts who were smokers. ORR was higher with TIS plus chemo vs chemo alone for both smokers and

	non-smokers. Treatment emergent adverse events (TEAEs) occurring in smokers and non-smokers are summarized in the table.
Network meta-analysis	
Tislelizumab plus chemotherapy versus pembrolizumab plus chemotherapy for the first-line treatment of advanced non-small cell lung cancer: systematic review and indirect comparison of randomized trials[18] (2023)	• An indirect comparison to explore the optimal choice between pembrolizumab and tislelizumab in first-line treatment for advanced NSCLC combined with chemotherapy demonstrated that there was no significant difference between tislelizumab plus chemotherapy and pembrolizumab plus chemotherapy in terms of PFS, the incidence of grade 3 or higher AEs, and AEs leading to death. In PFS subgroup analysis, the results demonstrate no significant differences in PFS by PD-L1 TPS expression level, age, liver metastasis status, and smoking status between tislelizumab plus chemotherapy and pembrolizumab plus chemotherapy
Comparative efficacy of immune checkpoint inhibitors combined with chemotherapy in patients with advanced driver-gene negative non-small cell lung cancer: A systematic review and network meta-analysis[19] (2024)	• Tislelizumab + chemotherapy showed the highest effectiveness in improving OS compared to the other treatments, with a hazard ratio (HR) of 0.61 and a 95 % confidence interval of [0.50, 0.73] • In terms of improving OS, tislelizumab + chemotherapy exhibited similar efficacy to nivolumab combined with ipilimumab and chemotherapy, camrelizumab combined with atezolizumab and chemotherapy, durvalumab combined with toripalimab and chemotherapy, pembrolizumab combined with chemotherapy • Tislelizumab achieved the highest position in terms of OS improvement among NSCLC patients, with a SUCRA value of 87.1%
Identifying optimal first-line immune checkpoint inhibitors based regiments for advanced non-small cell lung cancer without oncogenic driver mutations: A systematic review and network meta-analysis[20] (2023)	• Chemo-immunotherapy (CIT) regimens significantly outperformed ICI monotherapy and doublet ICIs in terms of both progression-free survival (PFS) and overall survival (OS), particularly in non-squamous NSCLC, where pembrolizumab-based CIT ranked as the most effective treatment (OS HR 0.50 [0.40–0.64]. • Tislelizumab-based chemo-immunotherapy demonstrated significant PFS benefit over chemotherapy alone and ranked among other leading CIT

	regimens such as atezolizumab, nivolumab + ipilimumab and pembrolizumab in terms of PFS, indicating comparative efficacy in this network meta-analysis
Real-world evidence	
Comparison of the efficacy and safety of domestically produced tislelizumab, camrelizumab, and imported pembrolizumab in the treatment of advanced NSCLC: a real-world retrospective study [21] (2025)	• The results showed that the median progression-free period was 11.3 m vs 10.1 m vs 8.9 m; *p* = 0.754; and the objective response rate was 63.2% vs 50% vs 57.5%; *P* = 0.510 for pembrolizumab, tislelizumab, and camrelizumab, respectively. • There was no significant difference in median PFS between PD-L1 expression subgroups. • TRAEs of all grades in the pembrolizumab, tislelizumab, and camrelizumab groups were 84.2%, 78.9%, and 72.6%, respectively. The TRAEs of ≥ grade 3 were 31.5%, 18.4%, and 13.7%, respectively. There were no statistically significant differences in all grades of TRAE (p= 0.46) and TRAE ≥ grade (*p* = 0.077) among the three groups.
A multicenter, real-world study on effectiveness and safety of first-line modified PD-1 inhibitors with chemotherapy in advanced non-small cell lung cancer (aNSCLC) with drive gene-negative [22] (2024)	The analysis demonstrated that there was no significant difference between tislelizumab plus chemotherapy versus pembrolizumab plus chemotherapy in terms of: • PFS (HR = 1.04, 95% CI: 0.82–1.31) • ORR (RR = 0.79, 95% CI: 0.59–1.07) • Incidence of grade 3 or higher AEs (RR = 0.99, 95% CI: 0.87–1.12) • AEs leading to death (RR = 0.70, 95% CI: 0.23–2.09) In a PFS subgroup analysis, the results demonstrated no significant differences in PFS by PD-L1 expression level (as measured by Tumour Proportion Score [TPS]), age, liver metastasis status, and smoking status between tislelizumab plus chemotherapy versus pembrolizumab plus chemotherapy.[18]

Real-World Data of Different Immune Checkpoint Inhibitors for Non-Small Cell Lung Cancer in China [23] (2022)	The efficacy and safety of different ICIs for NSCLC showed no statistically significant differences: • Survival analysis revealed similar efficacy across the ICIs, with median PFS ranging from 6.8 to 10.4 months. • Camrelizumab had the longest median PFS (10.4 months) • ORR ranged from 45.0% to 54.2%. Tislelizumab had the highest ORR (54.2%).
Comparative Cost/Cost-Effectiveness and Budget Impact Studies	
The Cost-Effectiveness of Tislelizumab Plus Chemotherapy for Locally Advanced or Metastatic Non-squamous Non-Small Cell Lung Cancer[24] (2022)	• The analysis found that tislelizumab plus platinum-pemetrexed increased effectiveness by 0.99 quality-adjusted life years (QALYs) at an additional cost of $28,749, resulting in an incremental cost effectiveness ratio (ICER) of $28,749/QALY, which was below the willingness-to-pay (WTP) threshold. • Subgroup analysis showed the greatest benefit for patients with PD-L1 expression ≥50%, liver metastasis, and current/former smokers. ICERs ranged from $27,018 to $33,074/QALY, consistently below the WTP threshold.
Tislelizumab plus chemotherapy is more cost-effective than chemotherapy alone as first-line therapy for advanced non-squamous non-small cell lung cancer[25] (2023)	• Compared with chemotherapy alone, tislelizumab plus chemotherapy resulted in an extra 0.64 QALYs and 1.48 life-years gained, at a cost of $16,631 per patient. This resulted in an ICER of $26,162 per QALY gained. • The incremental net health benefits (INHB) and incremental net monetary benefits (INMB) were $7,510 and 0.20 QALYs at a WTP threshold of $38,017/QALY, respectively.
Economics of first-line treatment with tislelizumab in patients with non-squamous non-small cell lung cancer[26] (2024)	• The base-case analysis showed that tislelizumab plus chemotherapy group had an extra 1.06 QALYs compared with the chemotherapy-alone group (3.967 QALYs versus 2.909 QALYs). This was at an incremental cost of U.S. dollars $19,594.75 ($43,390.52 versus $23,795.77). • The resulting ICER was $18,512.47 per QALY gained. • The authors note that this ICER is below the Chinese WTP threshold of $36,672.23 per QALY gained.

Table 3. Risk of bias assessment

Trial	Description	Reference for Primary Source
Selection bias		
RATIONALE 304	Patients were randomised 2:1 to receive either tislelizumab in combination with chemotherapy (arm A) or chemotherapy alone (arm B) using an interactive response technology system. Randomisation was stratified according to tumour cell (TC) PD-L1 membrane expression (<1% versus 1%–49% versus ≥50%) and disease stage (IIIB versus IV).	Lu, S, et al[5]
RATIONALE 307	Patients were randomised. (1:1:1) to tislelizumab plus paclitaxel and carboplatin (Arm A) : tislelizumab plus nab-paclitaxel and carboplatin (Arm B) : paclitaxel and carboplatin (Arm C). Patients were stratified by disease stage and tumour programmed cell death 1 ligand 1 (PD-L1) expression (<1% vs 1%-49% vs≥50%).	Wang J, et al[4]
Performance bias		
RATIONALE 304	While this was an open-label study design, all study drugs were administered at the study site under the supervision of the study staff to maximise compliance.	Lu, S, et al[5]
RATIONALE 307	While this was an open-label study design, assessment of the patient response to treatment and disease progression was evaluated by the blinded IRC using RECIST v1.1 for radiologic images. The results of PD-L1 expression were blinded to patients, investigators, study site personnel, sponsor staff, and representatives of the sponsor.	Wang J, et al[4]
Detection bias		
RATIONALE 304	Open-label design. assessment of the patient response to treatment and disease progression was evaluated by the blinded IRC using RECIST v1.1 for radiologic images. The same evaluator was to perform assessments, when possible, to ensure internal consistency across visits. The results of PD-L1 expression were blinded to patients, investigators, study site personnel, sponsor staff, and representatives of the sponsor. Secondary endpoints, including objective response rate and duration of response were also assessed by a blinded independent review committee.	Lu, S, et al[5]

Trial	Description	Reference for Primary Source
	Incidence and severity of treatment-emergent AEs (TEAEs) graded according to National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE), v4.03. All efficacy and safety assessments used in this study were standard, namely, they were widely used and generally recognized as reliable, accurate, and relevant.	
RATIONALE 307	Assessment of the patient response to treatment and disease progression was evaluated by the blinded IRC using RECIST v1.1 for radiologic images Secondary endpoints, including objective response rate and duration of response were also assessed by an independent review committee. Incidence and severity of treatment-emergent AEs (TEAEs) graded according to National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE), v4.03	Wang J, et al[4]
Attrition bias		
RATIONALE 304	Disposition and discontinuation reasons were recorded for both the intervention and comparator arms. Radiographic progression was the primary reason for treatment discontinuation in both arms with a higher proportion in Arm B (64.9%) compared to Arm A (49.8%). A total of 34 patients discontinued from treatment due to withdrawal of consent with a higher proportion in Arm B (12.6%) than in Arm A (9.0%). Death was the primary reason for study discontinuation in both treatment arms, accounting for 43% of patients in Arm A and 41.4% in Arm B. The percentage of patients who were lost to follow-up for study discontinuation was higher in Arm B (3.6%) than in Arm A (1.3%). When combined, voluntary withdrawal and lost to follow-up occurred more frequently in Arm B (Arm A: 3.6% versus Arm B: 13.5%).	Lu, S, et al[5]
RATIONALE 307	Disposition and discontinuation reasons were recorded for both the intervention and comparator arms. Progressive disease was the main reason for treatment discontinuation for Arm A and Arm B (45.0% and 42.9%, respectively), whereas most of the patients in Arm C (66.9%) completed the chemotherapy regimen prior to progressive disease and only 7.4% had disease progression before regimen completion.	Wang J, et al[4]

Trial	Description	Reference for Primary Source
	Treatment discontinuation caused by AEs were similar in 3 arms (13.3% in Arm A versus 11.8% in Arm B versus 13.2% in Arm C). More patients in Arm A and Arm B remained in the study compared with Arm C (57.5% in Arm A versus 56.3% in Arm B versus 43.8% in Arm C). The most common primary reason for study discontinuation in all treatment arms was death (40.0% in Arm A versus 39.5% in Arm B versus 43.0% in Arm C). Notably, fewer patients discontinued the study because of voluntary withdrawal or lost to follow-up in Arm A (2.5%) and Arm B (3.4%) compared with Arm C (12.4%.).	
Reporting bias		
RATIONALE 304	All prespecified efficacy and safety outcomes were reported	Lu, S, et al[5]
RATIONALE 307	All prespecified efficacy and safety outcomes were reported	Wang J, et al[4]
Other sources of bias		
RATIONALE 304	As of the data cutoff date, 50.5% of patients received subsequent check point inhibitors including a total of 40 patients (36.0%) in Arm B who had crossed over to receive tislelizumab monotherapy.	Lu, S, et al[5]
RATIONALE 307	A high proportion of patients (61.2%) in Arm C received subsequent treatment with immunotherapy, including 56.2% of patients who crossed over to tislelizumab following disease progression and 5.0% who received other immune checkpoint inhibitors. In contrast, 9.2% of patients in Arm A and 6.7% in Arm B subsequently received treatment with immunotherapy.	Wang J, et al[4]

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