

RATIONALE-303

2/3L NSCLC



RATIONALE-303 Trial Design



Phase 3

Study Identifier:
BGB-A317-303, NCT03358875

Primary Endpoint: OS in ITT and PD-L1 $\geq 25\%$ populations
Key Secondary Endpoints: ORR, DoR, PFS, HRQOL, safety

Key eligibility criteria

- Histologically confirmed Stage IIIB or IV NSCLC with progressive disease during or following treatment with ≥ 1 platinum-containing regimen
- No prior docetaxel or PD-1 or PD-L1 therapy
- No EGFR sensitizing mutation or ALK gene translocation
- ECOG PS ≤ 1

Treatment

Screening

R 2:1

Tislelizumab
200 mg IV Q3W
(n=535)

Docetaxel
75 mg/m² IV Q3W
(n=270)

Treatment until unacceptable toxicity or disease progression

Tislelizumab 200 mg IV Q3W (optional)^a

Follow-up

Safety and survival

Stratification

- Squamous vs non-squamous
- 2nd vs 3rd line of therapy
- PD-L1 status ($< 25\%$ vs $\geq 25\%$ TC staining)

PD-L1 $\geq 25\%$ population included all patients with $\geq 25\%$ of TCs with PD-L1 membrane staining (assessed via Ventana SP263 assay)

^aPatients receiving tislelizumab were permitted to continue tislelizumab treatment beyond radio imaging progression if clinical benefit was seen in the absence of symptomatic deterioration and unacceptable toxicity per investigator's discretion.
2L=second line, 3L=third line, DoR=duration of response, ECOG PS=Eastern Cooperative Oncology Group performance status, HRQOL=health-related quality of life, IV=intravenous, NSCLC=non-small cell lung cancer, ORR=objective response rate, OS=overall survival, PD-1=programmed cell death protein 1, PD-L1=programmed death ligand 1, PFS=progression-free survival, Q3W=every 3 weeks, R=randomized.
ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03358875>. Accessed October 9, 2025.