

# RATIONALE-307

1L SQ-NSCLC



# RATIONALE-307 Trial Design



## Phase 3

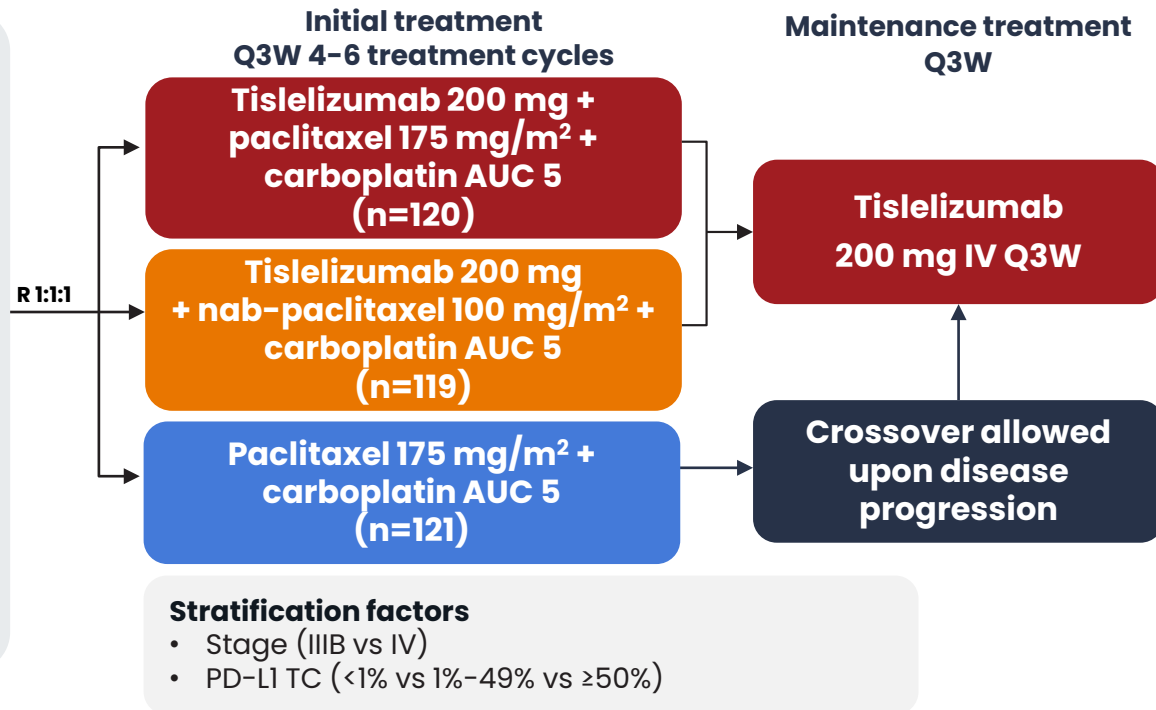
**Study Identifier:**  
BGB-A317-307, NCT03594747

**Primary Endpoint:** PFS (IRC)  
**Key Secondary Endpoints:** ORR, DoR, OS, Safety

### Key eligibility criteria

- Untreated squamous NSCLC; Stage IIIB or IV
- No prior systemic chemotherapy for advanced or metastatic disease<sup>a</sup>
- No EGFR-sensitizing mutations or known ALK gene translocations
- ECOG PS ≤1
- ≥1 measurable lesion
- Fresh or archival tissue for PD-L1 assessment (Ventana SP263 assay)

### Treatment



### Follow-up

Treatment until disease progression, intolerable toxicity, or treatment discontinuation

Safety and survival

Tislelizumab, carboplatin, and paclitaxel were administered on D1. Nab-paclitaxel was administered on D1, D8, and D15.

<sup>a</sup>Patients receiving prior neoadjuvant or adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a disease-free interval of ≥6 months from the last dose of chemotherapy and/or radiotherapy prior to randomization.

IL=1st line, DoR=duration of response, ECOG PS=Eastern Cooperative Oncology Group performance status, IRC=independent review committee, ITT=intent-to-treat, NSCLC=non-small cell lung cancer, ORR=objective response rate, OS=overall survival, PD-L1=programmed death ligand 1, PFS=progression-free survival, PK=pharmacokinetic, Q3W=every 3 weeks, R=randomized.

ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03594747>. Accessed October 9, 2025.