

# RATIONALE-304

1L NSQ-NSCLC



# RATIONALE-304 Trial Design



## Phase 3

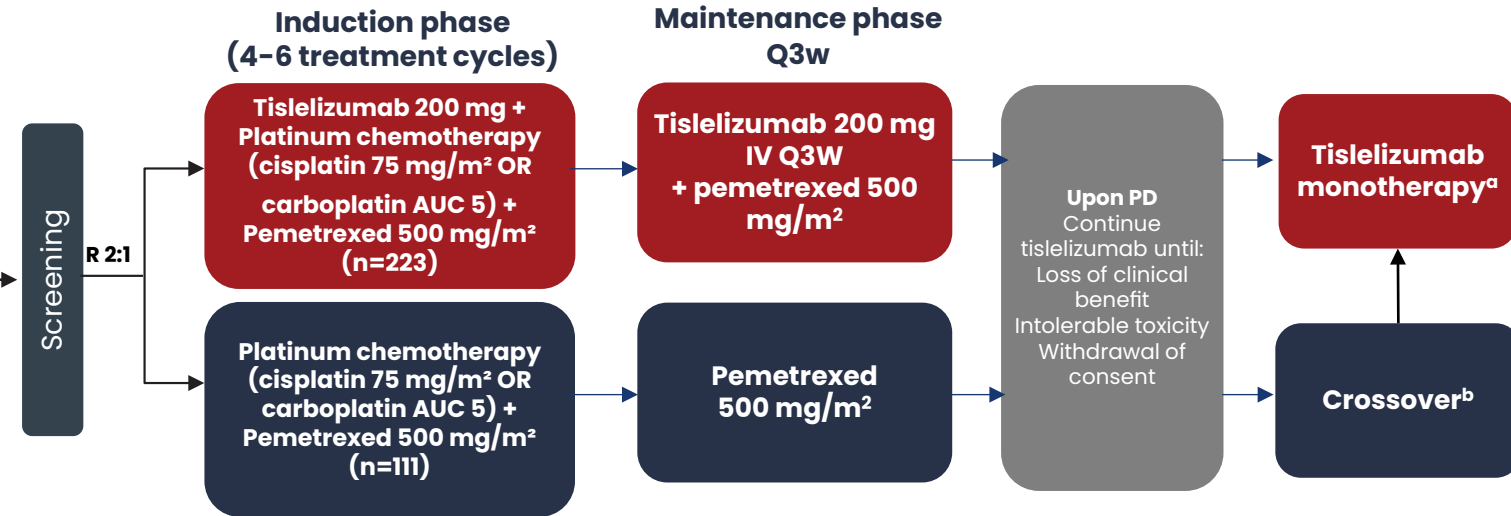
**Study Identifier:**  
BGB-A317-304, NCT03663205

**Primary Endpoint:** PFS by IRC in ITT population  
**Key Secondary Endpoints:** OS, ORR, DoR, safety, and QoL

### Key eligibility criteria

- Histologically confirmed, Stage IIIB not amenable to curative surgery or radiotherapy, or Stage IV nsq-NSCLC
- No prior systemic chemotherapy for advanced or metastatic disease\*
- No EGFR-sensitizing mutations or known ALK gene translocation
- ECOG  $\leq$  1
- $\geq$  1 measurable lesion
- Fresh or archival tissue for PD-L1 assessment (Ventana SP263 assay)

### Treatment



#### Stratification factors

- Disease stage (IIIB vs IV)
- PD-L1 TC expression (<1% vs 1%-49% vs  $\geq$ 50%)

\* Patients with prior neoadjuvant or adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a disease-free interval of  $\geq$  6 months from the last dose of chemotherapy and/or radiotherapy prior to randomization. <sup>a</sup>Continue tislelizumab until loss of clinical benefit, intolerable toxicity, or withdrawal of consent. <sup>b</sup>Optional crossover to tislelizumab. AE=adverse event, ALK=anaplastic lymphoma kinase, AUC=area under the curve, DoR=duration of response, EGFR=epidermal growth factor receptor, IRC=independent review committee, ITT=intent-to-treat, IV=intravenous, NSCLC=non-small cell lung cancer, ORR=objective response rate, OS=overall survival, PD-L1=programmed death ligand 1, PFS=progression-free survival, Q3W=every 3 weeks, QoL=quality of life, R=randomized. 1. Ma Z et al. Poster Presentation at ESMO-Asia 2024;632P. 2. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03663205>. Accessed October 9, 2025.