RATIONALE-315

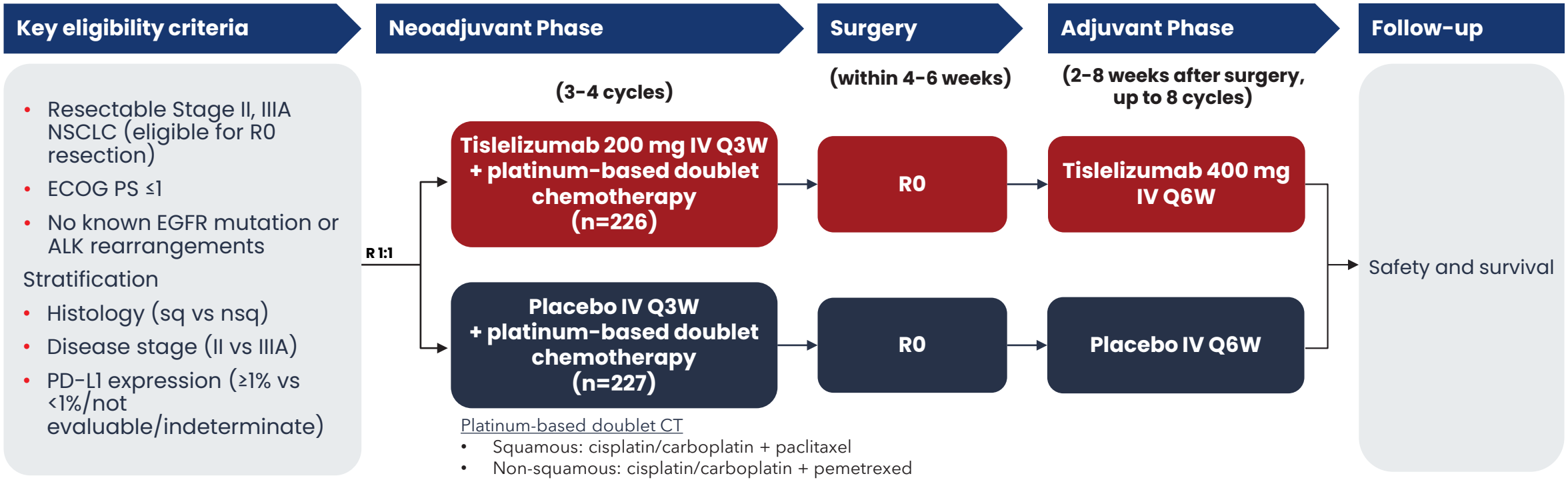
Neo/Adj NSCLC

RATIONALE-315 Trial Design

Phase 3

Study Identifier:
BGB-A317-315, NCT04379635

Primary Endpoint: MPR and EFS (by BICR) in ITT set
Key Secondary Endpoints: OS, pCR, ORR, DFS, INV-assessed EFS, HRQoL, safety



Planned interim analysis:
- Final analysis of MPR and pCR per blinded IRC
- EFS at 75% of the target number of events

Statistical Considerations
- The ITT analysis set (TIS + CT, n=226; PBO + CT, n=227) included all randomized patients
- The safety analysis set (TIS + CT, n=226; PBO + CT, n=226) included all randomized patients who received ≥1 dose of any study drug
- 1-sided α at 0.005 is allocated for the MPR test; if MPR is statistically significant, 0.005 will pass to the pCR test

ALK=anaplastic lymphoma kinase, BICR, blinded independent central review, DFS=disease-free survival, ECOG PS=Eastern Cooperative Oncology Group performance status, EFS=event-free survival, EGFR=epidermal growth factor receptor, HRQOL=health-related quality of life, INV=investigator, ITT=intent-to-treat, IV=intravenous, MPR=major pathological response, NSCLC=non-small cell lung cancer, ORR=objective response rate, OS=overall survival, pCR=pathological complete response, Q3W=every 3 weeks, Q6W=every 6 weeks R=randomized, R0=resection with curative intent.
ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04379635. Accessed October 9, 2025.