RATIONALE-309

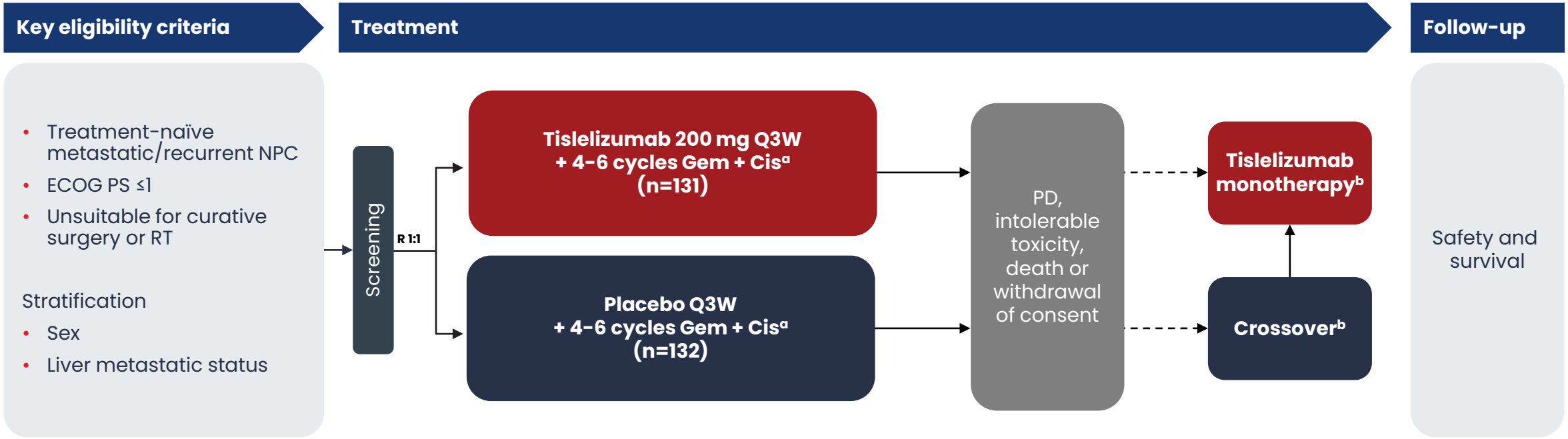
1L NPC

RATIONALE-309 Trial Design

Phase 3

Study Identifier:
BGB-A317-309, NCT03924986

Primary Endpoint: PFS by IRC
Key Secondary Endpoints: OS, ORR, DoR, INV-assessed PFS and PFS2, Safety; **Exploratory**: Biomarker analysis



[a]Q3W Gemcitabine 1g/m² on day 1 and day 8 + cisplatin 80 mg/m² on day 1; [b]if considered beneficial by investigator.
Chemo=chemotherapy, Cis=cisplatin, DoR=duration of response, ECOG PS=Eastern Cooperative Oncology Group performance status, Gem=gemcitabine, INV=investigator, IRC=independent review committee, IV=intravenous, NPC=nasopharyngeal cancer, ORR=objective response rate, OS=overall survival, PD=progressive disease, PFS=progression-free survival, PFS2=progression-free survival on subsequent treatment, Q3W=every 3 weeks, R=randomized, RT=radiotherapy.111.
1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03924986. Accessed October 9, 2025; 2. Fang W et al. Oral Presentation at ESMO Asia 2024.