

RATIONALE-301

1L HCC



RATIONALE-301 Trial Design



Phase 3

Study Identifier:
BGB-A317-301, NCT03412773

Primary Endpoint: OS
Key Secondary Endpoints: ORR, PFS, DoR, TTP

Key eligibility criteria

- Histologically confirmed, BCLC Stage C or BCLC Stage B disease not amenable to or has relapsed after LRT
- Child-Pugh A
- ECOG PS ≤ 1
- No previous systemic therapy for HCC

Treatment

Screening

R 1:1

Tislelizumab 200 mg IV Q3W
(n=342)

Sorafenib
(n=332)

Treatment until unacceptable toxicity, disease progression or loss of clinical benefit

Follow-up

Safety and survival