Article details

Title of article

A global Phase III study of tislelizumab versus sorafenib as first-line treatment for unresectable hepatocellular carcinoma

Authors

Shukui Qin, Richard S Finn, Masatoshi Kudo, Tim Meyer, Arndt Vogel, Michel Ducreux, Teresa Mercade Macarulla, Gianluca Tomasello, Frederic Boisserie, Jeannie Hou, Xin Li, James Song & Andrew X Zhu

Article URL

www.futuremedicine.com/doi/10.2217/fon-2019-0097

Trial registration number

NCT03412773

Primary objectives/rationale

Primary objective

Compare OS of tislelizumab- and sorafenib-treated patients

Secondary objectives

Key secondary objective: compare ORR of tislelizumab and sorafenib, assessed by BIRC per RECIST v1.1

Other secondary objectives: compare tislelizumab and sorafenib in terms of other efficacy endpoints, HRQoL, and safety and tolerability

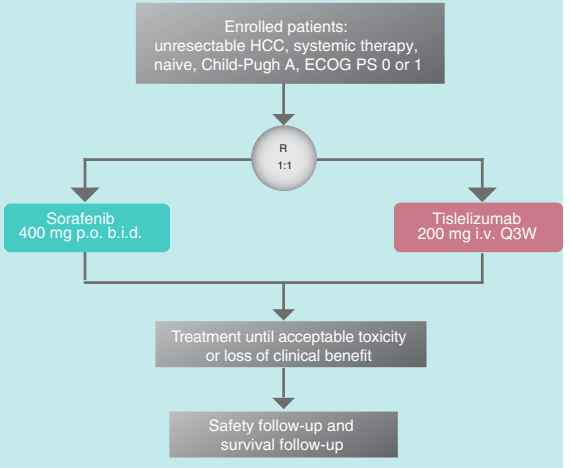
Study design and treatment including planned sample size, planned study period and study procedures

Patients will be randomized 1:1 to receive tislelizumab 200 mg intravenously every 3 weeks or sorafenib 400 mg orally twice daily

Tumor response will be evaluated every 9 weeks during Year 1 and every 12 weeks from Year 2 onwards

Study period: December 2017 to May 2022

Study design, treatment and study procedures



Key eligibility criteria

Age ≥18 years

Histological confirmed HCC

BCLC stage C disease classification, or BCLC stage B disease not amenable to, or relapsed after, locoregional therapy and not amenable to a curative treatment approach

No previous treatment with systemic therapy

ECOG score ≤1

Child-Pugh A classification

≥1 measurable lesion per RECIST v1.1

Outcome measures/end points

Primary end point:
OS

Secondary end points:
ORR, PFS, DoR, TTP, DCR, CBR, AEs, immune-related AEs, laboratory parameters

Glossary

AEs: Adverse events; BCLC: Barcelona clinic liver cancer-stage C; CBR: Clinical benefit rate; DCR: Disease control rate; DoR: Duration of response; ECOG: Eastern Cooperative Oncology Group; HCC: Hepatocellular carcinoma; HRQoL: Health-related quality of life; ORR: Objective response rate; OS: Overall survival; PFS: Progression-free survival; RECIST v1.1: RECIST: Response Evaluation Criteria in Solid Tumors; TTP: Time to progression