In the European/North American (EU/NA) subgroup, tislelizumab demonstrated numerically longer median overall survival (OS) and more durable antitumor response compared with sorafenib, as first-line treatment in patients with unresectable hepatocellular carcinoma (HCC). Tislelizumab had a favorable safety profile compared with sorafenib in the EU/NA subgroup. The results obtained in the EU/NA subgroup were consistent with published results from the overall study population.

Background

HCC is one of the most commonly diagnosed cancers globally. Most cases occur in Asia, particularly in China, with 410,000 reported in 2020; however, the number of patients affected in other regions is also high, with over 87,000 HCC cases in Europe and 45,000 in the USA in 2020. Tislelizumab, a monoclonal antibody with high affinity and binding specificity for programmed cell death protein 1, was specifically engineered to minimize Fc γ receptor binding on macrophages.

Methods

The study design has been previously described. A summary of the safety findings is shown in Table 1. **Abbreviations:** ECOG PS, Eastern Cooperative Oncology Group performance status; BOR, best overall response; DoR, duration of response; EU/NA, European/North American; OS, overall survival; PFS, progression-free survival.

Results

Baseline Characteristics

- Of 474 randomly assigned patients, 172 (36.5%) were enrolled in the EU/NA subgroup (tislelizumab, n=86; sorafenib, n=86).
- Distribution of baseline characteristics was generally similar between the EU/NA subgroup and the overall population. Of note, the EU/NA subgroup had a higher number of patients with cirrhosis (38 of 172 patients (22.1%) vs 23 of 332 patients (6.9%)) in the tislelizumab arm compared with the sorafenib arm, similar to the overall population (Table 1).
- In general, more patients in the EU/NA subgroup had less advanced disease (BCLC Stage C) compared with the overall population (Table 1).
- At data cutoff (July 11, 2022), median OS follow-up in the EU/NA subgroup was 37.9 months in the tislelizumab arm and 30.5 months in the sorafenib arm.
- In the EU/NA subgroup, tislelizumab demonstrated numerically longer median OS, which was consistent across most studied subgroups (Table 2) and, similar median PFS (Figure 4), longer median DoR, and a higher DCR than sorafenib (Table 2). These results were similar to the exception of median OS (Table 2).

Conclusions

Tislelizumab demonstrated clinical activity and was generally well tolerated in patients with previously treated advanced HCC (NCT02448981). In the RATIONALE-301 (NCT01427273) study in patients with unresectable HCC, tislelizumab showed noninferior OS vs sorafenib and demonstrated a favorable safety profile. Here, we report data from the EU/NA subgroup in the RATIONALE-301 study.

References


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Disclosure

Disclosure information is available online with the abstract details.