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Liver resection versus continued atezolizumab plus bevacizumab (atezo/bev) in locally advanced hepatocellular carcinoma (HCC) after atezo/bev treatment (TALENTop): A multicenter, open-label, randomized phase III trial

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Background

For advanced-stage HCC patients (pts) who respond to systemic therapy, the benefit of liver resection remains controversial. Here, we report the interim analysis results from TALENTop, evaluating the efficacy and safety of liver resection versus continued atezo/bev in pts without progressive disease (PD) after first-line atezo/bev treatment.

Methods

Treatment-naïve HCC pts with vascular invasion and no extrahepatic metastasis (EHS) were enrolled and received an induction phase of 3-cycle atezo/bev and 1-cycle atezo. Pts who achieved partial response or stable disease and deemed eligible for liver resection were randomized (1:1) to receive either liver resection followed by 1 year of atezo/bev (arm A) or continued atezo/bev until loss of clinical benefit or intolerable toxicity (arm B). The primary endpoint was independent review facility (IRF)-assessed time-to-treatment failure (TTF), defined as the time from randomization to the first documented treatment failure (i.e. local recurrence or progression [RECIST V1.1], EHS, or death) in intention-to-treat population. Secondary endpoints included OS and safety.

Results

489 pts received induction-phase treatment, with 201 subsequently randomized to arm A (n=101) or arm B (n=100). With a median follow-up of 18.43 months since randomization, IRF-assessed TTF was significantly improved in arm A vs. arm B (No. of events, 37 vs 59; median TTF, 20.4 vs 11.8 months; stratified HR, 0.60; 95% CI, 0.39-0.91; $p = 0.015$; pre-specified two-sided alpha boundary was 0.0341). OS data remain immature (No. of events, 15 vs 23; HR, 0.67; 95% CI, 0.35-1.29). Grade ≥ 3 atezo/bev-related adverse events occurred in 27.7% of pts in arm A vs. 21.0% in arm B. Grade ≥ 3 surgical complication rate was 21.7%.

Conclusions

For locally advanced HCC pts with PR or SD and eligible for resection after initial atezo/bev treatment, liver resection provided statistically significant and clinically meaningful benefits and showed a trend toward OS benefit compared to continued atezo/bev treatment.

Clinical trial identification

NCT04649489.

Legal entity responsible for the study

Zhongshan Hospital, Fudan University.

Funding

Shanghai Roche Pharmaceuticals Ltd., China.

Disclosure

H. Sun: Financial Interests, Personal, Invited Speaker: AstraZeneca, Bayer, BeiGene, Eisai, Hengrui, Innovent, MSD, Roche, Zelgen; Financial Interests, Personal and Institutional, Funding: Sino Biopharmaceutical, Eisai, Innovent, Roche, MSD. X. Zhu: Financial Interests, Personal, Invited Speaker: BeiGene, Eisai, Hengrui, Innovent, MSD, Roche. All other authors have declared no conflicts of interest.

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