

1003P

Baseline (BL) liver function and outcomes in patients (pts) with unresectable hepatocellular carcinoma (HCC) in KEYNOTE-240

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Background

Albumin/bilirubin (ALBI) score measures liver function in HCC using objective laboratory variables. KEYNOTE-240 (NCT02702401) was a phase III study in pts with previously treated, advanced HCC that demonstrated reduced risk of death with pembrolizumab (pembro) vs placebo (pbo), but prespecified significance criteria were not met. We hypothesized that deterioration of liver function, as measured by change in ALBI score, would not be adversely affected by pembro vs pbo.

Methods

Eligible pts had confirmed HCC, progression on/intolerance to sorafenib, Child-Pugh A disease, and ECOG performance status 0-1. Pts were randomized 2:1 to pembro 200 mg or pbo IV every 3 wk + best supportive care for ≤35 cycles or until confirmed progression/unacceptable toxicity. This post hoc analysis assessed change from BL in ALBI score and time to increase in ALBI grade in both arms. Efficacy was assessed in ALBI grade 1 and 2 subgroups. Data cutoff: 2 Jan 2019.

Results

Of 413 pts, 116 had BL ALBI grade 1 (pembro, n=74; pbo, n=42) and 279 had BL ALBI grade 2 (pembro, n=193; pbo, n=86). Change from BL in ALBI score to the end of treatment was similar in both arms (difference in least-squares mean -0.037; 95% CI -0.167, 0.093). Time to ALBI grade increase was similar in both arms (median 7.8 mo on pembro vs 6.9 mo on pbo; hazard ratio [HR] 0.863 [95% CI 0.625, 1.192]) (Table). Regardless of BL ALBI grade, pembro improved overall survival (OS; grade 1: HR 0.725 [95% CI 0.454, 1.158]; grade 2: HR 0.827 [95% CI 0.612, 1.119]).

Conclusions

Liver function in pts with HCC as measured by change in ALBI score from BL was not adversely affected by pembro vs pbo. Time to ALBI grade increase was similar in both arms. OS benefit with pembro was observed in both ALBI grade groups. Table: 1003P

Analysis of Time to ALBI Grade Increase

Treatment	N	Events, n (%)	Median, ^a months (95%CI)	HR (95% CI) ^b	P Value ^c
Pembro	278	118 (42.4)	7.8 (6.4, 14.3)	0.863 (0.625, 1.192)	0.1828
Pbo	133	56 (42.1)	6.9 (4.9, 12.7)		

^aFrom product-limit (Kaplan-Meier) method for censored data. ^bBased on stratified Cox regression model with treatment as a covariate. ^cOne-sided P value based on stratified log-rank test.

Clinical trial identification

NCT02702401, March 8, 2016.

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Legal entity responsible for the study

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Disclosure

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