

Effects of Tislelizumab (TIS) Monotherapy on Health-Related Quality of Life in Patients With Previously Treated Unresectable Hepatocellular Carcinoma (HCC)

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Background

In a multi-national phase 2 study (NCT03419897), single-agent TIS, an anti-PD-1 antibody, was well tolerated and demonstrated durable antitumor activity in patients with previously systemically treated unresectable HCC. This study also assessed the effects of TIS on health-related quality of life (HRQoL) using the EORTC QLQ-C30 and QLQ-HCC18 instruments. Here we present the results from the QLQ-C30 global health status (GHS)/QoL scale and the QLQ-HCC18 index and the scales for the key symptom of fatigue.

Methods

Tislelizumab (200 mg) was administered IV every 3 weeks until no further clinical benefit was observed. HRQoL was assessed at baseline and every 6 weeks thereafter up to cycle 12. Least-squares mean score change from baseline to cycles 6 and 12 was assessed using a mixed model for repeated measurement; change from baseline ≥10 points was considered clinically meaningful. Analysis was conducted for the overall population and by subgroups with 1 prior or ≥2 prior lines of therapy.

Results

Of the 249 enrolled patients (1 prior line, n=138; ≥2 prior lines, n=111), most were male (87%), median age was 62 years (28-90 years), and the majority (94%) had previously received sorafenib. Across the population, median treatment duration was 4.1 months and the median number of cycles completed was 6. At cycles 6 and 12 GHS/QoL, index and fatigue scores remained stable (**Table**).

Table.

		All (N=249)		1 Prior Line (n=138)		≥2 Prior Lines (n=111)	
		LS mean change (95% CI)		LS mean change (95% CI)		LS mean change (95% CI)	
		Cycle 6	Cycle 12	Cycle 6	Cycle 12	Cycle 6	Cycle 12
QLQ-30		n = 127	n = 59	n = 75	n = 34	N = 52	n = 25
	GHS/QoL	-2.0 (-4.7, 0.6)	0.4 (-3.3, 4.1)	-2.4 (-5.8, 1.0)	-0.9 (-5.8, 4.0)	-1.7 (-5.6, 2.3)	1.7 (-3.9, 7.4)
QLQ-HCC-18		n = 128	n = 60	n = 75	n = 35	n = 53	n = 25
	Index	2.6 (0.8, 4.4)	2.2 (0.4, 4.1)	0.9 (-1.5, 3.3)	4.1 (1.7, 6.5)	4.3 (1.6, 7.0)	0.3 (-2.5, 3.1)
	Fatigue	3.7 (0.4, 6.9)	1.3 (-1.9, 4.5)	0.6 (-3.6, 4.9)	3.5 (-0.7, 7.7)	6.7 (1.7, 11.6)	-0.9 (-5.8, 4.0)

Abbreviations CI, confidence interval; GHS/QoL, global health status/quality of life scale; LS mean, least-squares mean.

Conclusions

These results showed no deterioration of HRQoL in patients treated with TIS with unresectable HCC, a patient population where HRQoL often deteriorates overtime. These results, along with promising efficacy and manageable tolerability findings from this trial, are promising results highlighting a good benefit risk profile of TIS in HCC patients particularly in pretreated patients.