Camrelizumab monotherapy or plus Apatinib for PD-L1-positive advanced pulmonary sarcomatoid carcinoma: A single-arm, open-label, multicenter, phase II study

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Background

Pulmonary sarcomatoid carcinoma (PSC) is insensitive to chemotherapy or radiotherapy and no optimal treatment has been established yet.

Because of the high expression of programmed death-ligand 1 (PD-L1), immune checkpoint inhibitors (ICIs) were documented to possess encouraging efficacy in PSC patients (pts).

Here we evaluated camrelizumab (Camre) in treating PD-1-positive PSC. Apatinib (Apa) may be used simultaneously with Camre based on the PD-L1 level.

Methods

In this study, pts with an age of 18-80 years old, ECOG PS 0-2, PD-L1 positive, histologically or cytologically confirmed stage IIIB-IV PSC regardless of prior therapy lines were enrolled to receive Camre (200 mg, IV, Q3W) plus Apa (250mg, QD) for PD-L1 TPS 1-49%, or Camre monotherapy (200 mg IV Q3W) for PD-L1 TPS≥50%. The primary endpoint was ORR according to RECIST v1.1.

Results

From Sep 2020 to Nov 2021, 16 pts (Camre plus Apa, n=3; Camre monotherapy, n=13) were enrolled. Until the final follow-up (Nov 30, 2020), 14 pts received at least one efficacy evaluation. In Camre plus Apa group, ORR was 66.7% (2/3) , DCR was 66.7% (2/3), median DoR was 2.53 [95% CI 1.4-3.1] months. In Camre monotherapy group, ORR was 54.5% (6/11), DCR was 90.9% (10/11), median DOR was 3.19 [95% CI 1.1-6.9] months. Median PFS and OS data were not mature. Grade 3 or 4 adverse events were AST/ALT increased [1 (6.25%)], hypophysitis [1 (6.25%)], with no unexpected adverse effects. Adverse events that led to the discontinuation of any agent occurred in 1.9% (3/16) of the pts. No treatment-related deaths were reported.

Characteristic	Camre+Apa N=3	Camre N=13
Age		
Median(IQR), years	62(55-66)	65(42-69)
<65 years	2(66.7%)	5(35.7%)
Sex		
Male	2(66.7%)	11(85.7%)
Female	1(33.3%)	2(15.4%)
ECOG PS, n		
0-1	3(100%)	12(92.9%)
2	0	1(7.1%)
History of smoking, n		
Smoker	1(33.3%)	9(71.4%)
Non-Smoker	2(66.7%)	4(28.6%)
Brain Metastases	1(33.3%)	2(15.4%)
Liver Metastases	0	3(23.1%)

Table 1: Baseline characteristics

TRAE	All treated patients N=16	
	Grade 1–2	Grade 3-4
Reactive cutaneous capillary endothelial proliferation	6(37.5%)	0
Fever	2(12.5%)	0
Hypophysitis	2(12.5%)	1(6.25%)
Hepatic function abnormal	1(6.25%)	1(6.25%)
Rash	1(6.25%)	0
Pneumonitis	2(12.5%)	0

Table 2: Treatment-related adverse events(TRAE) occurring in at least 1% of the patients

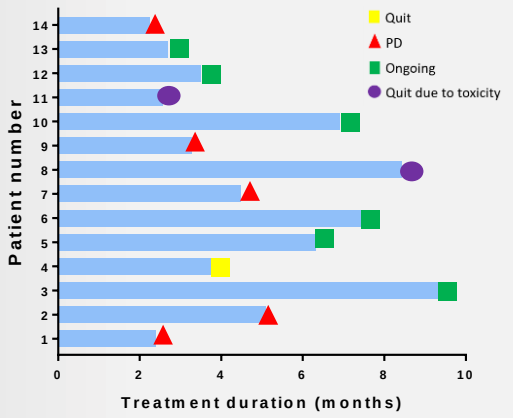

Figure 1: Response duration

Conclusion

Camre monotherapy or plus Apa showed promising antitumour activity with manageable toxicity profile for PD-L1-positive PSC pts. This encourages the clinical practice with ICIs in PSC.