PRELIMINARY ANALYSIS OF A REAL-WORLD STUDY (RWS) OF CAMRELIZUMAB TREATMENT IN PRIMARY LIVER CANCER (PLC)

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Background Immune checkpoint inhibitors (ICIs) have revolutionized the landscape of PLC management at all evolutionary stages.¹ As an anti-programmed cell death-1 (PD-1) antibody, camrelizumab monotherapy and in combination with apatinib, an anti-angiogenetic tyrosine kinase inhibitor of vascular endothelial growth factor receptor (VEGFR)-2, chemotherapy or locoregional therapy, have demonstrated their efficacy in advanced hepatocellular carcinoma (HCC).^{2 3 4 5}

Methods This prospective, open-label, multi-center, observational RWS was conducted to evaluate efficacy and safety of camrelizumab in treatment of PLC in clinical practice. Eligible patients were histopathologically or cytologically identified HCC or intrahepatic cholangiocarcinoma, who were going to receive camrelizumab treatment, with age ≥ 18 ages, Eastern Cooperative Oncology Group performance status (ECOG PS) score of 0–2 and Child-Pugh score ≤ 9 . Patients were treated at clinician discretion. Three hundred patients were planned to enroll, including advanced or peri-operative PLC. The primary endpoint was progress-free survival for advanced PLC, whose efficacy was available to analysis. Efficacy was assessed per Response Evaluation Criteria in Solid Tumors version 1.1.

Results From March 29, 2020 to June 10, 2021, a total of 147 eligible patients of advanced PLC were enrolled and included in this interim analysis, with 128 (87.1%) men, 130 (94.9%) ECOG PS of 0–1, 139 (94.6%) HCC, 74 (50.4%) Barcelona Clinic Liver Cancer stage C, 98 (66.7%) Child-Pugh B, and 72 (49.0%) with extrahepatic metastases, shown in table 1. Of the 147 patients, 45 (30.1%) patients were treated with camrelizumab monotherapy, 79 (53.8%) patients with combination with angiogenesis inhibitors, of which 55 (37.4%) in combination with apatinib, 21 (14.3%) patients with camrelizumab and chemotherapy. Patients, who had at least one efficacy assessment, were included in the efficacy analyses. Up to July 19, 2021, with a median follow time of 6.2 months, 132 patients were available for efficacy analyses. Patient disposition was shown in figure 1. Objective response rate (ORR) and disease control rate (DCR) were 10%/30.8%/35.3% and 75.0%/86.5%/70.6% in camrelizumab monotherapy/combined with apatinib/combined with chemotherapy, respectively. (table 2) The most common camrelizumab-treatment related adverse events (AEs) included reactive cutaneous capillary endothelial proliferation (RCCEP) (12, 8.2%), ICI-induced pneumonia (2, 1.4%), enterocolitis (2, 1.4%), and nephritis (1, 0.7%), of which all these AEs recovered. Other AEs included increase of transaminase (5, 3.4%) and hypertension (4, 2.7%). All AEs were 1–2 grade and no treatment-related death occurred.

Abstract 452 Table 1 Baseline characteristics

Baseline characteristics (N=147)		
Average age		57.79 $\pm$ 13.06
Sex	Male	128(87.1%)
	Female	19(12.9%)
ECOG PS score	0	60 (40.8%)
	1	73 (49.7%)
	2	14 (9.5%)
Histopathological features	HCC	139 (94.6%)
	ICC	8 (5.4%)
BCLC stage	UK	24 (16.3%)
	B	49 (33.3%)
	C	74 (50.4%)
Child-Pugh	A	49 (33.3%)
	B	98 (66.7%)

Data are n (%). ECOG-PS, Eastern Cooperative Oncology Group Performance Status; HCC, hepatocellular carcinoma; ICC, intrahepatic cholangiocarcinoma; BCLC, Barcelona Clinic Liver Cancer; UK, unknown.

Abstract 452 Figure 1 Patient disposition

Abstract 452 Table 2 Confirmed tumor response assessed by investigators per RECIST v1.1

Confirmed tumor response assessed by investigators per RECIST v1.1						
Camrelizumab treatment regimen (N=132)	CR, n (%)	PR, n (%)	SD, n (%)	PD, n (%)	ORR (%)	DCR (%)
Monotherapy (N=40)	0	4(10.0%)	26(65.0%)	10(25.0%)	10.0%	75.0%
Combined with anti-angiogenic agents (N=73)	1(1.4%)	21(28.7%)	40(54.8%)	11(15.1%)	30.1%	84.9%
Combined with apatinib (N=52)	1(1.9%)	15(28.8%)	29(55.8%)	7(13.5%)	30.8%	86.5%
Combined with chemotherapy (N=17)	1(5.9%)	5(29.4%)	6(35.3%)	5(29.4%)	35.3%	70.6%
Combined TACE or radiotherapy (N=2)	0	1(50.0%)	1(50.0%)	0	50%	100%

RECIST v1.1: Response Evaluation Criteria in Solid Tumors version 1.1; CR, complete response; PR, partial responses; SD, steady disease; PD, progressive disease; ORR, objective response rate; DCR, disease control rate; TACE, transarterial chemoembolization; NA, not available.

Conclusions Camrelizumab, combined with anti-angiogenic agents or chemotherapy, or monotherapy, demonstrated good efficacy and safety in treatment of PLC.

Trial Registration ChiCTR2000034264

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Ethics Approval This study was approved by China registered clinical trial ethics review committee with No. ChiECRCT20200042.

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