Clinical benefit of camrelizumab + rivoceranib in unresectable hepatocellular carcinoma patients with macrovascular invasion and extrahepatic spread, CARES-310

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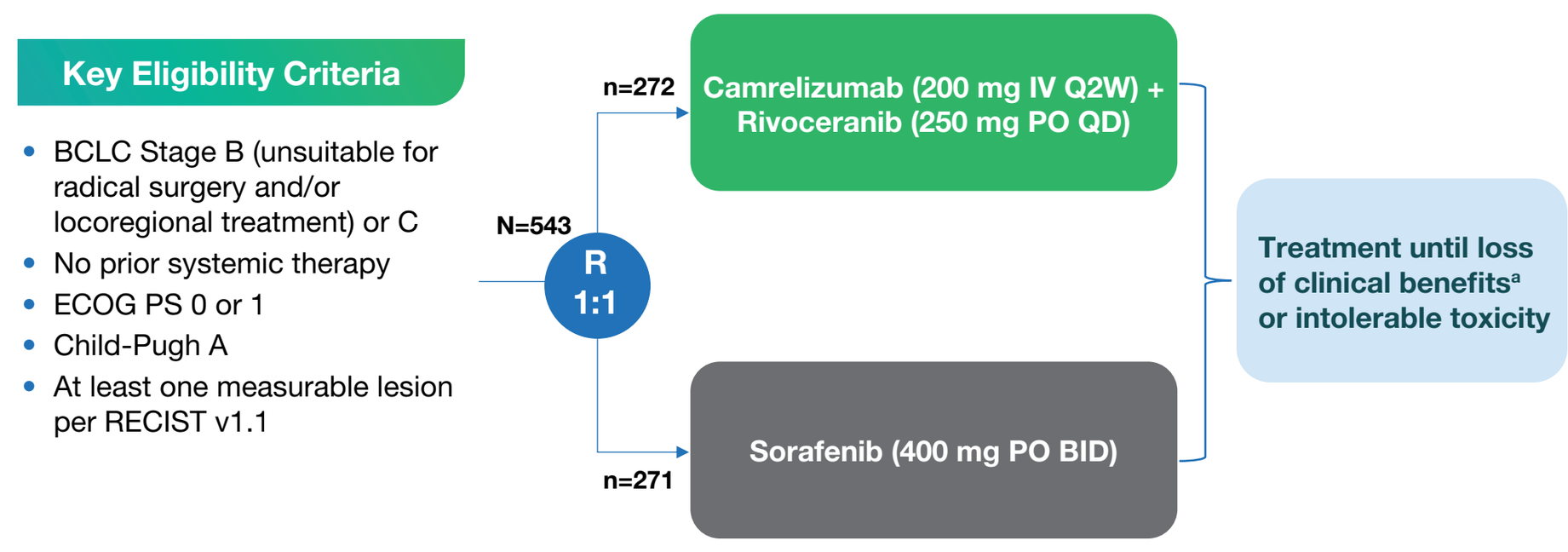
BACKGROUND

- CARES-310 (NCT03764293) compared the combination of the anti-programmed cell death protein-1 (PD-1) antibody camrelizumab plus the vascular endothelial growth factor receptor 2 (VEGFR2)-targeted tyrosine kinase inhibitor (TKI) rivoceranib versus sorafenib for the treatment of unresectable hepatocellular carcinoma (uHCC).[1]
- In the CARES-310 final analysis, camrelizumab plus rivoceranib showed clinically relevant improvement in median overall survival (mOS) and median progression-free survival (mPFS) compared with sorafenib (mOS, 23.8 months vs 15.2 months; HR, 0.64 [95% CI, 0.52, 0.79]; mPFS, 5.6 months vs 3.7 months; HR, 0.54 [95% CI, 0.44, 0.67]).[2]
- The most common (≥5%) grade 3-4 treatment-related adverse events (TRAEs) for camrelizumab plus rivoceranib were hypertension (38%) and increased aspartate aminotransferase (AST; 17%) vs palmar-plantar erythrodysesthesia syndrome (16%) for sorafenib.[2]
- Extrahepatic spread (EHS) is a marker of advanced HCC and is associated with poor prognosis.[3] Macrovascular invasion (MVI) predicts recurrence and correlates with reduced OS.[4]
- Therefore, we performed a post hoc exploratory analysis of the CARES-310 study evaluating the impact of the presence and absence of MVI and EHS on efficacy and safety outcomes.

METHODS

CARES-310 Study Design and Endpoints[1]



Stratification Factors
- MVI and/or EHS (yes vs no)
- Geographical region (Asia vs non-Asia)
- Baseline serum AFP (<400 vs ≥400 ng/mL)

Primary Endpoints
- PFS[b]
- OS

Key Secondary Endpoint
- ORR[b]

[a]Treatment beyond progression allowed if there was evidence of clinical benefits per investigator. [b]By BIRC per RECIST v1.1.
AFP, alpha-fetoprotein; BCLC, Barcelona Clinic Liver Cancer; BID, twice daily; BIRC, blinded independent review committee; ECOG PS, Eastern Cooperative Oncology Group performance status; EHS, extrahepatic spread; IV, intravenous; MVI, macrovascular invasion; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PO, by mouth; Q2W, every 2 weeks; QD, once daily; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

Post Hoc Analysis

- This post hoc analysis of the CARES-310 final data set evaluated efficacy (intention-to-treat population) and safety (safety population) in subgroups with presence and absence of MVI and EHS. mOS, PFS, duration of response, and time to progression were estimated with the Kaplan–Meier method, and confidence intervals (CIs) were calculated with the Brookmeyer and Crowley method.

RESULTS

- In patients with EHS, treatment with camrelizumab plus rivoceranib significantly improved mOS (HR, 0.54; 95% CI, 0.42, 0.70; *P*<0.0001) and mPFS (HR, 0.47; 95% CI, 0.37, 0.61; *P*<0.0001) compared with sorafenib (**Figures 1 and 5**). Among patients without EHS, treatment with camrelizumab plus rivoceranib significantly improved mPFS versus sorafenib (HR, 0.69; 95% CI, 0.48, 0.98; *P*=0.0197) (**Figure 6**).
- For patients with MVI, treatment with camrelizumab plus rivoceranib significantly improved mPFS compared with sorafenib (HR, 0.56; 95% CI, 0.34, 0.94; *P*=0.0133) (**Figure 7**). In those without MVI, treatment with camrelizumab plus rivoceranib significantly improved both mOS (HR, 0.67; 95% CI, 0.53, 0.85; *P*=0.0004) and mPFS (HR, 0.54; 95% CI, 0.43, 0.67; *P*<0.0001) versus sorafenib (**Figures 4 and 8**).
- TRAEs were similar across EHS and MVI subgroups. The most common (≥5%) grade 3-4 TRAE for camrelizumab + rivoceranib was increased AST and for sorafenib was palmar-plantar erythrodysesthesia syndrome (**Tables 5 and 6**).

RESULTS

Table 1: Baseline Characteristics by EHS Subgroup (ITT Population)

	EHS Presence		EHS Absence	
	Camrelizumab + Rivoceranib (n=175)	Sorafenib (n=180)	Camrelizumab + Rivoceranib (n=97)	Sorafenib (n=91)
Mean age, years	55.4	55.3	59.9	56.4
Male sex, n (%)	145 (82.9)	149 (82.8)	82 (84.5)	81 (89.0)
Geographic region, n (%)				
Asia[a]	146 (83.4)	150 (83.3)	79 (81.4)	74 (81.3)
Non-Asia[b]	29 (16.6)	30 (16.7)	18 (18.6)	17 (18.7)
ECOG PS, n (%)				
0	73 (41.7)	74 (41.1)	47 (48.5)	42 (46.2)
1	102 (58.3)	106 (58.9)	50 (51.5)	49 (53.8)
BCLC Stage, n (%)				
B (Middle Stage)	0	0	38 (39.2)	40 (44.0)
C (Advanced Stage)	175 (100.0)	180 (100.0)	59 (60.8)	51 (56.0)
Child-Pugh Score, n (%)				
A5	154 (88.0)	148 (82.2)	82 (84.5)	82 (90.1)
A6	21 (12.0)	32 (17.8)	15 (15.5)	9 (9.9)
ALBI Grade, n (%)				
Grade 1	135 (77.1)	136 (75.6)	65 (67.0)	72 (79.1)
Grade 2	40 (22.9)	44 (24.4)	32 (33.0)	19 (20.9)
Grade 3	0	0	0	0
MVI, n (%)				
Presence	15 (8.6)	32 (17.8)	25 (25.8)	20 (22.0)
Absence	160 (91.4)	148 (82.2)	72 (74.2)	71 (78.0)
AFP, n (%)				
<400 ng/mL	116 (66.3)	115 (63.9)	60 (61.9)	56 (61.5)
≥400 ng/mL	59 (33.7)	65 (36.1)	37 (38.1)	35 (38.5)
HCC Etiology, n (%)				
HBV	131 (74.9)	129 (71.7)	77 (79.4)	68 (74.7)
HCV	14 (8.0)	18 (10.0)	8 (8.2)	11 (12.1)
Non-viral	30 (17.1)	33 (18.3)	12 (12.4)	12 (13.2)

[a]Includes mainland China, Hong Kong, Taiwan, and South Korea. [b]Includes Belgium, Italy, Germany, Poland, Russia, Spain, Turkey, Ukraine, and USA.
AFP, alpha-fetoprotein; ALBI, albumin-bilirubin; BCLC, Barcelona Clinic Liver Cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; EHS, extrahepatic spread; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; ITT, intent-to-treat; MVI, macrovascular invasion.

Table 2: Baseline Characteristics by MVI Subgroup (ITT Population)

	MVI Presence		MVI Absence	
	Camrelizumab + Rivoceranib (n=40)	Sorafenib (n=52)	Camrelizumab + Rivoceranib (n=232)	Sorafenib (n=219)
Mean age, years	58.6	54.4	56.7	56.0
Male sex, n (%)	35 (87.5)	43 (82.7)	192 (82.8)	187 (85.4)
Geographic region, n (%)				
Asia[a]	34 (85.0)	45 (86.5)	191 (82.3)	179 (81.7)
Non-Asia[b]	6 (15.0)	7 (13.5)	41 (17.7)	40 (18.3)
ECOG PS, n (%)				
0	14 (35.0)	17 (32.7)	106 (45.7)	99 (45.2)
1	26 (65.0)	35 (67.3)	126 (54.3)	120 (54.8)
BCLC Stage, n (%)				
B (Middle Stage)	0	0	38 (16.4)	40 (18.3)
C (Advanced Stage)	40 (100.0)	52 (100.0)	194 (83.6)	179 (81.7)
Child-Pugh Score, n (%)				
A5	33 (82.5)	43 (82.7)	203 (87.5)	187 (85.4)
A6	7 (17.5)	9 (17.3)	29 (12.5)	32 (14.6)
ALBI Grade, n (%)				
Grade 1	24 (60.0)	37 (71.2)	176 (75.9)	171 (78.1)
Grade 2	16 (40.0)	15 (28.8)	56 (24.1)	48 (21.9)
Grade 3	0	0	0	0
EHS, n (%)				
Presence	25 (62.5)	20 (38.5)	72 (31.0)	71 (32.4)
Absence	15 (37.5)	32 (61.5)	160 (69.0)	148 (67.6)
AFP, n (%)				
<400 ng/mL	20 (50.0)	20 (38.5)	156 (67.2)	151 (68.9)
≥400 ng/mL	20 (50.0)	32 (61.5)	76 (32.8)	68 (31.1)
HCC Etiology, n (%)				
HBV	30 (75.0)	38 (73.1)	178 (76.7)	159 (72.6)
HCV	3 (7.5)	6 (11.5)	19 (8.2)	23 (10.5)
Non-viral	7 (17.5)	8 (15.4)	35 (15.1)	37 (16.9)

[a]Includes mainland China, Hong Kong, Taiwan, and South Korea. [b]Includes Belgium, Italy, Germany, Poland, Russia, Spain, Turkey, Ukraine, and USA.
AFP, alpha-fetoprotein; ALBI, albumin-bilirubin; BCLC, Barcelona Clinic Liver Cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; EHS, extrahepatic spread; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; ITT, intent-to-treat; MVI, macrovascular invasion.

Table 3: Summary of Response Rate by BIRC Assessment by EHS Subgroup (RECIST v1.1) (ITT Population)

	EHS Presence		EHS Absence	
	Camrelizumab + Rivoceranib (n=175)	Sorafenib (n=180)	Camrelizumab + Rivoceranib (n=97)	Sorafenib (n=91)
Best overall response, n (%)				
Complete response	3 (1.7)	1 (0.6)	2 (2.1)	1 (1.1)
Partial response	48 (27.4)	12 (6.7)	20 (20.6)	2 (2.2)
Stable disease	84 (48.0)	80 (44.4)	55 (56.7)	49 (53.8)
Progressive disease	28 (16.0)	67 (37.2)	17 (17.5)	33 (36.3)
Not evaluable	12 (6.9)	20 (11.1)	3 (3.1)	6 (6.6)
Objective response rate, n (%) [95% CI][a]	51 (29.1) [22.5, 36.5]	13 (7.2) [3.9, 12.0]	22 (22.7) [14.8, 32.3]	3 (3.3) [0.7, 9.3]
Difference [95% CI][b] in ORR (vs sorafenib)	21.9 [14.2, 29.6]		19.4 [10.3, 28.5]	
P value[c]	<0.0001		<0.0001	
Disease control rate[d], n (%) [95% CI][a]	135 (77.1) [70.2, 83.1]	93 (51.7) [44.1, 59.2]	77 (79.4) [70.0, 86.9]	52 (57.1) [46.3, 67.5]
Difference [95% CI][b] in DCR (vs sorafenib)	25.5 [15.9, 35.1]		22.2 [9.3, 35.2]	
P value[c]	<0.0001		0.0003	
Median duration of response, months [95% CI][e]	NR [14.8, NR]	8.3 [3.7, 14.8]	8.4 [5.6, 21.5]	NR
Median time to response, months	1.9	2.7	2.0	3.8
Median time to progression, months [95% CI][e]	6.3 [5.5, 9.2]	3.7 [2.8, 3.7]	7.2 [5.6, 9.2]	3.7 [1.9, 5.5]

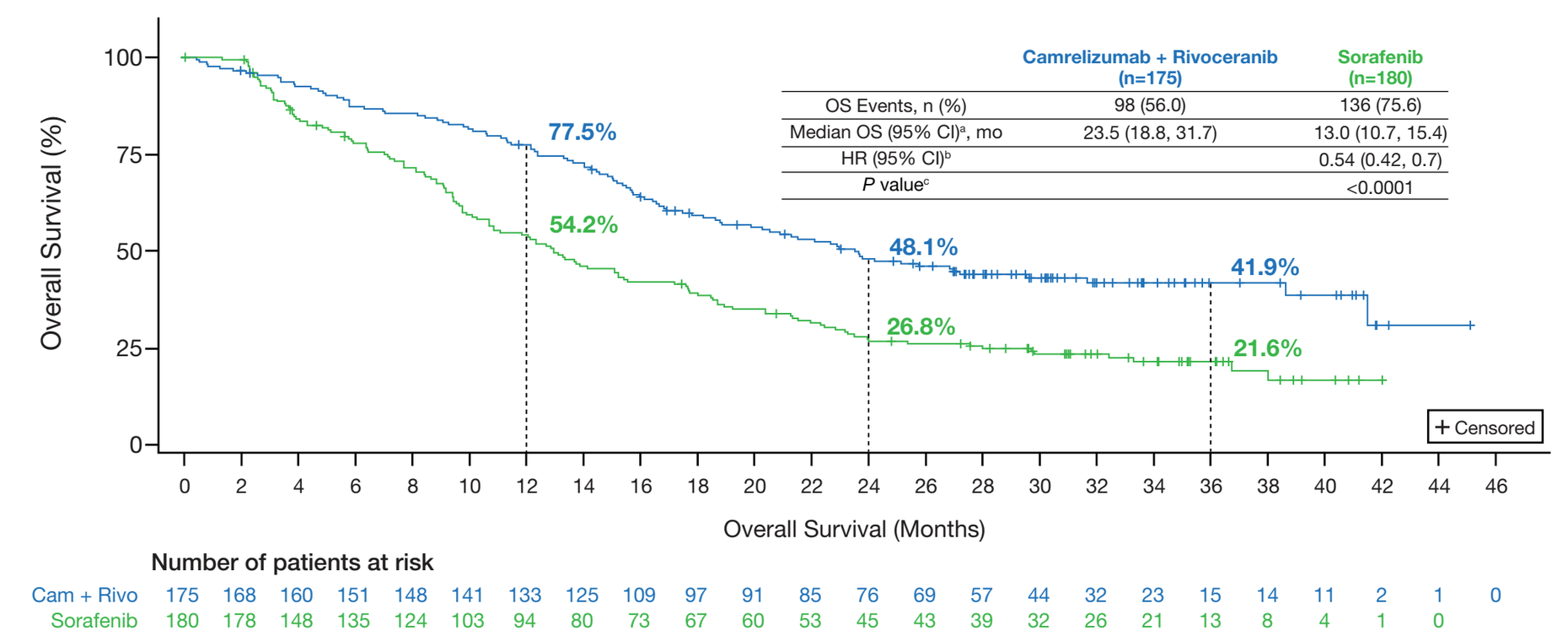
[a]95% CI is calculated using Clopper–Pearson method; [b]95% CI is calculated using normal approximation in binomial proportions; [c]*P* value (one-sided) is calculated using Cochran–Mantel–Haenszel test stratified by randomization stratification factors; [d]Disease control rate is defined as the percentage of patients with complete response, partial response, or stable disease ≥7 weeks; [e]95% CI is calculated using Brookmeyer and Crowley method.
BIRC, blinded independent review committee; DCR, disease control rate; EHS, extrahepatic spread; ITT, intent-to-treat; NR, not reached; ORR, objective response rate; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

Table 4: Summary of Response Rate by BIRC Assessment by MVI Subgroup (RECIST v1.1) (ITT Population)

	MVI Presence		MVI Absence	
	Camrelizumab + Rivoceranib (n=40)	Sorafenib (n=52)	Camrelizumab + Rivoceranib (n=232)	Sorafenib (n=219)
Best overall response, n (%)				
Complete response	0	0	5 (2.2)	2 (0.9)
Partial response	9 (22.5)	1 (1.9)	59 (25.4)	13 (5.9)
Stable disease	19 (47.5)	24 (46.2)	120 (51.7)	105 (47.9)
Progressive disease	8 (20.0)	21 (40.4)	37 (15.9)	79 (36.1)
Not evaluable	4 (10.0)	6 (11.5)	11 (4.7)	20 (9.1)
Objective response rate, n (%) [95% CI][a]	9 (22.5) [10.8, 38.5]	1 (1.9) [0.0, 10.3]	64 (27.6) [21.9, 33.8]	15 (6.8) [3.9, 11.0]
Difference [95% CI][b] in ORR (vs sorafenib)	20.6 [7.1, 34.0]		20.7 [14.1, 27.4]	
P value[c]	0.0013		<0.0001	
Disease control rate[d], n (%) [95% CI][a]	28 (70.0) [53.5, 83.4]	25 (48.1) [34.0, 62.4]	184 (79.3) [73.5, 84.3]	120 (54.8) [47.9, 61.5]
Difference [95% CI][b] in DCR (vs sorafenib)	21.9 [2.3, 41.6]		24.5 [16.1, 32.9]	
P value[c]	0.0518		<0.0001	
Median duration of response, months [95% CI][e]	8.4 [3.4, NR]	9.2 [NR, NR]	17.5 [10.1, NR]	9.2 [5.3, NR]
Median time to response, months	1.9	1.8	2.0	3.7
Median time to progression, months [95% CI][e]	6.2 [3.8, 9.2]	3.7 [1.9, 4.6]	7.3 [5.6, 9.1]	3.7 [3.6, 3.8]

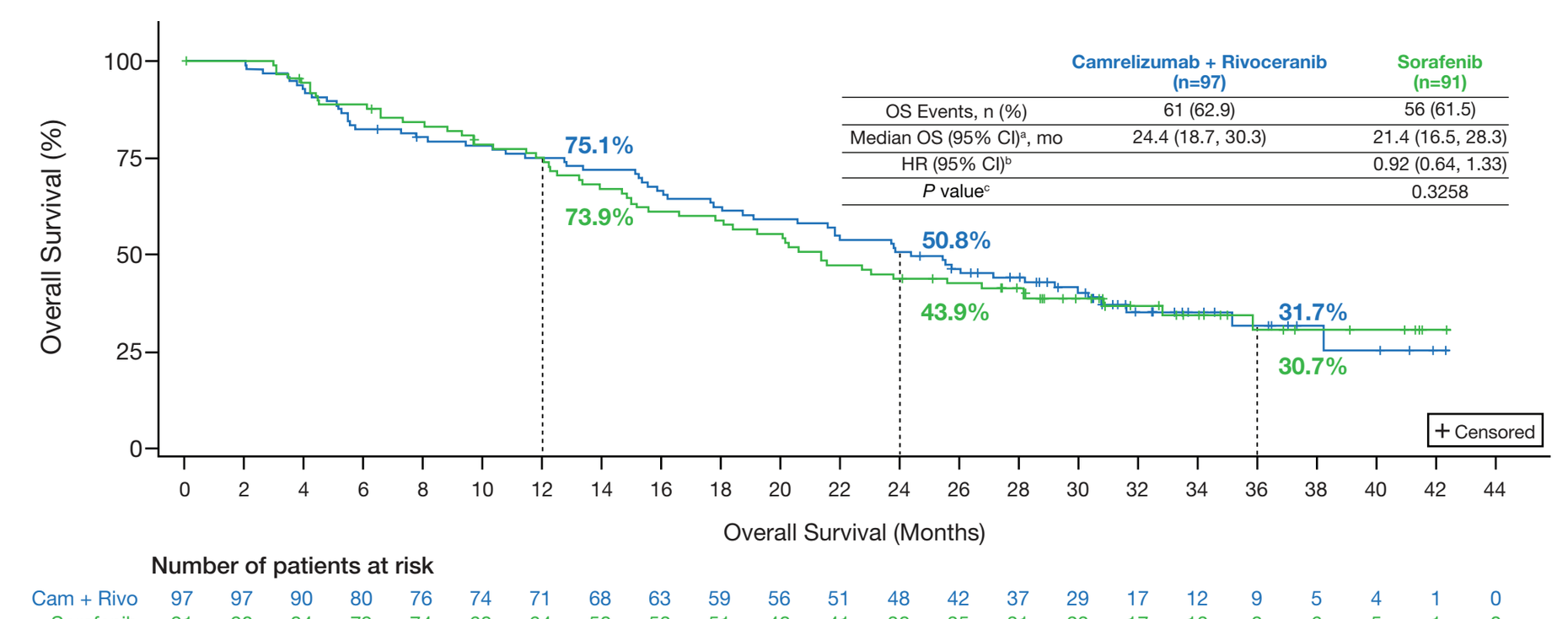
[a]95% CI is calculated using Clopper–Pearson method; [b]95% CI is calculated using normal approximation in binomial proportions; [c]*P* value (one-sided) is calculated using Cochran–Mantel–Haenszel test stratified by randomization stratification factors; [d]Disease control rate is defined as the percentage of patients with complete response, partial response, or stable disease ≥7 weeks; [e]95% CI is calculated using Brookmeyer and Crowley method.
BIRC, blinded independent review committee; DCR, disease control rate; ITT, intent-to-treat; MVI, macrovascular invasion; NR, not reached; ORR, objective response rate; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

Figure 1: Overall Survival for Patients With EHS



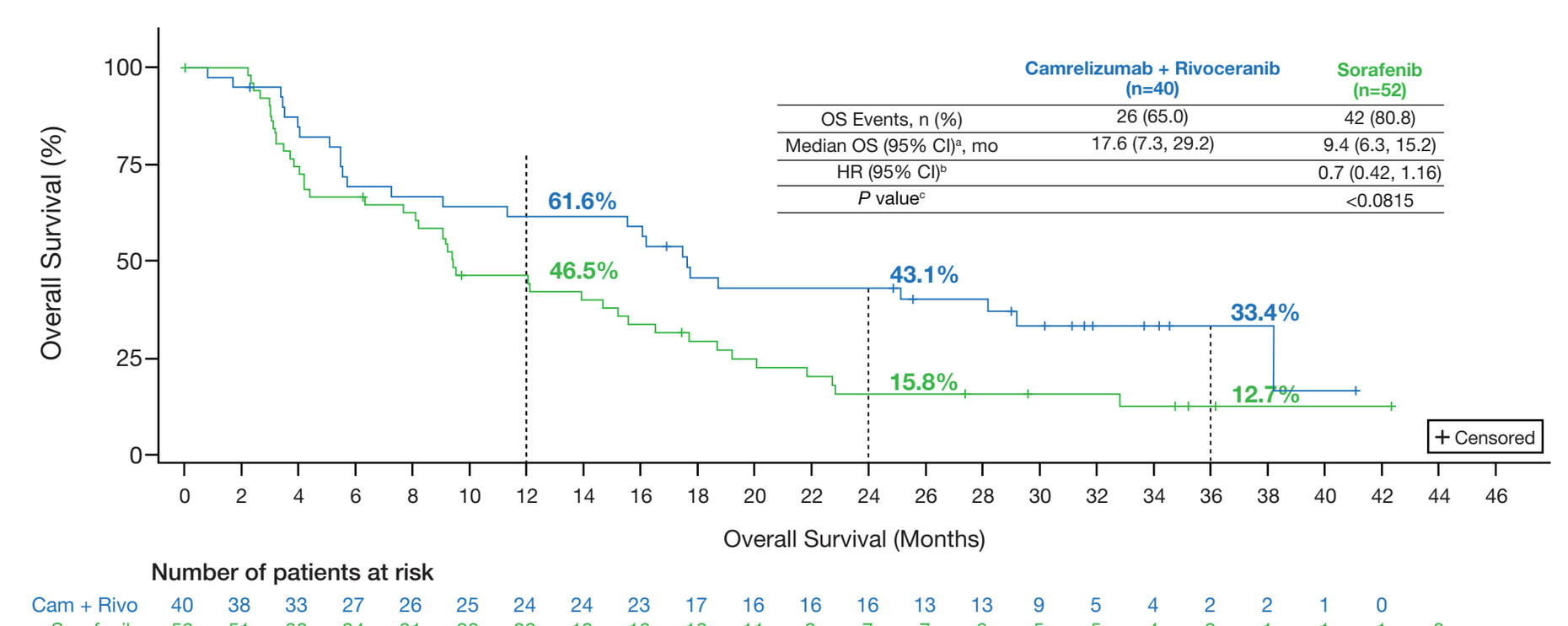
[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; OS, overall survival; Rivo, rivoceranib.

Figure 2: Overall Survival for Patients Without EHS



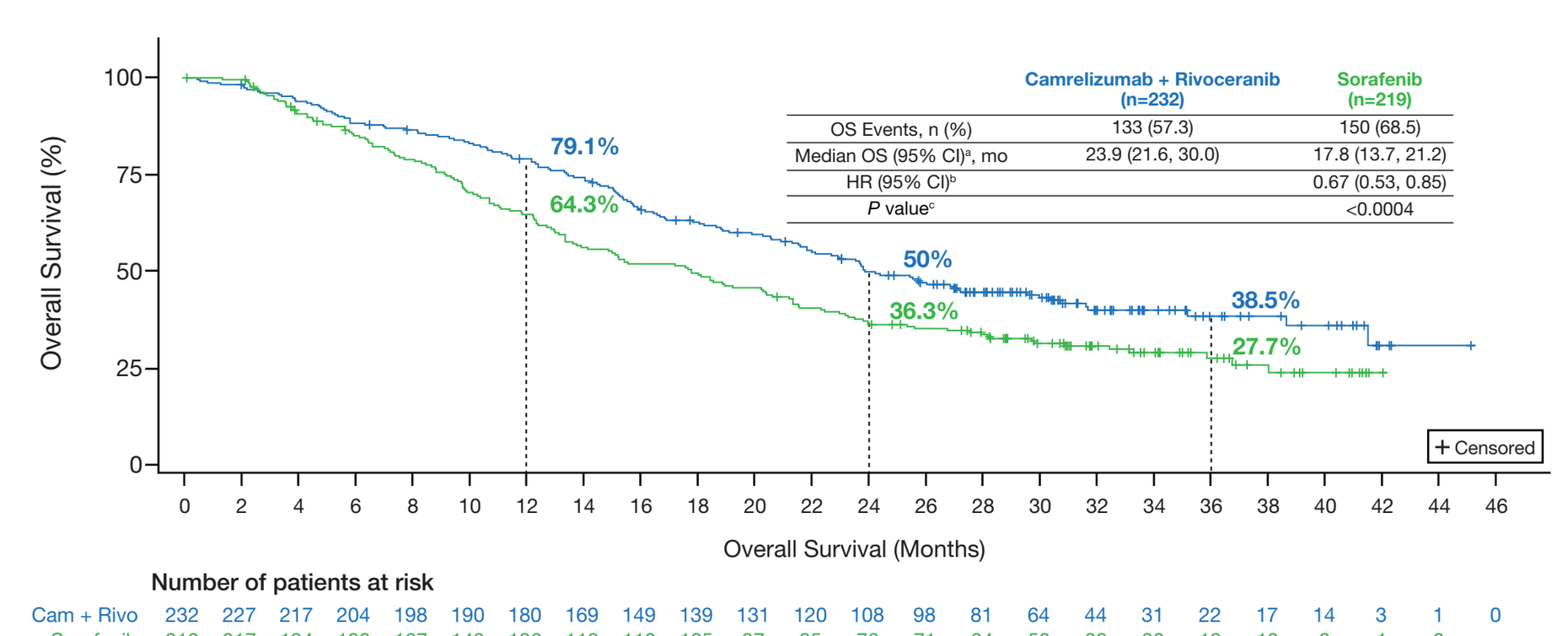
[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; OS, overall survival; Rivo, rivoceranib.

Figure 3: Overall Survival for Patients With MVI



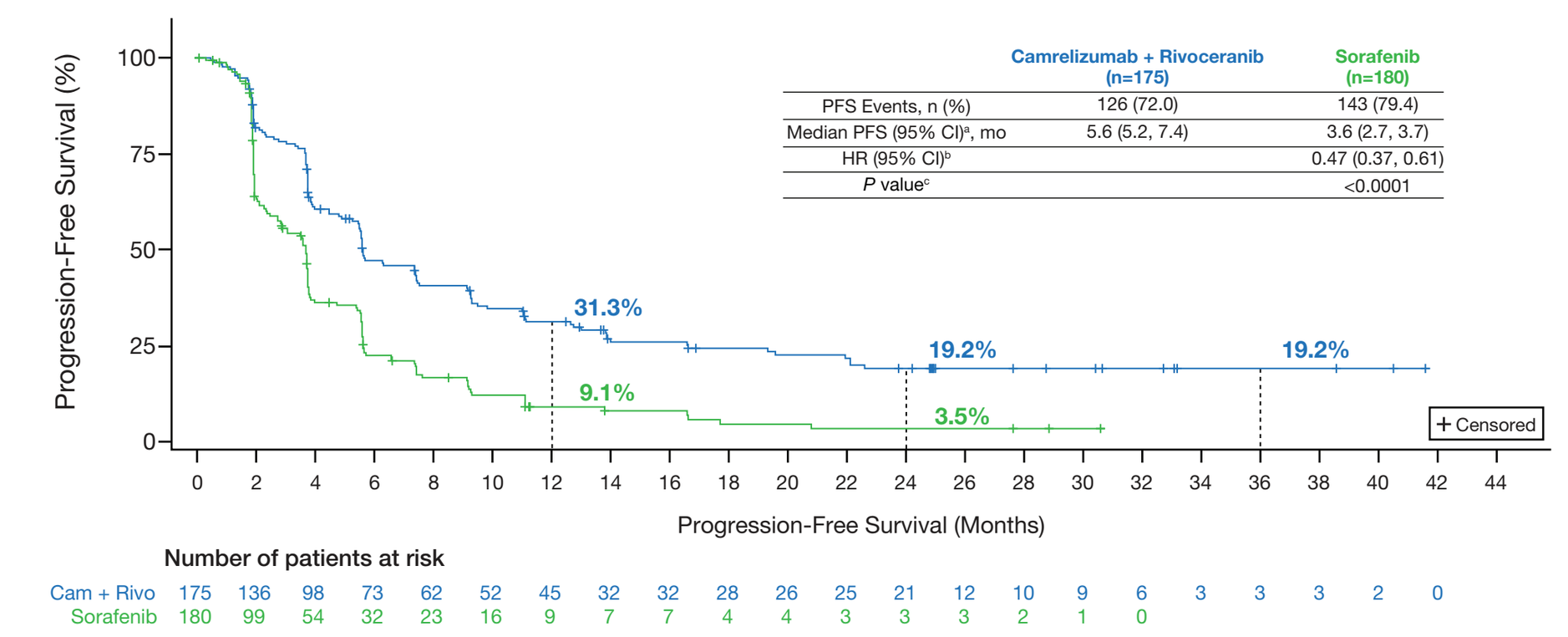
[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; OS, overall survival; Rivo, rivoceranib.

Figure 4: Overall Survival for Patients Without MVI



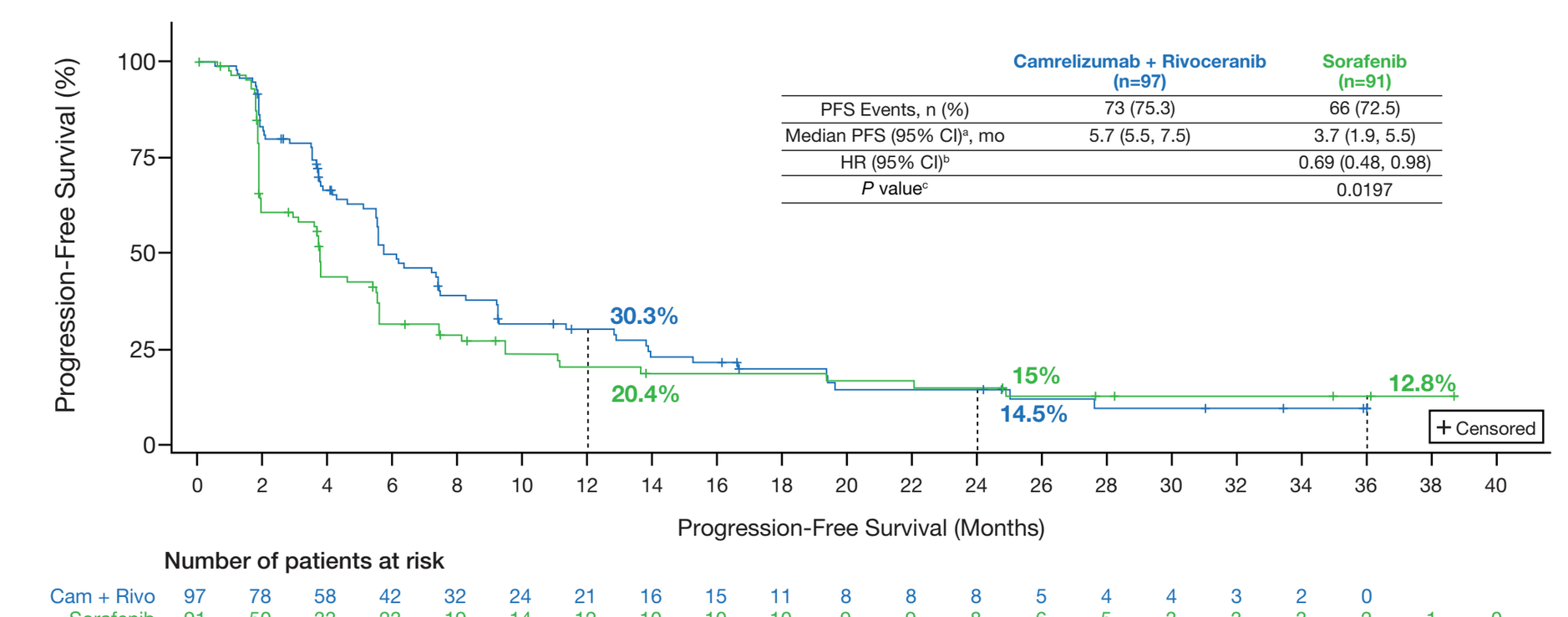
[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; OS, overall survival; Rivo, rivoceranib.

Figure 5: Progression-Free Survival for Patients With EHS



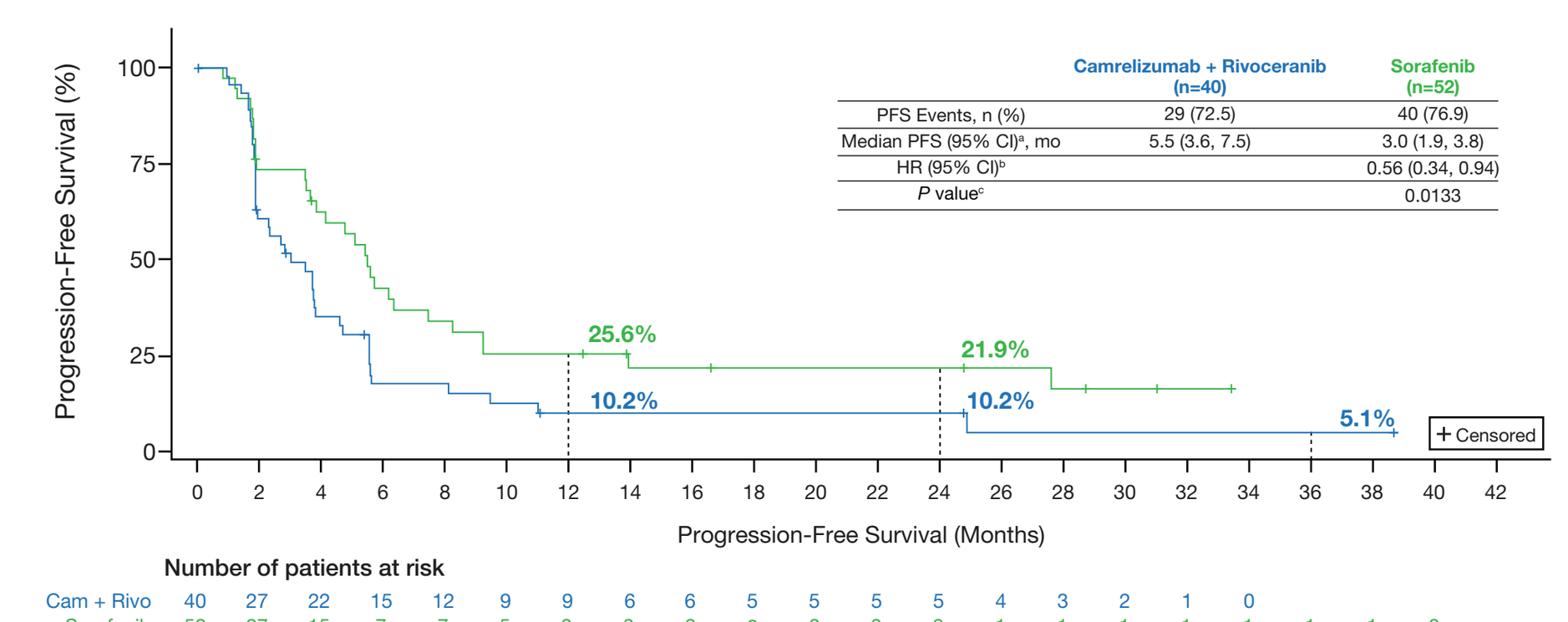
[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; PFS, progression-free survival; Rivo, rivoceranib.

Figure 6: Progression-Free Survival for Patients Without EHS



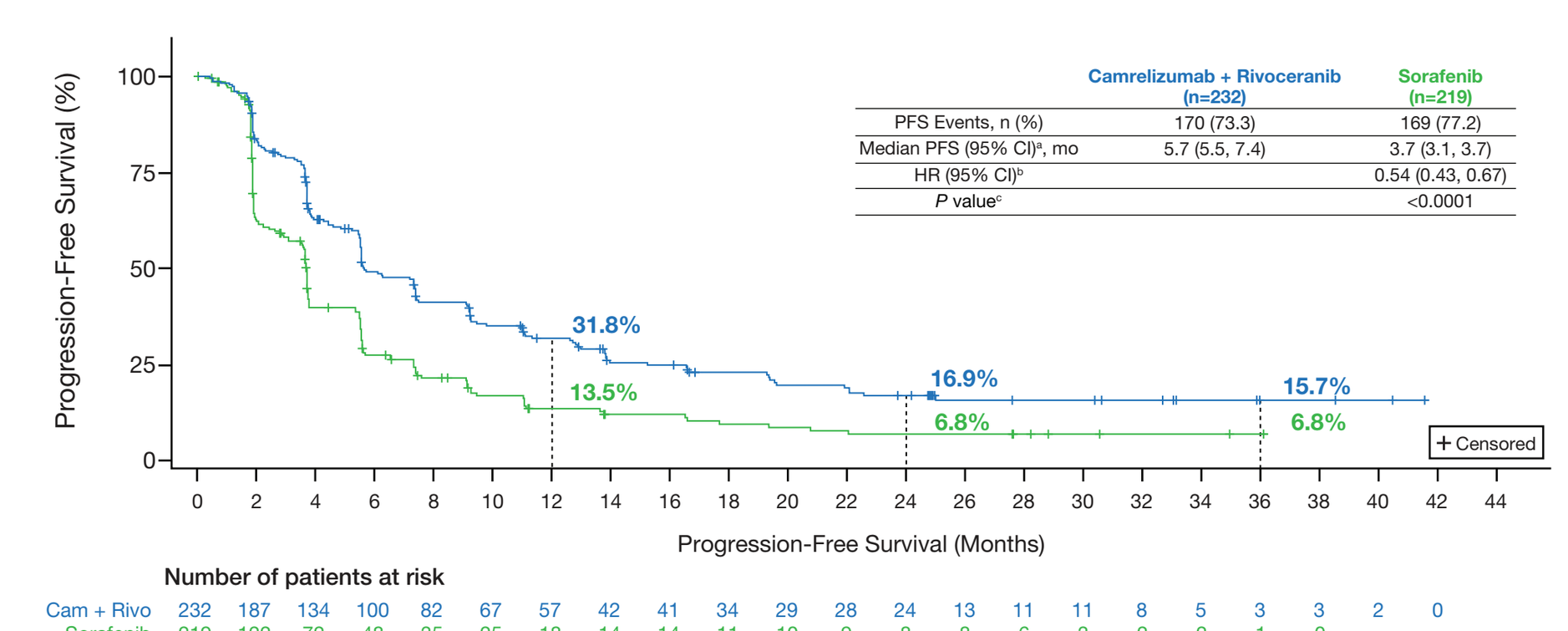
[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; PFS, progression-free survival; Rivo, rivoceranib.

Figure 7: Progression-Free Survival for Patients With MVI



[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; PFS, progression-free survival; Rivo, rivoceranib.

Figure 8: Progression-Free Survival for Patients Without MVI



[a]Medians were estimated using the Kaplan–Meier method with CIs calculated using Brookmeyer and Crowley method.
[b]Hazard ratios and the corresponding 95% CIs were stratified by geographical region (Asia vs countries outside of Asia) and baseline AFP (AFP <400 ng/mL vs AFP ≥400 mg/mL) in the interactive response technology system.
[c]*P* value (one-sided) is calculated based on log-rank test.
AFP, alpha-fetoprotein; Cam, camrelizumab; EHS, extrahepatic spread, mo, month; PFS, progression-free survival; Rivo, rivoceranib.

Table 5: Most Common (≥20%) Any Grade or (≥5%) Grade 3-4 TRAEs in Either Treatment Arm by EHS Subgroup (Safety Population)

	EHS Presence				EHS Absence			
	Camrelizumab + Rivoceranib (n=175)		Sorafenib (n=179)		Camrelizumab + Rivoceranib (n=97)		Sorafenib (n=90)	
TRAE, n (%)	Any Grade	Grade 3-4	Any Grade	Grade 3-4	Any Grade	Grade 3-4	Any Grade	Grade 3-4
AST increased	75 (42.9)	22 (12.6)	65 (36.3)	7 (3.9)	37 (38.1)	14 (14.4)	36 (40.0)	7 (7.8)
ALT increased	64 (36.6)	20 (11.4)	49 (27.4)	4 (2.2)	29 (29.9)	8 (8.2)	32 (35.6)	4 (4.4)
Platelet count decreased	50 (28.6)	10 (5.7)	58 (32.4)	3 (1.7)	34 (35.1)	15 (15.5)	32 (35.6)	1 (1.1)
Blood bilirubin increased	49 (28.0)	6 (3.4)	47 (26.3)	3 (1.7)	34 (35.1)	9 (9.3)	28 (31.1)	1 (1.1)
Proteinuria	41 (23.4)	4 (2.3)	47 (26.3)	3 (1.7)	16 (16.5)	2 (2.1)	26 (28.9)	2 (2.2)
Neutrophil count decreased	32 (18.3)	8 (4.6)	18 (10.1)	2 (1.1)	18 (18.6)	5 (5.2)	10 (11.1)	1 (1.1)
WBC decreased	32 (18.3)	3 (1.7)	23 (12.8)	4 (2.2)	20 (20.6)	2 (2.1)	15 (16.7)	0
GGT increased	27 (15.4)	10 (5.7)	31 (17.3)	11 (6.1)	21 (21.6)	11 (11.3)	18 (20.0)	8 (8.9)
Diarrhea	23 (13.1)	1 (0.6)	60 (33.5)	7 (3.9)	17 (17.5)	0	46 (51.1)	7 (7.8)
Bilirubin conjugated increased	22 (12.6)	4 (2.3)	23 (12.8)	6 (3.4)	17 (17.5)	6 (6.2)	13 (14.4)	2 (2.2)
Hypertension	16 (9.1)	6 (3.4)	74 (41.3)	28 (15.6)	8 (8.2)	3 (3.1)	43 (47.8)	12 (13.3)
Hypophosphatemia	10 (5.7)	2 (1.1)	26 (14.5)	9 (5.0)	6 (6.2)	0	14 (15.6)	3 (3.3)
Palmar-plantar erythro-dysesthesia syndrome	5 (2.9)	1 (0.6)	104 (58.1)	29 (16.2)	4 (4.1)	2 (2.1)	60 (66.7)	13 (14.4)
Alopecia	0	NR	36 (20.1)	NR	1 (1.0)	NR	16 (17.8)	NR

ALT, alanine aminotransferase; AST, aspartate aminotransferase; EHS, extrahepatic spread; GGT, gamma-glutamyl transferase; NR, not reported; TRAE, treatment-related adverse event; WBC, white blood cell.

Table 6: Most Common (≥20%) Any Grade or (≥5%) Grade 3-4 TRAEs in Either Treatment Arm by MVI Subgroup (Safety Population)

	MVI Presence				MVI Absence			
	Camrelizumab + Rivoceranib (n=40)		Sorafenib (n=51)		Camrelizumab + Rivoceranib (n=232)		Sorafenib (n=218)	
TRAE, n (%)	Any Grade	Grade 3-4	Any Grade	Grade 3-4	Any Grade	Grade 3-4	Any Grade	Grade 3-4
AST increased	12 (30.0)	3 (7.5)	20 (39.2)	7 (13.7)	100 (43.1)	33 (14.2)	81 (37.2)	7 (3.2)
GGT increased	4 (10.0)	3 (7.5)	8 (15.7)	5 (9.8)	44 (19.0)	18 (7.8)	41 (18.8)	14 (6.4)
ALT increased	11 (27.5)	2 (5.0)	15 (29.4)	4 (7.8)	82 (35.3)	26 (11.2)	66 (30.3)	4 (1.8)
Asthenia	8 (20.0)	1 (2.5)	1 (2.0)	0	NR	NR	NR	NR
Platelet count decreased	8 (20.0)	1 (2.5)	19 (37.3)	0	76 (32.8)	24 (10.3)	71 (32.6)	4 (1.8)
Proteinuria	8 (20.0)	0	14 (27.5)	2 (3.9)	49 (21.1)	6 (2.6)	59 (27.1)	3 (1.4)
Blood bilirubin increased	7 (17.5)	2 (5.0)	14 (27.5)	1 (2.0)	76 (32.8)	13 (5.6)	61 (28.0)	3 (1.4)
Diarrhea	5 (12.5)	0	15 (29.4)	2 (3.9)	35 (15.1)	1 (0.4)	91 (41.7)	12 (5.5)
Hypertension	3 (7.5)	0	20 (39.2)	8 (15.7)	21 (9.1)	9 (3.9)	97 (44.5)	32 (14.7)
Palmar-plantar erythro-dysesthesia syndrome	1 (2.5)	1 (2.5)	26 (51.0)	9 (17.6)	8 (3.4)	2 (0.9)	138 (63.3)	33 (15.1)
WBC count decreased	4 (10.0)	NR	10 (19.6)	NR	48 (20.7)	5 (2.2)	28 (12.8)	4 (1.8)
Alopecia	NR	NR	NR	NR	1 (0.4)	NR	47 (21.6)	NR
Neutrophil count decreased	5 (12.5)	1 (2.5)	6 (11.8)	1 (2.0)	45 (19.4)	12 (5.2)	22 (10.1)	2 (0.9)
Hypophosphatemia	2 (5.0)	NR	6 (11.8)	NR	14 (6.0)	2 (0.9)	34 (15.6)	12 (5.5)

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase; MVI, macrovascular invasion; NR, not reported; TRAE, treatment-related adverse event; WBC, white blood cell.

CONCLUSIONS

- Camrelizumab plus rivoceranib showed a consistent, clinically meaningful benefit with manageable AEs in the treatment of uHCC compared with sorafenib, regardless of MVI or EHS status.
- Among patients with EHS, those treated with camrelizumab plus rivoceranib had a mOS 10 months longer than those treated with sorafenib. Although EHS is typically associated with advanced disease and poor prognosis, mOS was similar in patients receiving camrelizumab plus rivoceranib regardless of EHS status. Additionally, patients with MVI treated with camrelizumab plus rivoceranib experienced markedly lower mOS compared with those without MVI. These findings support MVI as a marker of poor prognosis.
- Safety results showed that increased AST was the most common any grade TRAE, regardless of EHS or MVI presence or absence.

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