P089 Nivolumab in metastatic renal cell carcinoma (mRCC) patients with chronic hepatitis C virus (HCV) infection

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Introduction & Objectives: HCV interferes with activation of innate and adaptive immune responses. Theoretically, the effectiveness of immune checkpoint inhibitors in cancer patients infected with HCV may vary. Nevertheless, HCV has been an exclusion criteria for most checkpoint inhibitor trials. We evaluated the efficacy and safety of nivolumab in mRCC patients with or without chronic HCV infection.

Materials & Methods: In a case-control study data were collected retrospectively from 27 patient medical cases and 38 matched controls. Patients were required to have clear-cell mRCC, chronic HCV infection (case study group), no evidence of other malignancy or cirrhosis, and to have received nivolumab (3 mg/kg every 2 weeks) until disease progression or unacceptable toxicity. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), objective response rate (ORR) and rate of grade 3-4 adverse events (AEs) in study and control groups.

Results: A total of 44 matched patients were included. Groups were well-balanced (Table). HCV-infected patients had significantly longer OS and PFS. Despite no differences in ORR between groups, patients with HCV had more durable responses (P=0.01). Nivolumab was *well tolerated in all* HCV-infected patients (grade 3-4 toxicity was found in 5 of 27 cases (18.5%). No unexpected toxicity was observed.

	HCV-infected patients N=22	HCV-negative patients N=22	P-value
Age (years), mean (range)	62 (48-74)	63 (41-79)	-
Male, N (%)	16 (73)	16 (73)	-
IMDC poor risk factors, N (%) 0 1-2 ³3	 6 (27) 11 (50) 5 (23)	 6 (27) 11 (50) 5 (23)	-

Metastatic sites, N (%) 1 ³2	 4 (18) 18 (82)	 5 (23) 17 (77)	 -
Number of treatment lines before nivolumab, N (%) 1 2 3	 8 (36) 10 (46) 4 (18)	 8 (36) 13 (59) 1 (5)	 -
OS, median, months (95% CI)	27.5 (25.3-29.7)	21.7 (20.3-23.1)	0.005
PFS, median, months (95% CI)	7.5 (5.7-9.3)	4.9 (4-5.8)	0.013
ORR, N (%)	6 (27)	5 (23)	0.7
Grade 3-4 AEs, N (%)	5 (23)	3 (14)	0.45

Conclusions: The efficacy and safety profile observed in this study support the administration of nivolumab in mRCC patients infected with HCV and warrants further investigation.