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Phase I/II Safety and Antitumor Activity of Nivolumab in Patients with Advanced Hepatocellular Carcinoma (HCC): CA209-040 [Add to Collection](#)

Presented Saturday, May 30, 2015

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Authors:
 Anthony B. El-Khoueiry, Ignacio Meleró, Todd S. Crocenzi, Theodore Hobart Welling, Thomas Cheung Yau, Winnie Yeo, Akhil Chopra, Joseph Grosso, Lixin Lang, Jeffrey Anderson, Christine Marie Dela Cruz, Bruno Sangro; University of Southern California Norris Comprehensive Cancer Center, Los Angeles, CA; Clinica Universidad de Navarra and CIBERehd, Pamplona, Spain; Providence Cancer Center, Portland,...

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Abstract Disclosures

Background:
 Overexpression of PD-L1 in HCC has a poor prognosis. Safety and preliminary antitumor efficacy of nivolumab, a fully human IgG4 monoclonal antibody PD-1 inhibitor, was evaluated in a multiple ascending-dose, phase I/II study in patients (pts) with HCC.

Methods:
 Pts with histologically confirmed advanced HCC with Child-Pugh (CP) score \leq B7 and progressive disease (PD) on, intolerant of, or refusing sorafenib were enrolled. Dose escalation occurred in parallel cohorts based on etiology: no active hepatitis virus infection or virus-infected HCC pts. Pts received nivolumab 0.1 – 10 mg/kg intravenously for up to two years. The primary endpoint was safety. Secondary endpoints included antitumor activity using mRECIST criteria, pharmacokinetics, and Immunogenicity.

Results:
 The study has enrolled 41 pts with a CP score of 5 (n = 35) or 6 (n = 6), ECOG score of 0 (n = 26) or 1 (n = 15), 73% with extrahepatic metastasis and/or portal vein invasion, and 77% with prior sorafenib use. Eighteen pts remain on study, and 23 discontinued treatment due to PD (n = 17), complete response (CR; n = 2), drug-related adverse events (AEs; n = 2) and non-drug-related AEs (n = 2). Drug-related AEs of any grade occurred in 29 pts (71%; 17% grade 3/4), with \geq 10% of pts experiencing aspartate aminotransferase (AST) increase and rash (each 17%), alanine aminotransferase (ALT) and lipase increase (each 15%), and amylase increase (12%). Grade 3 and 4 AEs \geq 5% were AST increase (12%), ALT increase (10%) and lipase increase (5%). A dose-limiting toxicity occurred in an uninfected pt at 10 mg/kg; no maximum tolerated dose was defined in any cohort. Response was evaluable in 39 pts: 2 CR (5%) and 7 partial responses (PR; 18%). Response duration was 14–17+ months for CR, < 1–8+ months for PR, and 1.5–17+ months for stable disease (SD). Overall survival (OS) rate at 6 months is 72%.

Conclusions:
 Nivolumab has a manageable AE profile and produced durable responses across all dose levels and HCC cohorts, with a favorable 6-month OS rate. Updated safety, antitumor activity, and biomarker data will be presented. Clinical trial information: NCT01658878

Best overall response.

	Uninfected (n = 20)	Viral infected (n = 19)	Total (N = 39)
CR (n)	2	0	2
PR (n)	1	6	7
SD (n)	12	6	18
PD (n)	5	7	12

First Author: Anthony B. El-Khoueiry, MD

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