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Clinical and immunologic response of patients with advanced solid tumors vaccinated with an optimized cryptic hTERT peptide (Vx-001).

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Sub-category: Vaccines
Category: Developmental Therapeutics: Immunotherapy
Meeting: 2008 ASCO Annual Meeting

Abstract No: 3030
Citation: *J Clin Oncol* 26: 2008 (May 20 suppl; abstr 3030)
Author(s): A. Kotsakis, K. Vetsika, N. Christou, M. Drogaris, N. Pantazopoulos, D. Aggouraki, G. Konsolakis, K. Kosmatopoulos, D. Mavroudis, V. Georgoulias

Abstract:

Background: The clinical and immunologic efficacy of the optimized peptide $TERT_{572Y}$ (Vx-001) presented by HLA- A*0201 in patients with advanced malignancies was investigated. **Methods:** In the context of an expanded phase I-II study, 71 patients with advanced solid tumors (breast cancer n=10; NSCLC n=11; prostate cancer n=10; mCRC n=2; RCC n=6; pancreatic cancer/cholangiocarcinoma n=14; melanoma n=8; HCC n=3; others n=7) who had been previously treated with standard chemotherapy (disease status at enrollment: stable disease n=21 and progressive disease n=50) received two subcutaneous injections of 2 mg of the optimized $TERT_{572Y}$ peptide followed by four injections of 2 mg of the native $TERT_{572}$ peptide given every three weeks. The peptide-specific immune responses were assessed by interferon-γ Elispot at baseline, before the 3rd (early response) and after the 6th (late response) vaccination. Clinical outcome was evaluated after the 6th vaccination (based on RECIST criteria) and every three months thereafter for patients who did not progress. **Results:** Thirty-seven (52%) out of 71 patients completed the vaccination program. The main toxicity was grade 1 local skin reactions. An early and late immunologic response was detected in 29 of 56 (51.8%) and 25 of 30 (83%) evaluable patients, respectively. There were three (4.2%) objective clinical responses (HCC n=1; NSCLC n=2) and 22 (31%) disease stabilizations. All disease stabilizations occurred in early immunologically responding patients. Among the patients with PD before vaccination the median overall survival was 23.5 versus 7 months (p=0.056) in early immune responders versus non-responders, respectively, and was significantly higher in patients with late immunologic response (not reached) than in non-responding patients (9.5 months) (p=0.007). **Conclusions:** Vx-001 is a strongly immunogenic vaccine capable of inducing clinical responses in immunologically responding patients with progressive advanced solid tumors. Detailed and updated results will be presented at the meeting.

Abstract Disclosures

Associated Presentation(s):

1. **Clinical and immunologic response of patients with advanced solid tumors vaccinated with an optimized cryptic hTERT peptide (Vx-001).**
Meeting: 2008 ASCO Annual Meeting
Presenter: A. Kotsakis
Session: Developmental Therapeutics: Immunotherapy (Poster Discussion)
slides

Other Abstracts in this Sub-Category

1. **Clinical and immunologic responses to a novel in situ lymphoma vaccine maneuver: Preliminary results of a phase II trial of intra-tumoral CpG 7909.**
Meeting: 2008 ASCO Annual Meeting Abstract No: 3003 First Author: J. Brody**
Category: Developmental Therapeutics: Immunotherapy - Vaccines
2. **Correlation of effector and regulatory T cell responses with clinical outcome in metastatic renal cell carcinoma patients treated with MVA-5T4 vaccine and high-dose interleukin-2.**
Meeting: 2008 ASCO Annual Meeting Abstract No: 3004 First Author: H. L. Kaufman
Category: Developmental Therapeutics: Immunotherapy - Vaccines
3. **Overall survival (OS) analysis of a phase II study using a pox viral-based vaccine, PSA-TRICOM, in the treatment of metastatic, castrate-resistant prostate cancer (mCRPC): Implications for clinical trial design.**
Meeting: 2008 ASCO Annual Meeting Abstract No: 3005 First Author: R. A. Madan
Category: Developmental Therapeutics: Immunotherapy - Vaccines

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Abstracts by A. Kotsakis

1. **Clinical and immunologic response of patients with advanced solid tumors vaccinated with an optimized cryptic hTERT peptide (Vx-001).**
Meeting: 2008 ASCO Annual Meeting Abstract No: 3030 First Author: A. Kotsakis
Category: Developmental Therapeutics: Immunotherapy - Vaccines
2. **Cetuximab plus bevacizumab in patients (pts) with metastatic colorectal cancer (mCRC) who have failed on irinotecan, oxaliplatin and fluoropyrimidines-based chemotherapy.**
Meeting: 2007 ASCO Annual Meeting Abstract No: 14576 First Author: J. Souglakos
Category: Gastrointestinal (Colorectal) Cancer - Colorectal Cancer (including liver metastases)
3. **Phase III randomized study of oral vinorelbine (oV) and gemcitabine (G) (oVG) versus docetaxel (D) and gemcitabine (DG) as first-line treatment of patients with advanced non-small cell lung cancer (NSCLC): A preliminary report.**
Meeting: 2007 ASCO Annual Meeting Abstract No: 7538 First Author: S. Agelaki
Category: Lung Cancer - Non-Small Cell Lung Cancer

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