



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

Sub-category: [Vaccines](#)

Category: Developmental Therapeutics: Immunotherapy

Meeting: [2008 ASCO Annual Meeting](#)

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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 TERT₅₇₂ 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):

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