







Abstract CT012: Personalized neoantigen vaccine with or without pembrolizumab in patients with microsatellitestable metastatic colorectal cancer FREE

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Cancer Res (2025) 85 (8_Supplement_2): CT012.

https://doi.org/10.1158/1538-7445.AM2025-CT012

Abstract

Background:

Novel immune strategies are needed to improve outcomes in patients (pts) with microsatellitestable metastatic colorectal cancer (MSS mCRC). Our personalized peptide vaccine platform termed NeoAg-VAX - targets up to 10 tumor-derived neoantigens per pt. We hypothesize that this vaccine combined with anti-PD-1 can enhance antitumor immunity and revert the cold status of the MSS CRC tumor microenvironment (TME).

Methods:

This is a single-center, non-randomized, open-label, investigator-led pilot study of NeoAg-VAX +/- pembrolizumab (pembro) in MSS mCRC pts. Tumor antigens were selected based on predicted HLA-binding affinity using whole-exome/RNA sequencing and tandem mass spectrometry with bioinformatics tools. Key eligibility criteria: biopsiable disease, ≥ 1 line of standard therapy, ECOG 0-1. Cohort A: NeoAg-VAX alone. Cohort B: NeoAg-VAX + pembro 200 mg IV Q3W. Vaccines were given subcutaneously with topical imiquimod adjuvant on weeks 0, 1, 3-6, 9, 12, 15, 18, 21, 27, 30, 39, and 51. Primary endpoints: feasibility, toxicity. Secondary endpoints: ORR, PFS, 12-week PFS rate, T cell response by IFNy ELISPOT. Spatial proteomic analysis of TME immune features was performed using imaging mass cytometry (IMC) of pretreatment tumors.

Results:

SA total pf-248 ots nyerre treated with NeoAg-VAX +/- pembro (Cohort A: n=13, Cohort B: n=15). Of note, 8 pts from Cohort A were sequentially retreated in Cohort B. In 24 of 28 pts, NeoAg-VAX was manufactured within 12 weeks of enrollment with at least 1 dose given, indicating a feasibility rate of 85.7%. Most treatment-emergent adverse events were grade 1-2 in severity,



responses with a median 5.9-fold increase (range: 1.3-18.1) compared to baseline. IMC of pretreatment tumors (n=9) revealed heterogeneity in immune cell composition across different metastatic sites (6 lung, 2 liver, 1 ovary). Neighborhood analysis revealed shorter distances between T cells and tumor cells as well as longer distances between myeloid cells and tumor cells in lung vs liver mets. Lastly, there was a positive correlation between the magnitude of vaccine-induced T cell response and density of intratumor T cells (r=0.72, p=0.043), B cells (r=0.88, p=0.0043) and macrophages (r=0.72, p=0.044) at baseline.

Conclusions:

Personalized immunotherapy with NeoAg-VAX +/- anti-PD-1 was feasible, safe, and immunogenic in MSS mCRC pts. Although clinical responses were modest, spatial proteomics revealed key features of tumor immune contexture that may inform future therapeutic approaches.

Citation Format:

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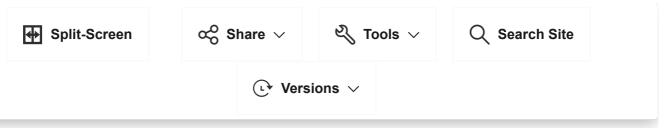
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