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

Saurav Daniel Haldar; Gayathri Anandappa; Arjun Katailiha; Amjad Talukder; Sarah Shin; Jae Lee; Erin Coyne; Alens Valentin; Sapna Parshottam; Chantale Bernatchez; Jane Thomas; Jason Roszik; Anirban Maitra; Scott Kopetz; Elizabeth Jaffee; Won Jin Ho; Gregory Lizee; Michael Overman

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Abstract

Background:

Novel immune strategies are needed to improve outcomes in patients (pts) with microsatellite-stable 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 IFNγ ELISPOT. Spatial proteomic analysis of TME immune features was performed using imaging mass cytometry (IMC) of pre-treatment tumors.

Results:

A total of 28 pts were 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,

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responses with a median 5.9-fold increase (range: 1.3-18.1) compared to baseline. IMC of pre-treatment 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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