

Meeting Abstract: 2021 ASCO Annual Meeting I

FREE ACCESS | Gastrointestinal Cancer—Colorectal and Anal | May 28, 2021

A phase II trial of pembrolizumab and poly-ICLC in patients with metastatic mismatch repair-proficient colon cancer.

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3

Abstract

e15552

Background: Single agent programmed cell death protein 1 (PD1) inhibitor is ineffective against mismatch repair proficient (MMRp) colon cancer with response rates in single digits. Polyinosinic-Polycytidylic (Poly-ICLC) is a synthetic double stranded ribonucleic acid that generates inflammatory response increasing epitope recognition, develops tumor reactive T cells and induces interferon production which increases PD-L1 expression. In this trial, we test the effectiveness of combination of poly-ICLC and pembrolizumab in MMRp metastatic colon cancer. **Methods:** In this open label, single arm, single institution, phase 2 study, we enrolled 12 MMRp metastatic colon cancer patients from 1/25/2019 to 2/10/2021. Eligible patients had histologically confirmed MMRp metastatic colon cancer, ECOG 1-2 and progression on at least 2 lines of therapy. Treatment (Tx) consisted of Pembrolizumab (200 mg q3 weeks) and poly-ICLC (2 mg twice weekly, 3 days apart) for 1 year of treatment. Tx continued until progression, discontinuation or withdrawal. The primary endpoint was objective response rate by RECIST 1.1. Secondary endpoints included duration of response, adverse event profiling, progression free survival (PFS) and overall survival (OS). Intention-to-treat analyses (ITT) included all patient receiving at least one dose of the study agent. **Results:** 12 patients with median age 68.5 years (range 54-75) and 33% (4/12) male had been enrolled till 2/10/2021. Objective response rate was 8.3% (1 patient had partial response). The duration of response was 196 days. Among these 12 patients, median PFS was 63.5 days and median OS was 196 days. Treatment related adverse events of any grade were reported in 12/12 (100%) patients with the most common toxicities being nausea, vomiting, anorexia, dehydration and dizziness. 3/12 (25%) had serious (grade ≥ 3) toxicities and one patient died after experiencing leukocytosis, dehydration and hyperbilirubinemia attributed to the trial drugs. **Conclusions:** Poly-ICLC was not effective in combination with pembrolizumab for MMRp metastatic colon cancer in 3rd line setting and it did not seem to improve response rates to immunotherapy. Novel strategies for stimulating immunogenicity of cold tumors are needed. [Clinical trial information: NCT02834052.](#)

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