



CURRENT ISSUE ✓ COLLECTIONS ✓ ABOUT ✓

SUBMIT

Meeting Abstract: 2021 Gastrointestinal Cancers Symposium

colorectal cancer (mCRC): Interim analysis.

ADVERTISEMENT

FREE ACCESS | Colorectal Cancer | January 22, 2021

Phase II study of pembrolizumab plus capecitabine and bevacizumab in microsatellite stable (MSS) metastatic

Authors: Andrea Grace Bocobo, Renee Wang, Spencer Behr, Julia C. Carnevale, Pelin Cinar, Eric Andrew Collisson, Lawrence Fong, ... SHOW ALL ..., and **AUTHORS INFO & AFFILIATIONS** Chloe Evelyn Atreya

Publication: Journal of Clinical Oncology • Volume 39, Number 3_suppl • https://doi.org/10.1200/JCO.2021.39.3_suppl.77

№ 13

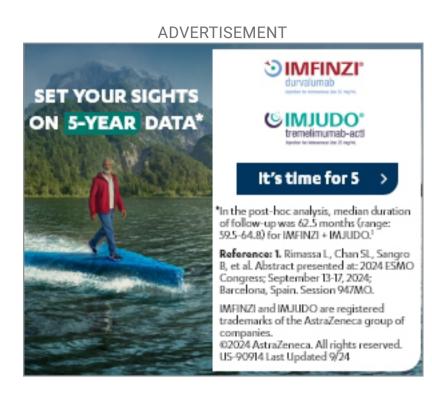








<





ASCO Career Center

Pediatric Neuro-Oncologist

Rochester, Minnesota (US) DOE

Mayo Clinic Children's is seeking a Pediatric Neuro-Oncologist to join the growing Division of Pediatric Hematology/Oncology. Mayo Clinic is an NC...

Employer: Mayo Clinic Apply for this job

Outpatient Hem/Onc | Idaho | Top 100 Hospital in Nation | 4 Day Week, 550K Base Idaho Competitive

Salary and Benefits Package

A Level-III Trauma Center

JACKSON

located in Northern Idaho are seeking a Hem/Onc physician to join their team of 3 Oncologists and 3 NP's. This hospital h...

Employer: Jackson Physician Search Apply for this job



Recommended Articles

GASTROINTESTINAL CANCER-COLORECTAL AND ANAL **JUNE 2022**

Phase II study of pembrolizumab plus capecitabine and bevacizumab in microsatellite stable (MSS) metastatic colorectal cancer (mCRC).

COLORECTAL CANCER FEBRUARY 2020

First-line durvalumab + monalizumab, mFOLFOX6, and bevacizumab or cetuximab for metastatic microsatellite-stable colorectal cancer (MSS-CRC).

COLORECTAL CANCER JANUARY 2025

Nelmastobart (hSTC810) combined with capecitabine therapy in metastatic colorectal cancer with resistance or intolerance to oxaliplatin and irinotecan-based chemotherapy: A phase 1b clinical trial.

COLORECTAL CANCER JANUARY 2022

A phase II study of pembrolizumab, binimetinib, and bevacizumab in patients with microsatellite-stable, refractory, metastatic colorectal cancer (mCRC).

COLORECTAL CANCER | JANUARY 2023

Trial in progress: A phase II, multicenter, open-label study of PolyPEPI1018 in combination with atezolizumab in participants with relapsed or refractory microsatellitestable metastatic colorectal (MSS mCRC) cancer (Oberto-301).

Abstract

77

Background: MSS mCRC rarely responds to pembrolizumab monotherapy, but capecitabine and bevacizumab may induce immune-stimulatory effects. This study evaluates the safety, tolerability and preliminary efficacy of pembrolizumab in combination with capecitabine and bevacizumab in MSS mCRC. We present results at the planned interim analysis. Methods: Design:single-arm, open-label, single-site phase 2 trial with a safety lead-in to confirm the recommended phase 2 dose (RP2D) for capecitabine and expansion cohorts. Per the Simon's 2-stage design, ≤1 response in 29 patients (pts) requires trial suspension. Key eligibility criteria: MSS mCRC with stable disease (SD) or progressive disease (PD) on prior fluoropyrimidine-based therapy. Treatment: RP2D PO capecitabine on days 1-14 plus 200 mg IV pembrolizumab and 7.5 mg/kg IV bevacizumab on day 1 in 21-day cycles. Pts are followed for toxicity and radiographic response. Results: From 04/2018-09/2020, 29 pts were enrolled, of whom 15 (52%) were female; 21 (72%) white; and median age was 55 years (range 36-77 years). Prior therapies: 2 (7%) pts had SD and 27 (93%) pts had PD on fluoropyrimidine-containing regimens; 24 (83%) pts had prior exposure to bevacizumab. The RP2D for capecitabine was 1000 mg/m2 PO BID, with no dose limiting toxicities observed. Complete toxicity data are available for 25 offtreatment pts. The most common related adverse events (AEs) were palmar-plantar erythrodysesthesia (PPE) (64%) and fatigue (68%). Grade ≥3 related AEs occurred in 9 (36%) pts, including immune-related AEs of Grade 3 dyspnea, hypophosphatemia, and pancreatitis in 1 pt each. Treatment related AEs leading to dose interruptions, reductions, or delays occurred in 15 (60%) pts, most commonly PPE in 13 (52%) pts. No pt had a related AE leading to treatment discontinuation or death. Disposition: of 29 pts enrolled, 24 were removed for PD and 1 was removed for an unrelated AE. Best response by RECIST 1.1 in 23 evaluable pts: partial response (PR) in 2 (9%); SD in 14 (61%); PD in 7 (30%). Median time on treatment was 6 months (range 2-26 months). Conclusions: Combination of pembrolizumab with capecitabine and bevacizumab was found to be tolerable with an expected toxicity profile in MSS mCRC pts. With 2 responses, the study met interim analysis criteria to continue accrual. Tissue and blood-based immune correlatives are

This is an ASCO Meeting Abstract from the 2021 Gastrointestinal Cancers Symposium. This abstract does not include a full text component.

planned. Clinical trial information: NCT03396926.

JOURNALS Journal of Clinical Oncology JCO Oncology Practice JCO Global Oncology **JCO Clinical Cancer Informatics** JCO Precision Oncology

PUBLICATIONS ASCO Educational Book ASCO Daily News ASCO Connection The ASCO Post **ASCO Podcasts**

CONTENT **Journal Podcasts Topics** Meeting Abstracts **ASCO Guidelines**

INFORMATION Author Center Subscriber Center Permissions Reprints Advertise E-Alerts View My Profile **About ASCO Journals**

FOLLOW US JCO_ASCO JCOOP_ASCO JCOGO_ASCO JCOPO_ASCO JCOCCI_ASCO JCOOA_ASCO

JCO Oncology Advances

Contact Us

ASCO ASCO WEBSITES About ASCO asco.org **Press Center ASCO Career Center** Meetings & Education **Conquer Cancer**