A Study of Nivolumab-relatlimab Fixed-dose Combination Versus Regorafenib or TAS-102 in Participants With Later-lines of Metastatic Colorectal Cancer

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Histological confirmed previously treated colorectal cancer with adenocarcinoma histology with metastatic or recurrent unresectable disease at study entry

• Participants must have: 1. progressed during or within approximately 3 months following the last administration of approved standard therapies (at least 1, but not more than 4 prior lines of therapies), which must include a fluoropyrimidine, oxaliplatin, irinotecan, an anti-VEGF therapy, and anti-EGFR therapy (if KRAS wild-type), if available in the respective country, or; 2. been intolerant to prior systemic chemotherapy regimens if there is documented evidence of clinically significant intolerance despite adequate supportive measures

• Must have sufficient tumor tissue & evaluable PD-L1 expression to meet the study requirements

• Must have measurable disease per RECIST v1.1. Participants with lesions in a previously irradiated field as the sole site of measurable disease will be permitted to enroll provided the lesion(s) have demonstrated clear progression and can be measured accurately

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Exclusion Criteria:

• Prior treatment with either an immunotherapy or with regorafenib or with TAS-102

• Untreated central nervous system (CNS) metastases, participants are eligible if CNS metastases have been treated and participants have neurologically returned to baseline (except for residual signs or symptoms related to the CNS treatment)

• History of refractory hypertension not controlled with anti-hypertensive therapy, myocarditis (regardless of etiology), uncontrolled arrhythmias, acute coronary syndrome within 6 months prior to dosing, Class II congestive heart failure (as per the New York Heart Association Functional Classification), interstitial lung disease/pneumonitis or an active, known or suspected autoimmune disease

• Confirmed tumor microsatellite instable high/deficient mismatch repair (MSI-H/dMMR) status as per local standard testing; MSI/MMR test results from initial diagnosis are acceptable. Other protocol-defined inclusion/exclusion criteria apply

Conditions & Interventions

Interventions:
Drug: Nivolumab-relatlimab FDC, Drug: Regorafenib, Drug: TAS-102
Conditions:
Colorectal Neoplasms
Keywords:
Micro-satellite Stable (MSS) Metastatic Colorectal Cancer (mCRC), Relatlimab, Nivolumab, BMS-986213, Regorafenib, Stivarga, Lonsurf

More Information

Contact(s): BMS Study Connect Contact Center www.BMSStudyConnect.com - Clinical.Trials@bms.com
Principal Investigator:
Phase: Phase 3
IRB
Number:
System ID: NCT05328908
