A Study of Amivantamab and FOLFIRI Versus Cetuximab/Bevacizumab and FOLFIRI in Participants With KRAS/NRAS and BRAF Wild-type Colorectal Cancer Who Have Previously Received Chemotherapy

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Have histologically or cytologically confirmed adenocarcinoma of the colon or rectum. Participants must have recurrent, unresectable or metastatic disease * Determined to have kirsten rat sarcoma viral oncogene/neuroblastoma RAS viral oncogene homolog (KRAS/NRAS), G12, G13 and v-raf murine sarcoma viral oncogene homolog B (BRAF) V600X (X represents any single amino acid change from the original amino acid) wild type status by local and/or central next-generation sequencing (NGS) testing * Must agree to the submission of fresh or archival tumor tissue post progression from the most recent therapy, if clinically feasible * Have measurable disease according to response evaluation criteria in solid tumors (RECIST) version (v) 1.1 * Have an eastern cooperative oncology group (ECOG) performance status (PS) of 0 or 1 * Participant must have received 1 line of systemic therapy (fluoropyrimidine-based and oxaliplatin-based) for metastatic colorectal cancer (mCRC), with documented radiographic disease progression on or after this line of therapy. Participants can receive anti-VEGF as prior line of therapy

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Exclusion Criteria:

* Has medical history of (noninfectious) interstitial lung disease (ILD) /pneumonitis/pulmonary fibrosis or has current ILD/pneumonitis/pulmonary fibrosis, or where suspected ILD/pneumonitis/pulmonary fibrosis cannot be ruled out by imaging at screening * Has known allergies, hypersensitivity, or intolerance to excipients of any of the following: amivantamab, cetuximab or bevacizumab or any component of FOLFIRI * Has a prior or concurrent second malignancy other than the disease under study or one whose natural history or treatment is likely to interfere with any study endpoints of safety or the efficacy of the study treatment(s) * Participant with known mismatch repair deficiency (dMMR)/ high microsatellite instability (MSI-H) status who has not received immunotherapy treatments * Participant with known human epidermal growth factor receptor 2 (HER2)- positive/amplified tumor * Has prior exposure to irinotecan, any agents that target epidermal growth factor receptor (EGFR) or mesenchymal epithelial transition (MET)

Conditions & Interventions

Interventions:
BIOLOGICAL: Amivantamab, BIOLOGICAL: Cetuximab, BIOLOGICAL: Bevacizumab, DRUG: 5-fluorouracil, DRUG: Leucovorin calcium/Levoleucovorin, DRUG: Irinotecan
Conditions:
Colorectal Neoplasms

More Information

Contact(s): Study Contact - Participate-In-This-Study1@its.jnj.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06750094
