

A Study of Amivantamab and mFOLFOX6 or FOLFIRI Versus Cetuximab and mFOLFOX6 or FOLFIRI as First-line Treatment in Participants With KRAS/NRAS and BRAF Wild-type Unresectable or Metastatic Left-sided Colorectal Cancer

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 left-sided colorectal cancer. Participants must have unresectable or metastatic disease * Determined to have Kirsten rat sarcoma viral oncogene (KRAS), neuroblastoma RAS viral oncogene homolog (NRAS), and v-raf murine sarcoma viral oncogene homolog B (BRAF) wild-type (WT) tumor by local and/or central testing (if available) * Must agree to the submission of fresh tumor tissue * Have measurable disease according to RECIST v1.1 * Have an eastern cooperative oncology group (ECOG) performance status (PS) of 0 or 1

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: (a) amivantamab or cetuximab, (b) any component of mFOLFOX6 and, (c) 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 and human epidermal growth factor receptor 2 (HER2)-positive/amplified tumor * Has prior exposure to any agents that target epidermal growth factor receptor (EGFR) or mesenchymal epithelial transition (MET)

Conditions & Interventions

Interventions:

BIOLOGICAL: Amivantamab, BIOLOGICAL: Cetuximab, DRUG: 5-fluorouracil, DRUG: Leucovorin calcium/Levoleucovorin, DRUG: Oxaliplatin, DRUG: Irinotecan Hydrochloride

Conditions:

Colorectal Neoplasms

More Information

Contact(s): Study Contact - Participate-In-This-Study1@its.jnj.com

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06662786

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