ForPatients
by Roche

Colorectal Cancer (CRC)

A Study to Evaluate the Efficacy and Safety of Inavolisib When Administered in Combination With Bevacizumab and FOLFOX or FOLFIRI as First Line Therapy in Participants With Colorectal Cancer

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07323576 2025-523014-84-00 WO46300

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Inavolisib With Bevacizumab Plus Folfox or Folfiri as First Line Therapy in Patients With PIK3CA-Mutated Metastatic Colorectal Cancer

Trial Summary:

This is a blinded Phase 2 study designed to evaluate the safety and efficacy of inavolisib with bevacizumab and chemotherapy, in participants with metastatic colorectal cancer (mCRC) whose tumors have a PIK3CA mutation. The study has a safety run-in period followed by a randomized period.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) <=1

- Histologically confirmed adenocarcinoma originating in the colon or rectum of the Stage 4 (treatment plan does not include resection or curative ablation) per American Joint Committee on Cancer (AJCC) v8
- Measurable disease per RECIST v1.1
- No prior systemic therapy in the metastatic setting
- Confirmation of biomarker eligibility: documentation of a PIK3CA mutation from either central testing of tissue, or from a validated historically obtained (pre-existing) test of tumor tissue or blood may be used to confirm eligibility
- Adequate hematologic and organ function within 14 days prior to initiation of study treatment
- Agreement to adhere to the contraception requirements

Exclusion Criteria:

- Biomarker eligibility as per definition
- Type 2 diabetes requiring ongoing systemic treatment at the time of study entry or any history of Type 1 diabetes
- Residual Grade 2 or higher neuropathy due to prior oxaliplatin exposure (unless the participant is planned to be treated with FOLFIRI)
- Symptomatic, untreated, or actively progressing CNS metastases
- History of gastrointestinal (GI) fistula, GI perforation, or intra-abdominal abscess within 6 months prior to Day 1 of Cycle 1
- Treatment with strong cytochrome P450 (CYP) 3A4 inducers or strong CYP3A4 inhibitors within 1 week or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study treatment (only for patients who will receive FOLFIRI)
- Known HIV positive status with exceptions for well controlled and on stable treatment
- History of malignancy within 5 years prior to screening, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death