Phase 2 mCRC (M14-064)

Phase 2 Study Comparing Efficacy and Safety of ABT-165 Plus FOLFIRI vs Bevacizumab Plus FOLFIRI in Metastatic Colorectal Cancer Previously Treated with Fluoropyrimidine/Oxaliplatin and Bevacizumab

Patient Population

- ≥ 18 years of age
- Histologically or cytologically confirmed metastatic adenocarcinoma of the colon or rectum

Study Design

N = 100

1:1 Randomization

FOLFIRI + ABT-165

FOLFIRI + Bevacizumab

Endpoints

Primary Endpoint

- Progression free survival (PFS)

Secondary Endpoints

- Overall response rate (ORR)
- Overall survival (OS)

Key Inclusion Criteria

- Progression following treatment with fluoropyrimidine/oxaliplatin/bevacizumab regimen in the metastatic setting
- Eastern Cooperative Oncology Group (ECOG) performance score of 0 or 1
- At least 1 lesion on CT scan that is measurable as defined by RECIST, Version 1.1

Key Exclusion Criteria

- Any prior therapy with irinotecan
- Unresolved clinically significant toxicities from prior anticancer therapy, defined as any CTCAE ≥ Grade 2
- Clinically significant conditions that increase the risk for antiangiogenic therapy
- History of any of the following during first-line therapy with bevacizumab-containing regimen: arterial thrombotic/thromboembolic event, bowel perforation, Grade 4 hypertension, Grade 3 proteinuria or Grade 3–4 bleeding event

ABT-165 is an investigational agent that has not been approved by regulatory health agencies. Safety and efficacy has not been established.


To learn more about these studies, please visit https://ClinicalTrials.gov or email abbvieclinicaltrials@abbvie.com