ForPatients
by Roche

Colorectal Cancer (CRC)

A Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Metastatic Colorectal Cancer (Morpheus-CRC)

Trial Status	Trial Runs In	Trial Identifier
Terminated	5 Countries	NCT03555149 2017-004566-99 CO39612

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 Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Metastatic Colorectal Cancer (Morpheus-CRC)

Trial Summary:

A phase Ib/II, open-label, multicenter, randomized study designed to assess the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of immunotherapy-based treatment combinations in patients with metastatic colorectal cancer (mCRC) that became refractory to first- and second-line standard therapies. Eligible patients will be assigned to one of several treatment arms.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

NCT03555149 2017-004566-99 CO39612
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy # 3 months, as determined by the investigator

- Histologically confirmed adenocarcinoma originating from the colon or rectum
- Metastatic disease not amenable to local treatment
- Disease progression during or following not more than two separate lines of treatment for metastatic colorectal cancer (mCRC) that consisted of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy in combination with a biologic agent
- Measurable disease (at least one target lesion) according to RECIST v1.1
- Adequate hematologic and end-organ function obtained within 14 days prior to initiation of study treatment

Exclusion Criteria:

- High microsatellite instability (MSI-H) tumor
- Presence of BRAFV600E mutation
- Prior treatment with any of the protocol-specified study treatments
- Prior treatment with T-cell co-stimulating or immune checkpoint blockade therapies including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Biologic treatment within 2 weeks prior to initiation of study treatment, or other systemic treatment for CRC within 2 weeks or 5 half-lives of the drug (whichever is shorter) prior to initiation of study treatment
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Eligibility only for the control arm
- Prior allogeneic stem cell or solid organ transplantation
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 half-lives of the drug (whichever is longer) prior to the initiation of study treatment
- Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressant medication during study treatment
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during atezolizumab treatment or within 5 months after the last dose of atezolizumab
- Current treatment with anti-viral therapy for HBV
- Uncontrolled pleural effusion, pericardial effusion, ascites requiring recurrent drainage procedures (once monthly or more frequently), or tumor related-pain,
- Uncontrolled or symptomatic hypercalcemia (ionized calcium >1.5 mmol/L, calcium >12 mg/dL, or corrected serum calcium >ULN)
- Symptomatic, untreated, or actively progressing CNS metastases
- History of leptomeningeal disease
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- History of malignancy other than CRC within 2 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Active tuberculosis
- Severe infection within 4 weeks prior to initiation of study treatment
- Significant cardiovascular disease
- Grade #3 hemorrhage or bleeding event within 28 days prior to initiation of study treatment
- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- History of severe allergic reactions to chimeric or humanized antibodies or fusion proteins
- Inability to swallow medications
- Malabsorption condition that would alter the absorption of orally administered medications
- Evidence of inherited bleeding diathesis or significant coagulopathy at risk of bleeding
- Urine dipstick # 2+ protein or # 3.5 g of protein in a 24-hour urine collection