

ForPatients

by Roche

Metastatic Colorectal Cancer

A Study to Investigate CEA-PRIT 2.0 in Participants With Metastatic Colorectal Cancer (mCRC)

Trial Status

Not yet recruiting

Trial Runs In

Trial Identifier

NCT07416552 2025-523322-40-00
BP45930

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 I, Open-Label, Escalation and Expansion Study to Evaluate Dosimetry, Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of CEA-Pre-Targeted 212Pb Therapy in Participants With Metastatic Colorectal Cancer

Trial Summary:

This study will evaluate the dosimetry, safety, efficacy, pharmacokinetics (PK), pharmacodynamics and immunogenicity of CEA-PRIT 2.0 in participants with metastatic microsatellite-stable (MSS) mCRC who are intolerant to or have progressed after having received available standard-of-care (SOC) therapies.

Hoffmann-La Roche

Sponsor

Phase 1

Phase

NCT07416552 2025-523322-40-00 BP45930

Trial Identifiers

Eligibility Criteria:

Gender

All

Age

#18 Years

Healthy Volunteers

No

Inclusion Criteria:

- Histologically confirmed adenocarcinoma originating from the colon or rectum
- Metastatic disease (Stage IV American Joint Committee on Cancer, Version 7)
- Confirmed MSS and/or proficient mismatch repair (MMR) status

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- Experienced disease progression during or within 3 months following the last administration of systemic anti-cancer therapies for metastatic disease
- Presence of measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
- Life expectancy estimated by the Investigator to be ≥ 12 weeks
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-1
- Adequate cardiovascular, hematological and renal function and laboratory parameters

Exclusion Criteria:

- Pregnant or breastfeeding or intending to become pregnant
- Participants with active central nervous system (CNS) metastases
- History of malignancy other than the one under investigation
- Any unresolved toxicities from prior therapy, i.e., radiotherapy, chemotherapy, targeted therapy or surgical procedure
- Major surgery or significant traumatic injury < 4 weeks prior to the first CEA-PRIT 2.0 administration (excluding biopsies) or anticipation of the need for major surgery during study treatment
- Participants have a known confirmed positive test for HIV
- Positive hepatitis B surface antigen (HBsAg) test, and/or positive total hepatitis B core Ab (HBcAb) test at screening.
- Positive hepatitis C (HCV) Ab test result at screening
- Any anticancer treatment or any investigational agent within 4 weeks (or 5 times the half-life, whichever is shorter) prior to C1D1
- Prior treatment with a CEA-targeted agent or systemic radio therapy