ForPatients
by Roche

Colorectal Cancer (CRC)

A Study of BLYG8824A in Participants With Locally Advanced or Metastatic Colorectal Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT04468607 2023-503409-12-00 GO41751

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, Dose-Escalation Study Of The Safety And Pharmacokinetics Of BLYG8824A Administered Intravenously In Patients With Locally Advanced Or Metastatic Colorectal Cancer

Trial Summary:

This study will evaluate the safety, tolerability, and pharmacokinetics of BLYG8824A and will make a preliminary assessment of the anti-tumor activity of BLYG8824A in patients with locally advanced or metastatic colorectal cancer.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT04468607 2023-503409-12-00 GO41751
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- ECOG performance status of 0 or 1
- Life expectancy of at least 12 weeks
- Histologically or cytologically documented invasive CRC: incurable, unresectable, locally advanced or metastatic CRC previously treated with multimodality therapy or mCRC
- Locally advanced or metastatic CRC that has relapsed or is refractory to established therapies
- Prior disease progression (or intolerance) following oxaliplatin, irinotecan, fluoropyrimidines, and anti-EGFR monoclonal antibodies

- An archival tissue specimen or fresh baseline biopsy (when archival is not available) is required for enrollment into the study
- Measurable disease, according to the Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Non-measurable evaluable disease is acceptable for dose-escalation.
- Adequate hematologic and end organ function
- Acute, clinically significant treatment-related toxicity from prior therapy resolved to Grade # 1 prior to study entry

Expansion Cohort-Specific Inclusion Criteria

- MSS or MSI-L disease as determined by polymerase chain reaction (PCR) and/or IHC
- Measurable disease by RECIST v1.1 with at least one measurable target lesion in the expansion cohort
- Progression must have occurred during or after most recent treatment for locally advanced or metastatic colorectal cancer
- For patients enrolled in either a dedicated biopsy cohort or other expansion cohorts where biopsy is clinically feasible, willingness to consent to mandatory fresh pretreatment and on-treatment biopsies of safely accessible tumor lesions

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 4 months after the final dose of BLYG8824A
- Significant cardiopulmonary dysfunction
- Known clinically significant liver disease
- Positive serologic or PCR test results for acute or chronic HBV infection
- Acute or chronic HCV infection
- HIV seropositivity
- Poorly controlled Type 2 diabetes mellitus
- Current treatment with medications that are well known to prolong the QT interval
- Primary CNS malignancy, untreated CNS metastases, or active CNS metastases
- Leptomeningeal disease
- Spinal cord compression that has not been definitively treated with surgery and/or radiation
- History of autoimmune disease
- Prior allogeneic stem cell or solid organ transplantation