ForPatients
by Roche

Colorectal Cancer (CRC)Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung Carcinoma

Study to Evaluate the Safety, Pharmacokinetics, and Activity of GDC-1971 in Combination With Either Osimertinib in Participants With Unresectable, Locally Advanced, or Metastatic Non-Small Cell Lung Cancer, or With Cetuximab in Participants With Metastatic Colorectal Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	4 Countries	NCT05954871 2022-502530-10-00 GO44272

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 Study to Evaluate the Safety, Pharmacokinetics, and Activity of GDC-1971 in Combination With Either Osimertinib in Patients With Unresectable, Locally Advanced, or Metastatic Non-Small Cell Lung Cancer, or With Cetuximab in Patients With Metastatic Colorectal Cancer

Trial Summary:

The main purpose of the study is to evaluate the safety of GDC-1971 in combination with either osimertinib or cetuximab. The study consists of a dose-finding stage followed by an expansion stage.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT05954871 2022-502530-10-00 GO44272
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Evaluable or measurable disease per RECIST v1.1
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy of #12 weeks
- Adequate hematologic and organ function within 14 days prior to initiation of study Inclusion Criteria for Non-Small Cell Lung Cancer Cohorts
- Histologically confirmed unresectable, locally advanced or metastatic adenocarcinoma of the lung that has progressed on/after prior treatment with third-generation epidermal growth factor receptor (EGFR) inhibitor (e.g., osimertinib)
- Positive for an EGFR exon 19 deletion or exon 21 L858R mutation
- Negative for acquired on-target EGFR alterations Inclusion Criteria for Colorectal Cancer Cohorts
- Histologically confirmed metastatic adenocarcinoma of the colon or rectum that has progressed on/after prior treatment with an EGFR inhibitor (e.g., cetuximab or panitumumab)
- Negative for kirsten rat sarcoma viral oncogene homolog (KRAS) alterations
- Negative for neuroblastoma RAS viral oncogene homolog (NRAS) alterations
- Negative for proto-oncogene B-Raf (BRAF) V600E alterations
- In lieu of a fresh pre-treatment biopsy, a recently obtained biopsy performed after completion of osimertinib therapy will be acceptable

Exclusion Criteria:

- Treatment with chemotherapy, immunotherapy, biologic therapy, or an investigational agent as anti-cancer therapy within 3 weeks or 5 drug elimination half-lives, whichever is shorter, prior to initiation of study treatment
- Treatment with endocrine therapy within 2 weeks prior to initiation of study drug, except for hormonal therapy with gonadotropin-releasing hormone agonists or antagonists for endocrine-sensitive cancers
- Significant traumatic injury or major surgical procedure within 4 weeks prior to Cycle 1, Day 1
- Positive hepatitis C virus (HCV) antibody test at screening
- Positive hepatitis B surface antigen (HBsAg) test at screening
- Known HIV infection
- Clinically significant history of liver disease, including viral or other hepatitis, current alcohol abuse, or cirrhosis
- Uncontrolled hypercalcemia
- Substance abuse, as determined by the investigator, within 12 months prior to screening
- Poor peripheral venous access
- Inability or unwillingness to swallow pills
- Malabsorption syndrome or other condition that would interfere with enteral absorption Chronic diarrhea, short bowel syndrome, or significant upper GI surgery including gastric resection, a history of inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis), or any active bowel inflammation (including diverticulitis)
- Serious infection within 4 weeks prior to screening
- History of malignancy within 3 years prior to screening
- Known and untreated, or active central nervous system (CNS) metastases (progressing or requiring anticonvulsants or corticosteroids for symptomatic control)
- Leptomeningeal disease or carcinomatous meningitis
- History or presence of an abnormal electrocardiogram (ECG) that is deemed clinically significant by the investigator (e.g., complete left bundle branch block, second- or third-degree atrioventricular heart block) or evidence of prior myocardial infarction
- Left ventricular ejection fraction (LVEF) less than the institutional lower limit of normal (LLN) or <50%
- History or evidence of ophthalmic disease
- History of or active clinically significant cardiovascular dysfunction
- History of pulmonary firbrosis, organizing pneumonia, or pneumonitis

Other protocol-defined inclusion/exclusion criteria may apply.