ForPatients
by Roche

Solid Tumors

A Study to Evaluate the Safety and Effectiveness of Different Doses of RO7836748 Alone or in Combination With Other Cancer Therapies in People With Solid Tumors With a Rat Sarcoma Viral Oncogene Homolog Glycine 12 Valine (RAS G12V) Mutation

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07905924 2026-526415-11-00 BP46586

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 Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Activity of RO7836748 as Monotherapy and in Combination With Other Anti-Cancer Therapies in Participants With Advanced Solid Tumors With a RAS G12V Mutation

Trial Summary:

The study will evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary clinical activity of RO7836748 as monotherapy and in combination with other anti-cancer therapies, including cetuximab, pembrolizumab, or modified (m)FOLFIRINOX in participants with Kirsten rat sarcoma viral oncogene homolog (KRAS) G12V-positive solid tumors such as non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma (PDAC), and colorectal cancer (CRC), and other solid tumors.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT07905924 2026-526415-11-00 BP46586
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

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- Participants with measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) version (v)1.1 assessed by the Investigator
- Previously irradiated lesions can be considered as measurable disease only if progressive disease has been unequivocally documented at that site since radiation
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Adequate hematologic and end-organ function
- Life expectancy #12 weeks, as determined by the Investigator
- Presence of KRAS, neuroblastoma RAS viral oncogene homolog (NRAS) or Harvey rat sarcoma viral oncogene homolog (HRAS) G12V mutation in blood or tumor tissue previously determined by a local assay at any time prior to Screening
- Consent to provide archival tumor tissue, if available

Exclusion Criteria:

- Known hypersensitivity or medical contraindication to any component of the RO7836748 formulation
- Inability or unwillingness to swallow pills
- Refractory nausea and vomiting, malabsorption, external biliary shunt, or significant small bowel resection that would preclude adequate study treatment absorption
- Inability to comply with study and follow-up procedures
- Participants with 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, but not limited to, peptic ulcer disease, and diverticulitis).
- Known and untreated or active central nervous system (CNS) metastases (progressing or requiring anticonvulsants or corticosteroids for symptomatic control)
- Participants with any leptomeningeal disease

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