ForPatients
by Roche

Tumor

A Study to Evaluate the Safety, Tolerability, Pharmacokinetics (PK) and Preliminary Clinical Activity of RO7673396 in Participants With Advanced Solid Tumors Harboring Rat Sarcoma Viral Oncogene Homolog (RAS) Mutation(s)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT06884618 2024-519622-20-00 YO45758

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 and Preliminary Clinical Activity of RO7673396 as a Single Agent and in Combination With Other Anticancer Therapies in Patients With Advanced Solid Tumors Harboring RAS Mutation(s)

Trial Summary:

This study aims to evaluate the safety and tolerability of RO7673396 in participants with advanced solid tumors harboring RAS mutation(s). This study consists of two stages: Stage 1 (Dose Escalation) and Stage 2 (Dose Expansion). Stage 1 will define the recommended dose(s) for expansion (RDEs) of RO7673396. Stage 2 will evaluate preliminary anti-tumor activity of the RDE(s) defined in Stage 1 and of other doses of interest for future development in selected solid tumor indications.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT06884618 2024-519622-20-00 YO45758
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically documented, locally advanced, recurrent, or metastatic incurable solid tumors
- Participants with measurable disease according to RECIST v1.1 assessed by the investigator
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy #12 weeks
- Adequate hematologic and end-organ function
- Confirmed presence of the RAS mutation(s)

Exclusion Criteria:

- Current participant or enrollment in another interventional clinical trial
- Known hypersensitivity or medical contraindication to any component of RO7673396 formulation
- Refractory nausea and vomiting, malabsorption, external biliary shunt, or significant small bowel resection that would preclude adequate study treatment absorption
- Known and untreated, or active central nervous system (CNS) metastases
- Participants with chronic diarrhea, short bowel syndrome or significant upper gastrointestinal (GI) surgery including gastric resection, a history of inflammatory bowel disease
- Treatment with chemotherapy, immunotherapy, biologic therapy, or an investigational agent as anti-cancer therapy within 4 weeks or five half-lives prior to initiation of study treatment
- Major surgical procedure within 28 days prior to initiation of study treatment, or incomplete recovery from surgery that would interfere with the determination of safety or efficacy of study treatment, or anticipation of need for a major surgical procedure during the study
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Known clinically significant liver disease