ForPatients
by Roche

Pancreatic Ductal AdenocarcinomaNon-Small Cell Lung Cancer (NSCLC)Gastric CancerMetastatic Solid TumorsNon Small Cell Lung Carcinoma

A Study to Evaluate the Safety, Pharmacokinetics, and Activity of RO7496353 in Combination With a Checkpoint Inhibitor With or Without Standard-of-Care Chemotherapy in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	10 Countries	NCT05867121 2022-502615-11-00 GO44010

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, Open-Label, Multicenter Dose-Expansion Study Evaluating the Safety, Pharmacokinetics, and Activity of RO7496353 in Combination With a Checkpoint Inhibitor With or Without Standard-of-Care Chemotherapy in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

The purpose of this study is to evaluate the safety and tolerability of RO7496353 when administered in combination with a checkpoint inhibitor (CPI) with or without standard-of-care (SOC) chemotherapy in participants with locally advanced or metastatic solid tumors such as non-small cell lung cancer (NSCLC), gastric cancer (GC) and pancreatic ductal adenocarcinoma (PDAC). The study will be conducted in 2 stages: an initial safety run-in stage and an expansion stage.

Genentech, Inc.	Phase 1
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy at least 3 months
- Adequate hematologic and end organ function
- Histologically confirmed locally advanced, recurrent, or metastatic incurable solid tumor malignancy
- Measurable disease according to RECIST v1.1 on computed tomography (CT) or magnetic resonance imaging (MRI) images within 28 days prior to enrollment
- Availability of representative tumor specimens in formalin-fixed, paraffin-embedded (FFPE) blocks or at least 15 unstained slides

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 9 months after the final dose of oxaliplatin and within 6 months after the final dose of all other study treatment
- Any anti-cancer therapy, whether investigational or approved, including chemotherapy, hormonal therapy, and/or radiotherapy, within 3 weeks prior to initiation of study treatment
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Significant cardiovascular disease (such as New York Heart Association Class II or greater cardiac disease, myocardial infarction, or cerebrovascular accident) within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Positive test for human immunodeficiency virus (HIV) infection
- Positive hepatitis B surface antigen (HbsAg) test, and/or positive total hepatitis B core antibody (HbcAb) test at screening
- Positive hepatitis C virus (HCV) antibody test at screening
- Known allergy or hypersensitivity to any component of the RO7496353 formulation or any of the study drugs or their excipients

Other protocol-defined inclusion/exclusion criteria may apply.