ForPatients
by Roche

Squamous Cell CarcinomaAdvanced Solid TumorsNon-Small Cell Lung Cancer (NSCLC)Triple Negative Breast CancerColorectal Cancer (CRC)Gastric CancerNon Small Cell Lung CarcinomaUrothelial CarcinomaSquamous Cell Carcinoma of the Head and Neck (SCCHN)Esophageal CancerHepatocellular Carcinoma (HCC)Metastatic Solid TumorsMalignant MelanomaClear Cell Renal Cell CarcinomaMelanomaCervical Cancer

A Study to Evaluate the Safety, Pharmacokinetics, and Activity of RO7502175 as a Single Agent and in Combination With Checkpoint Inhibitor in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Recruiting	10 Countries	NCT05581004 2021-006708-34 GO43860

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 Ia/Ib, Open Label, Multicenter, Dose-escalation Study to Evaluate the Safety, Pharmacokinetics, and Activity of RO7502175 as a Single Agent and in Combination With Checkpoint Inhibitor in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This is a first-in-human study to evaluate the safety, tolerability, pharmacokinetics (PK), and anti-tumor activity of RO7502175 when administered as a single agent and in combination with atezolizumab or pembrolizumab in adult participants with locally advanced or metastatic solid tumors, including non-small-cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), melanoma, triple-negative breast cancer (TNBC), esophageal cancer, gastric cancer, cervical cancer, colorectal cancer (CRC), urothelial carcinoma (UC), clear cell renal cell carcinoma (RCC) and hepatocellular carcinoma (HCC). Participants will be enrolled in 2 stages: dose escalation and dose expansion.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT05581004 2021-006708-34 GO43860
Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

Inclusion Criteria:

- Life expectancy at least 12 weeks
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Measurable disease according to Response Evaluation criteria in Solid Tumors (RECIST) Version 1.1
- Histologically confirmed locally advanced, recurrent, or metastatic incurable solid tumor malignancy
- Tumor Specimen availability

Exclusion Criteria:

- Pregnant or breastfeeding or intention of becoming pregnant during the study or within 4 months after the final dose of RO7501275, or 4 months after the final dose of pembrolizumab, or 5 months after the final dose of atezolizumab
- Any anti-cancer therapy, whether investigational or approved, including chemotherapy, hormonal therapy, or radiotherapy, within 3 weeks prior to initiation of study treatment
- Active hepatitis B or C or tuberculosis
- Positive test for human immunodeficiency virus (HIV) infection
- Acute or chronic active Epstein-Barr virus (EBV) infection at screening
- Administration of a live, attenuated vaccine (e.g., FluMist) within 4 weeks before first RO7502175 infusion
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Active or history of autoimmune disease
- Prior allogeneic stem cell or organ transplantation