ForPatients

by Roche

Metastatic Solid TumorsAdvanced Solid TumorsSolid Tumors

A Study to Evaluate the Safety, Pharmacokinetics, and Activity of RO7566802 as a Single Agent and in Combination With Atezolizumab in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status Trial Runs In Trial Identifier

Recruiting 4 Countries NCT06031441 2023-509266-38-00
GO44431

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, Open-Label, Multicenter, Dose-Escalation Study Evaluating the Safety, Pharmacokinetics, and Activity of RO7566802 as a Single Agent and in Combination With Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This is a first-in-human Phase I, open-label, dose-escalation and expansion study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, pharmacodynamic, and preliminary anti-tumor activity of RO7566802 as a single agent and in combination with atezolizumab in participants with locally advanced, recurrent, or metastatic incurable solid tumor malignancies. Participants will be enrolled in 2 stages: dose escalation and expansion.

Genentech, Inc. Sponsor		Phase 1 Phase	
NCT06031441 2023-509266-38-00 GO44431 Trial Identifiers			
Eligibility Criter	ia:		
Gender All	Age #18 Years	Healthy Volunteers No	

Inclusion Criteria:

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- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1
- Life expectancy >= 3 months, in the investigator's judgment
- Adequate hematologic and end-organ function
- Histologically confirmed locally advanced, recurrent, or metastatic incurable solid tumor malignancy
 that has progressed after available standard therapy; or for whom standard therapy has proven to be
 ineffective or intolerable or is considered inappropriate; or for whom a clinical trial of an investigational
 agent is a recognized standard of care
- Measurable disease per RECIST v1.1
- Tumor specimen availability, for certain cohorts

Exclusion Criteria:

- Any anti-cancer therapy, whether investigational or approved, including chemotherapy, hormonal therapy, or radiotherapy, within 3 weeks prior to C1D1, with certain exceptions
- Active hepatitis B or C
- Active tuberculosis
- Positive test for HIV infection
- Administration of a live, attenuated vaccine (e.g., Flumist) within 4 weeks prior to RO7566802 infusion
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Active or history of autoimmune disease
- Prior allogeneic stem cell or organ transplantation
- Uncontrolled tumor-related pain
- Significant cardiovascular disease

Other protocol-defined inclusion/exclusion criteria may apply.