ForPatients
by Roche

Solid Tumors

A Study to Evaluate the Safety, Pharmacokinetics, and Activity of RO7759065 as a Single Agent and in Combination With Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	NCT06488716 GO45296

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 Study to Evaluate the Safety, Pharmacokinetics, and Activity of RO7759065 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 Ia/Ib, open-label, multicenter, dose escalation and dose expansion study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity, and preliminary anti-tumor activity of RO7759065 as a single agent (Phase Ia) or in combination with atezolizumab (Phase Ib) in patients with locally advanced, recurrent, or metastatic incurable solid tumor malignancies. Several key aspects of the study design and study population are summarized below.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT06488716 GO45296
Trial Identifiers

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
- Adequate hematologic and end-organ function
- 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
- Availability of representative tumor specimens required for patients in select cohorts.

Exclusion Criteria:

- Women who are pregnant or breastfeeding
- Any anti-cancer therapy, whether investigational or approved, including chemotherapy, hormonal therapy, and/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 RO7759065 infusion
- Primary, untreated, or active central nervous system (CNS) metastases
- Active or history of autoimmune disease or immune deficiency
- Prior allogeneic stem cell or organ transplantation
- Any history of a Grade 3 immune-mediated adverse event attributed to prior cancer immunotherapy that resulted in permanent discontinuation of that agent
- Any history of a Grade 4 immune-mediated adverse event attributed to prior cancer immunotherapy.