

Tumores Sólidos

Um estudo aberto de escalonamento de dose para avaliar XmAb24306 como agente único e em combinação com atezolizumabe em participantes com tumores sólidos localmente avançados ou metastáticos

An Open-Label Dose-Escalation Study to Evaluate XmAb24306 as a Single Agent and in Combination With Atezolizumab in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status
Ativo, sem recrutamento

Trial Runs In
9 Countries

Trial Identifier
NCT04250155 GO41596

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

A Phase Ia/Ib, Open-Label, Multicenter, Global, Dose-Escalation Study to Evaluate the Safety and Pharmacokinetics of XmAb24306 as a Single Agent and in Combination With Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This study will evaluate the safety, tolerability, pharmacokinetics, and activity of XmAb24306 alone or in combination with a checkpoint inhibitor treatment in participants with locally advanced or metastatic solid tumors.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT04250155 GO41596
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

Key General Inclusion Criteria

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy $\geq$ 12 weeks
- Adequate hematologic and end-organ function
- For participants receiving therapeutic anticoagulation: stable anticoagulant regimen
- Negative serum pregnancy test for women of childbearing potential
- Histologically confirmed locally advanced, recurrent, or metastatic incurable solid tumor malignancy
- Measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
- Availability of representative tumor specimens

Exclusion Criteria:

Key General Exclusion Criteria

- Pregnant or breastfeeding, or intending to become pregnant during the study
- Significant cardiovascular disease
- Current treatment with medications that prolong the QT interval
- Known clinically significant liver disease
- Poorly controlled Type 2 diabetes mellitus
- Symptomatic, untreated, or actively progressing CNS metastases
- History of leptomeningeal disease
- History of malignancy other than disease under study within 3 years prior to screening
- Active or history of autoimmune disease or immune deficiency
- Active tuberculosis, hepatitis B, hepatitis C, or known/suspected Epstein Barr virus infection
- Positive for HIV infection
- Prior allogeneic stem cell or solid organ transplantation