

Solid Tumors

A Study of RO7617991 in Patients With Locally Advanced or Metastatic MAGE-A4-Positive Solid Tumors

Trial Status Withdrawn	Trial Runs In	Trial Identifier NCT06372574 GO44669
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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 Study to Evaluate the Safety, Pharmacokinetics, and Preliminary Anti-Tumor Activity of RO7617991 in HLA-A*02-Positive Patients With Locally Advanced and/or Metastatic MAGE-A4-Positive Solid Tumors

Trial Summary:

This study will evaluate the safety, tolerability, and pharmacokinetics of RO7617991, and will make a preliminary assessment of the anti-tumor activity of RO7617991 in human leukocyte antigen (HLA)-A*02 eligible patients with locally advanced or metastatic melanoma-associated antigen A4 (MAGE-A4)-positive solid tumors.

Genentech, Inc. Sponsor	Phase 1 Phase
NCT06372574 GO44669 Trial Identifiers	

Eligibility Criteria:

Gender All	Age #18 Years	Healthy Volunteers No
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Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Body weight #40 kilograms
- Life expectancy of at least 12 weeks
- Confirmed eligible HLA-A*02 genotype and tumor with confirmed MAGE-A4 expression

ForPatients

by Roche

- Histologically confirmed locally advanced or metastatic solid tumor malignancy that has relapsed or is refractory to established therapies
- Measurable disease, according to RECIST v1.1
- Adequate hematologic and end-organ function
- Resolution to Grade #2 of all acute, clinically significant treatment-related toxicity from prior therapy
- An archival tumor tissue specimen or fresh baseline biopsy (when archival is not available) is required

Exclusion Criteria:

- Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 3 months after the final dose of RO7617991 or tocilizumab
- Clinically significant cardiopulmonary dysfunction
- Clinically significant liver disease
- Poorly controlled Type 2 diabetes mellitus
- Active hepatitis B or C infection
- Positive test for human immunodeficiency virus (HIV)
- History of allergic reactions to red meat or tick bites or known galactose-alpha-1,3-galactose (alpha-gal) hypersensitivity
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Symptomatic pleural effusion, pericardial effusion, or ascites or any prior procedural intervention for pleural effusion, pericardial effusion, or ascites within 6 weeks prior to enrollment
- Active or history of autoimmune disease or immune deficiency
- Treatment with systemic immunosuppressive medications
- Prior allogeneic stem cell or solid organ transplantation