ForPatients
by Roche

Solid Tumors

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

Trial Status	Trial Runs In	Trial Identifier
Withdrawn		NCT06372574 GO44669

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	Age	Healthy Volunteers
All	#18 Years	No

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

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- 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

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