ForPatients
by Roche

Solid Tumors

A Study to Evaluate Safety, Pharmacokinetics, and Preliminary Anti-tumor Activity of RO7444973 in Participants With Unresectable and/or Metastatic MAGE-A4-positive Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Terminated	6 Countries	NCT05129280 2021-000624-35 BE43244

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:

An Open-label, Multicenter, Phase I Study to Evaluate Safety, Pharmacokinetics, and Preliminary Anti-tumor Activity of RO7444973 in Participants With Unresectable and/or Metastatic MAGE-A4-positive Solid Tumors

Trial Summary:

This is a first-in-human, open-label, uncontrolled, multi-center, monotherapy dose-escalation and dose expansion study of RO7444973.The aim of this study is to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of RO7444973 in participants with unresectable and/or metastatic melanoma-associated antigen A4 (MAGE-A4)-positive, solid tumors, carrying the HLA-A*02:01 allele.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT05129280 2021-000624-35 BE43244
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Unresectable and/or metastatic solid tumors that have received standard-of-care (SOC) therapies previously and have no other SOC options available
- Confirmed HLA-A*02:01 haplotype

- Confirmed MAGE-A4 expression
- Radiologically measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
- Life expectancy of >/=12 weeks
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
- Absence of rapid disease progression, threat to vital organs or non-irradiated lesions >2 cm in diameter at critical sites
- No significant ongoing toxicity from prior anticancer treatment
- Adequate hematological function
- Adequate liver function
- Adequate renal function
- If applicable, willingness to use contraceptive measures.

Exclusion Criteria:

- History or clinical evidence of CNS primary tumors or metastases
- Another invasive malignancy in the last 2 years
- Uncontrolled hypertension
- Significant cardiovascular disease
- Known active or uncontrolled bacterial, viral, fungal, mycobacterial, parasitic or other infection
- Current or past history of CNS disease
- Dementia or altered mental status that would prohibit informed consent
- Active auto-immune disease or flare within 6 months prior to start of study treatment
- Expected need for regular immunosuppressive therapy or with systemic corticosteroids
- Insufficient washout from prior anti-cancer therapy
- Prior treatment with a bispecific T-cell engaging or adoptive cell therapy.