ForPatients
by Roche

Solid Tumors

A Study to Evaluate the Safety and Tolerability of RO7296682 in Participants With Advanced Solid Tumors.

Trial Status	Trial Runs In	Trial Identifier
Terminated	5 Countries	NCT04158583 2019-002830-35 WP41188

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 1 Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7296682, A CD25-Targeting, T-Regulatory Cell Depleting Antibody in Participants With Advanced and/or Metastatic Solid Tumor

Trial Summary:

This study was planned to evaluate the safety and tolerability of RO7296682 in participants with advanced solid tumors.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04158583 2019-002830-35 WP41188
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Diagnosis of advanced and/or metastatic solid tumors who have progressed on all standard therapies, are intolerant to Standard-Of-Care (SOC), and/or are non-amenable to SOC. Participants whose tumors have known sensitizing mutation must have experienced disease progression (during or after treatment) or intolerance to treatment with a respective targeted therapy.
- Measurable disease according to response evaluation criteria in solid tumors (RECIST) v1.1.
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1.
- Able to provide the most recent archival tumor tissue samples.

- Adequate cardiovascular, haematological, liver and renal function.
- Participants on therapeutic anticoagulation must be on a stable anticoagulant regimen.
- Women of Childbearing Potential: Agreement to remain abstinent (refrain from heterosexual intercourse) or use highly effective contraceptive methods.
- Men: Agreement to remain abstinent (refrain from heterosexual intercourse) or use highly effective contraceptive methods and refrain from donating sperm.

Exclusion Criteria:

- Pregnancy, lactation, or breastfeeding.
- Known hypersensitivity to any of the components of RO7296682, including but not limited to hypersensitivity to Chinese hamster ovary cell products or other recombinant human or humanized antibodies.
- History or clinical evidence of central nervous system (CNS) primary tumors or metastases.
- Participants with another invasive malignancy in the last two years.
- Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results.
- Participants with known active or uncontrolled infection.
- Positive human immunodeficiency virus (HIV) test at screening.
- Positive for Hepatitis B and C.
- Vaccination with live vaccines within 28 days prior to C1D1.
- Major surgical procedure or significant traumatic injury within 28 days prior to first RO7296682 infusion.
- Participants with wound healing complications.
- Dementia or altered mental status that would prohibit informed consent.
- History of Stevens-Johnson syndrome, toxic epidermal necrolysis, or DRESS (drug rash with eosinophilia and systemic symptoms).
- Active or history of autoimmune disease or immune deficiency.
- Prior treatment with checkpoint inhibitors (CPIs) (e.g. anti-CTLA4, anti-PD1, anti-PDL1), immunomodulatory monoclonal antibodies (mAbs) and/or mAb-derived therapies (approved or investigational) is approved.
- Prior treatment with a CC chemokine receptor 4 (CCR4)-targeting (e.g. mogamulizumab) or a CD25-targeting agent (e.g. basiliximab) is prohibited.
- Treatment with standard radiotherapy, any chemotherapeutic agent, targeted therapy or treatment with any other investigational drug (defined as treatment for which there is currently no regulatory authority-approved indication) within 28 days or 5 half-lives of the drug (whichever is shorter), prior to the first RO7296882 administration on C1D1.
- Radiotherapy within the last 4 weeks before start of study drug treatment, with the exception of limited palliative radiotherapy (for which no wash out period is required).