ForPatients
*by Roche*

Solid Tumors

# A Study to Evaluate Safety, Pharmacokinetics and Anti-Tumor Activity of RO7300490, as Single Agent or in Combination With Atezolizumab in Participants With Advanced Solid Tumors

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 5 Countries | NCT04857138 2020-004489-21 WP42627 |

*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, Dose-Escalation and Expansion, Phase I Study to Evaluate Safety, Pharmacokinetics, And Anti-Tumor Activity of RO7300490, A Fibroblast Activation Protein-# (FAP) Targeted CD40 Agonist, as Single Agent or in Combination With Atezolizumab in Participants With Advanced and/or Metastatic Solid Tumors

## *Trial Summary:*

A study to evaluate the safety, pharmacokinetics and anti-tumor activity of RO7300490 as a single agent or in combination with atezolizumab. The study will consist of 3 parts: [Part 1] Dose-Escalation of RO7300490 as a single agent; [Part 2] Dose-Escalation of RO7300490 in combination with atezolizumab and [Part 3] Dose-Expansion of RO7300490 in combination with atezolizumab in selected cancer types.

**Hoffmann-La Roche**
Sponsor

**Phase 1**
Phase

**NCT04857138 2020-004489-21 WP42627**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- Life expectancy of >= 12 weeks.

- Histologically confirmed diagnosis of locally advanced and/or metastatic solid tumors that are not amenable to standard therapy.
- Radiologically measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
- Agreement to provide protocol-specific biopsy material.
- Adverse Events (AEs) from prior anti-cancer therapy resolved to Grade =<1.
- Adequate performance status and cardiovascular, hematological, liver, renal and coagulation function.
- For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse), use contraceptive measures and refrain from donating eggs.
- For male participants: agreement to remain abstinent (refrain from heterosexual intercourse), use contraceptive measures and refrain from donating sperm.

## *Exclusion Criteria:*

- Known central nervous system (CNS) primary tumors or metastases, including leptomeningeal metastases, unless protocol-specific conditions are met.
- Active second invasive malignancy within two years prior to screening.
- Significant cardiovascular/cerebrovascular disease within 6 months prior to study treatment start.
- Any other diseases, metabolic dysfunction, physical examination finding or clinical laboratory finding that gives reasonable suspicion of a disease or condition that would contraindicate the use of an investigational drug.
- Prior allogeneic bone marrow transplantation or prior solid organ transplantation.
- Active or history of autoimmune disease.
- Known hypersensitivity to any of the components of RO7300490 formulation or to components of atezolizumab formulation.
- Pregnancy, lactation or breastfeeding.
- Dementia or altered mental status that would prohibit informed consent.
- Major surgery or significant traumatic injury within 28 days prior to the first study drug administration (excluding biopsies) or anticipation of the need for major surgery during study treatment.
- Treatment with radiotherapy, chemotherapy, hormonal therapy, targeted therapy, immunotherapy or investigational drug concurrent or within 28 days or 5 half-lives of the drug (whichever is shorter) before the first study drug administration.