ForPatients
by Roche

Colorectal Cancer (CRC)Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung CarcinomaPancreatic AdenocarcinomaOvarian NeoplasmsRenal Cell Carcinoma

Study of RO7515629 in Participants With HLA-G Positive Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT05769959 BP44068

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, Pharmacokinetics, and Preliminary Anti-Tumor Activity of RO7515629 in Participants With Unresectable and/or Metastatic HLA-G Positive Solid Tumors

Trial Summary:

The main purpose of this study is to evaluate the safety, tolerability, pharmacokinetics, immune response and preliminary anti-tumor activity of RO7515629 alone in participants with advanced or metastatic solid tumors expressing human leukocyte antigen G (HLA-G).

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT05769959 BP44068
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Unresectable and/or metastatic HLA-G-positive solid tumors, for which standard therapy does not exist, or has proven to be ineffective or intolerable
- Confirmed HLA-G tumor expression.
- Radiologically measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1

- Life expectancy of at least 12 weeks
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate hematological, liver, renal and pulmonary function
- Willingness to abide by protocol defined contraceptive requirements for the duration of the study.

Exclusion Criteria:

- History or clinical evidence of Central Nervous System (CNS) metastases unless protocol specified criteria are met
- Leptomeningeal metastases
- Rapid disease progression including lesions that are a threat to vital organs or non-irradiated lesions 2cm or larger at critical sites where tumor swelling may pose a risk to critical anatomical structures
- Participants with another invasive malignancy in the last 2 years unless protocol specified criteria are met
- Uncontrolled hypertension
- Active interstitial lung disease (ILD), pneumonitis or a history of ILD/pneumonitis requiring treatment with steroids, history of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest Computed Tomography (CT) scan
- Participants with central cavitation or tumor(s) shown to be invading or abutting major blood vessels by imaging or the Investigator determines the tumor(s) is likely to invade major blood vessels and cause fatal bleeding
- Participants with pulmonary military metastatic pattern or pulmonary lymphangitic carcinomatosis
- History of pulmonary embolism within 3 months prior to study entry
- Significant cardiovascular disease
- Presence of active or uncontrolled infection or any major episode of infection requiring treatment with IV antibiotics or hospitalization within 4 weeks prior to initiation of study treatment.
- Known hepatitis B or C (actively replicating) based on protocol specified criteria
- Known Human Immunodeficiency Virus (HIV) positivity
- Presence of an indwelling line or drain
- Active auto-immune disease that has required systemic therapy within the past 2 years unless protocol specified exceptions are met
- Major surgery within 28 days prior to first study treatment
- Last treatment with anti-cancer therapy or any investigational drug 28 days or less prior to the first study treatment
- Last dose of immunostimulating or immunosuppressive therapy 28 days or less prior to the first study treatment
- Regular dose of corticosteroids that exceeds prednisone 10 mg/day or equivalent within 28 days prior to first study treatment
- Prior treatment with T cell engaging or adoptive cell therapy
- Administration of a live, attenuated vaccine 28 days or less prior to first study treatment
- Contraindication or known hypersensitivity to any of the components of RO7515629 or tocilizumab or dexamethasone