ForPatients
by Roche

Advanced Solid Tumors

A Phase 1 Study of KSQ-4279 Alone and in Combination in Patients With Advanced Solid Tumors

A Phase 1 Study of RO7623066 Alone and in Combination in Patients With Advanced Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT05240898 KSQ-4279-1101 WP45169

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 1 Study of RO7623066 Alone and in Combination in Patients With Advanced Solid Tumors

Trial Summary:

This is a Phase 1 study to assess the safety and clinical activity of RO7623066 alone and in combination in patients with advanced solid tumors.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT05240898 KSQ-4279-1101 WP45169
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Age 18 years or older
- Life expectancy of # 12 weeks
- Measurable disease or non-measurable disease per RECIST v1.1 in dose escalation and the Food Effect Cohort only; patients in dose expansion and Backfill Cohorts are required to have measurable disease per RECIST v1.1
- Recovered to # Grade 1 or baseline toxicity (except alopecia) from prior therapy (per NCI-CTCAE v5.0)

- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Adequate bone marrow function defined as:
- absolute neutrophil count of # 1.5 × 109/L
- platelet count of # 100.0 × 109/L
- hemoglobin of # 10.0 g/dL (with or without transfusion)
- Adequate renal function defined as calculated creatinine clearance (Cockcroft- Gault) # 40 mL/min for patients with creatinine levels above institutional normal
- Adequate hepatic function defined as:
- Total bilirubin # 1.5 × upper limit of normal (ULN) unless associated with Gilbert's syndrome
- Aspartate aminotransferase and alanine aminotransferase # 2.5 × ULN (or # 5 × ULN in patients with liver metastases)
- Female patients who are women of childbearing potential (WOCP) (defined as physiologically and anatomically capable of becoming pregnant), confirmed of a negative pregnancy test and agreement to the use of a highly effective contraceptive method or at least 2 effective methods at the same time during study treatment period and for up to 3 months after the last dose of study treatment. Male patients must be willing to use effective barrier contraception (ie, condoms) during the study treatment period and for up 3 months after the last dose of study treatment
- Capable of understanding and complying with protocol requirements
- Signed and dated institutional review board (IRB)/independent ethics committee (IEC) approved informed consent form (ICF) before any protocol-directed Screening procedures are performed
- Does not require ongoing treatment with strong or moderate CYP3A4 inhibitors or inducers.
- Histologically or cytologically confirmed locally advanced (unresectable) or metastatic solid tumors who meet one of the following criteria (dose escalation only):
- Relapsed or progressed through standard therapy
- Have a disease for which no standard effective therapy exists
- Not a candidate for standard effective therapy Note: In men with prostate cancer, baseline testosterone levels must also be # 50 ng/dL (# 2.0 nM) and surgical or ongoing medical castration must be maintained throughout the duration of the study

Exclusion Criteria:

- Prior anticancer treatment including:
- Chemotherapy or small molecule-targeted therapy < 2 weeks prior to first dose of study treatment
- Any antibody therapy < 5 half-lives from first dose of study treatment (or 4 weeks since last therapy, whichever is the shortest)
- Programmed cell death protein-1 or programmed cell death ligand 1 inhibitor therapy < 4 weeks from first dose of study treatment
- Invasive surgery requiring general anesthesia < 30 days from first dose of study treatment
- Chemotherapy with nitrosoureas or mitomycin C < 45 days from first dose of study treatment
- Radiation therapy (including radiofrequency ablation) < 4 weeks prior to initiation of study treatment Note: Prior stereotactic body radiation therapy or local palliative radiation is allowed < 2 weeks prior to first dose of study treatment
- Ongoing Grade 2 or greater toxicity, except alopecia, related to any prior treatment (ie, chemotherapy, targeted therapy, radiation, or surgery)
- Prolongation of QT/QTc interval (QTc interval > 480 msec) using the Frederica method of QTc analysis
- Women who are pregnant or nursing
- Seropositive for human immunodeficiency virus (HIV) 1 or 2 or acquired immunodeficiency syndrome or active infection with hepatitis B virus (HBV) or hepatitis C virus (HCV) (Note: Patients with positive HCV antibody may be eligible if HCV ribonucleic acid [RNA] is undetectable on a quantitative HCV RNA assay, the Medical Monitor is available for advice)
- Primary malignant brain tumor

- Symptomatic and/or untreated brain metastases, active leptomeningeal disease, or central nervous system malignant disease requiring steroids or other therapeutic intervention Note: Patients with definitively treated brain metastases will be considered for enrollment after seeking advice from the Medical Monitor and must be clinically stable for # 2 weeks prior to the start of treatment
- Previous solid organ or hematopoietic cell transplant
- Need for treatment with steroids at stable doses (> 10 mg prednisone or equivalent per day). Note: Oral steroids up to 10 mg/day, topical, ophthalmic, or inhaled steroid medications are allowed
- Uncontrolled hypertension > 150/100 mm Hg despite aggressive therapy
- Concurrent participation in any other investigational therapeutic study
- History of stroke, transient ischemic attack, unstable angina, or myocardial infarction within 3 months prior to first dose of study treatment
- Unable to swallow whole tablets or capsules. Nasogastric or gastric-tube (G-tube)administration is not allowed
- GI disease that would impair ability to swallow, retain, or absorb drug is not allowed
- Uncontrolled concurrent disease or illness including but not limited to:
- Symptomatic congestive heart failure according to New York Heart Association (NYHA) classification, Class III or IV (per NYHA Classification) unstable angina pectoris, or clinically significant cardia arrhythmia
- Diabetes mellitus (ie, fasting blood glucose > 220 despite acceptable chronic diabetes therapy)
- Psychiatric illness that would limit compliance with study requirements, as determined by the Investigator
- Other severe, acute, or chronic medical condition or laboratory abnormality that may increase the risk associated with study participation or study drug administration, or that may interfere with the interpretation of the study results, and in the judgment of the Investigator, would make the patient inappropriate for the study
- Known hypersensitivity to any component of RO7623066 or excipient
- History of and/or ongoing adrenal disorder (eg, Cushing's disease, Addison's disease, adrenal gland suppression)
- Suspected pneumonitis or interstitial lung disease (confirmed radiography or by computed tomography [CT]) or a history of pneumonitis or interstitial lung disease in the last 6 months
- Known additional malignancy that is active and/or progressive requiring treatment; exceptions include basal cell or squamous cell skin cancer, or other cancer for which the patient has been disease-free for at least 2 years
- Myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML), or baseline features suggestive of MDS or AML on peripheral blood smear or bone marrow biopsy
- Treatment with strong or moderate CYP3A4 inhibitors or inducers for a period of 5 half-lives of the inhibitor or inducer prior to the first dose of RO7623066.
- Blood transfusions within 4 weeks prior to Screening