ForPatients
by Roche

Solid TumorsCancer

A Study to Investigate the Efficacy and Safety of Cobimetinib Plus Atezolizumab in Participants With Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT03264066 2017-000794-37 WO39760

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 II, Open-Label, Multicenter, Multicohort Study to Investigate the Efficacy and Safety of Cobimetinib Plus Atezolizumab in Patients With Solid Tumors

Trial Summary:

This is a study to evaluate the efficacy, safety, and pharmacokinetics of cobimetinib plus atezolizumab in participants with advanced solid tumors including the following cohorts: squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma (UC), and renal cell carcinoma (RCC).

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT03264066 2017-000794-37 WO39760
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

General Inclusion Criteria:

- Age #18 years
- Ability to comply with the study protocol, in the investigator's judgment
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1

- Life expectancy #3 months, as determined by the investigator
- Adequate hematologic and end-organ function

Cancer-Related Inclusion Criteria:

- Patients must have measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) scan per RECIST v1.1.
- Availability to provide a representative tumor specimen biopsy
- Evidence of tumor progression on or after the last treatment regimen received and within 6 months prior to study enrollment
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use a non-hormonal contraceptive method with a failure rate of <1% per year during the treatment period and for at least 5 months after the last dose of atezolizumab and within 3 months after the last dose of cobimetinib
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm during the treatment period and for at least 3 months after the last dose of cobimetinib

Exclusion Criteria:

General Exclusion Criteria:

- Inability to swallow medications
- Malabsorption condition that would alter the absorption of orally administered medications
- Poor peripheral venous access
- Prior treatment with cobimetinib or a MEK inhibitor
- Prior treatment with T-cell co-stimulating or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Treatment with investigational therapy within 14 days prior to initiation of study treatment
- Any anti-cancer therapy, including chemotherapy or hormonal therapy, within 2 weeks prior to initiation of study treatment
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to biopharmaceutical agents produced in Chinese hamster ovary cells or any component of the atezolizumab formulation, or any component of the cobimetinib formulation
- History of serous retinopathy, retinal vein occlusion (RVO), or evidence of ongoing serous retinopathy or RVO at baseline
- Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring repeated drainage more than once every 28 days
- Uncontrolled hypercalcemia (ionized calcium >1.5 millimoles per liter [mmol/L], calcium >12 milligrams per deciliter [mg/dL], or corrected calcium greater than the upper limit of normal [ULN]) or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy
- Active or untreated central nervous system (CNS) metastases
- Pregnancy or breastfeeding, or intending to become pregnant during the study

Exclusion Criteria based on Organ Function or Medical History

Cardiovascular

Patients who meet the following cardiovascular exclusion criterion will be excluded from study entry:

- Left ventricular ejection fraction (LVEF) below the institutional lower limit of normal or <50%, whichever is lower

Infections Patients who meet any of the following infection exclusion criteria will be excluded from study entry:

- Positive human immunodeficiency virus (HIV) test at screening
- Active hepatitis B virus (HBV) infection (chronic or acute)
- Active hepatitis C virus (HCV) infection
- Active tuberculosis
- Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment