

Solid TumorsCancer

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

**Trial Status**  
Completed

**Trial Runs In**  
6 Countries

**Trial Identifier**  
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**  
All

**Age**  
# 18 Years

**Healthy Volunteers**  
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