ForPatients
by Roche

Renal Cell Cancer (RCC)Renal Cell Carcinoma

A Study of Atezolizumab in Combination With Bevacizumab Versus Sunitinib in Participants With Untreated Advanced Renal Cell Carcinoma (RCC)

Trial Status	Trial Runs In	Trial Identifier
Completed	21 Countries	NCT02420821 2014-004684-20 WO29637

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 III, Open-Label, Randomized Study of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Bevacizumab Versus Sunitinib in Patients With Untreated Advanced Renal Cell Carcinoma

Trial Summary:

This multi-center, randomized, open-label study will evaluate the efficacy and safety of atezolizumab plus bevacizumab versus sunitinib in participants with inoperable, locally advanced, or metastatic RCC who have not received prior systemic active or experimental therapy, either in the adjuvant or metastatic setting.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02420821 2014-004684-20 WO29637
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Definitive diagnosis of unresectable locally advanced or metastatic RCC with clear-cell histology and/or a component of sarcomatoid carcinoma, with no prior treatment in the metastatic setting
- Evaluable Memorial Sloan Kettering Cancer Center risk score
- Measurable disease, as defined by RECIST v1.1

- Karnofsky performance status greater than or equal to 70%
- Adequate hematologic and end-organ function prior to randomization

Exclusion Criteria:

Disease-Specific Exclusions:

- Radiotherapy for RCC within 14 days prior to treatment
- Active central nervous system disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites
- Uncontrolled hypercalcemia
- Any other malignancies within 5 years except for low-risk prostate cancer or those with negligible risk of metastasis or death

General Medical Exclusions:

- Life expectancy less than 12 weeks
- Participation in another experimental drug study within 4 weeks prior to treatment
- Pregnant or lactating women
- Known hypersensitivity to any component of atezolizumab or other study medication
- History of autoimmune disease except controlled, treated hypothyroidism or type I diabetes mellitus
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis
- Positive human immunodeficiency virus test
- Active or chronic hepatitis B or C
- Severe infections within 4 weeks prior to treatment
- Exposure to oral or IV antibiotics within 2 weeks prior to treatment
- Live attenuated vaccines within 4 weeks prior to treatment (for influenza vaccination participants must agree not to receive live, attenuated influenza vaccine within 4 weeks prior to treatment, during treatment or within 5 months following the last dose)
- Significant cardiovascular disease
- Prior allogeneic stem cell or solid organ transplantation

Exclusion Criteria Related to Medications:

- Prior treatment with cluster of differentiation 137 agonists, anti-cytotoxic T-lymphocyte associated protein-4, anti-programmed death (PD)-1, or anti-PD-L1 therapeutic antibody or pathway-targeting agents
- Treatment with immunostimulatory agents for non-malignant conditions within 6 weeks or immunosuppressive agents within 2 weeks prior to treatment

Bevacizumab- and Sunitinib-Specific Exclusions:

- History of hypertensive crisis or hypertensive encephalopathy
- Baseline electrocardiogram showing corrected QT interval greater than 460 milliseconds