ForPatients
by Roche

Renal Cell Cancer (RCC)

A Study of Atezolizumab in Combination With Bevacizumab in Untreated Locally Advanced or Metastatic Clear Cell or Non-Clear Cell Renal Cell Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Withdrawn	7 Countries	NCT03693573 MO39939

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, Phase IIIB, Single Arm, Multicenter Safety Study of Atezolizumab in Combination With Bevacizumab in Untreated Locally Advanced or Metastatic Clear Cell or Non-Clear Cell Renal Cell Carcinoma

Trial Summary:

Study MO39939 is an open-label, single-arm, multicenter trial in patients with unresectable, locally-advanced or metastatic, clear or non-clear cell renal cell carcinoma (RCC) who have not received prior systemic therapy (who are treatment naïve in either the [neo]adjuvant or advanced/metastatic setting for clear and non-clear cell RCC). The study consists of a Screening Period, a Treatment Period, an End of Treatment Visit occurring approximately 30 days after the last dose of study medication, and a Follow-Up Period of 4 years after last patient enrolled.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03693573 MO39939
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Unresectable, advanced or metastatic RCC with clear cell or non-clear cell histology
- No prior treatment with active or experimental systemic agents for RCC
- Measurable and/or non-measurable but evaluable baseline disease per RECIST v1.1
- Confirmed diagnosis of RCC
- Karnofsky Performance Score (KPS) # 60
- Adequate hematologic and end-organ function
- Patients with asymptomatic CNS metastases are eligible, provided they meet all of the following criteria:
- Evaluable disease outside the CNS * No history of intracranial or spinal cord hemorrhage * No evidence of significant vasogenic edema * No stereotactic radiation within 7 days or whole-brain radiation or neurosurgical resection within 2 weeks before the start of study treatment * Have had a screening CNS radiography # 2 weeks since completion of radiotherapy or surgical resection
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- Prior treatment for RCC with active or experimental systemic agents, including treatment in the neoadjuvant or adjuvant setting - Confirmed prior treatment with placebo in the (neo)adjuvant setting is allowed
- Radiotherapy ongoing at the time of study entry
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently) - Patients with indwelling catheters are allowed
- Uncontrolled or symptomatic hypercalcemia - Patients who are currently receiving bisphosphonate therapy without current hypercalcemia are eligible
- History of malignancy other than RCC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death, such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer
- Life expectancy of < 12 weeks
- 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 - History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Active tuberculosis
- Significant renal disorder requiring dialysis
- 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
- Patients with active hepatitis B or hepatitis C
- Current treatment with anti-viral therapy for HBV
- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications