ForPatients
by Roche

Cancer

A Study of Atezolizumab in Locally Advanced or Metastatic Urothelial or Non-Urothelial Carcinoma of the Urinary Tract

Trial Status	Trial Runs In	Trial Identifier
Completed	32 Countries	NCT02928406 2016-002625-11 MO29983

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, Single Arm, Multicenter, Safety Study of Atezolizumab in Locally Advanced or Metastatic Urothelial or Non-Urothelial Carcinoma of the Urinary Tract

Trial Summary:

This Phase IIIb, multicenter study will assess the safety of atezolizumab as second- to fourth-line treatment for participants with locally advanced or metastatic urothelial or non-urothelial cancer of the urinary tract in addition to evaluate the efficacy of atezolizumab and potential tumor biomarkers associated with atezolizumab.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02928406 2016-002625-11 MO29983
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Participants with histologically documented locally advanced (tumor [T] 4b, any node [N]; or any T, N 2-3) or metastatic (M1, Stage IV) urothelial or non-urothelial carcinoma of the urinary tract
- Participants with measurable and/or non-measurable disease according to RECIST v1.1

- Participants must have progressed during or following treatment with at least one prior (and not more than 3) treatments for inoperable, locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract
- If available, a representative formalin-fixed paraffin-embedded (FFPE) tumor specimen block should be submitted
- Eastern cooperative oncology group (ECOG) performance status 0, 1 or 2

Exclusion Criteria:

- Treatment with more than three prior lines of systemic therapy for inoperable, locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract
- Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 4 weeks prior to study treatment initiation
- Participants who were in another clinical trial with therapeutic intent within 4 weeks of study treatment initiation but were not on active drug in that prior trial are eligible
- Participants who were in another clinical trial with therapeutic intent within 4 weeks of study treatment initiation but were in the follow-up phase of that prior trial and had stopped receiving active drug 4 or more weeks before study treatment initiation are eligible
- Malignancies other than the one studied in this protocol within 5 years prior to Cycle 1, Day 1
- Evidence of significant uncontrolled concomitant disease that could affect compliance with the protocol
- Significant renal disorder indicating a need for renal transplant