ForPatients
by Roche

Bladder CancerUrothelial Carcinoma

A Study of MOXR0916 in Combination With Atezolizumab Versus Atezolizumab Alone in Participants With Untreated Locally Advanced or Metastatic Urothelial Carcinoma Who Are Ineligible for Cisplatin-Based Therapy

Trial Status	Trial Runs In	Trial Identifier
Terminated	5 Countries	NCT03029832 2016-004165-58 GO39590

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, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study of MOXR0916 in Combination With Atezolizumab Versus Atezolizumab Alone in Patients With Untreated Locally Advanced or Metastatic Urothelial Carcinoma Who Are Ineligible for Cisplatin-Based Therapy

Trial Summary:

This is a Phase II, multicenter, randomized, placebo-controlled, double-blind study to evaluate the safety and efficacy of MOXR0916 in combination with atezolizumab versus placebo and atezolizumab in participants with locally advanced or metastatic urothelial carcinoma (UC) who have not received prior systemic therapy in the locally advanced/ metastatic setting and who are ineligible to receive cisplatin-based therapy.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT03029832 2016-004165-58 GO39590
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Age >= 18 years
- Eastern Cooperative Oncology Group (ECOG) performance status of <= 2
- Life expectancy >= 12 weeks
- Histologically or cytologically confirmed locally advanced or metastatic urothelial carcinoma (UC)
- Availability of a representative formalin-fixed paraffin-embedded tumor specimen
- No prior systemic therapy for inoperable locally advanced or metastatic UC
- Ineligible for cisplatin-based chemotherapy as defined by any one of the following criteria: Impaired renal function (glomerular filtration rate [GFR] > 30 but < 60 milliliter/minute [mL/min]); National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version (v) 4.0 Grade >= 2 audiometric hearing loss (of 25 Decibel at two contiguous frequencies or more severe); NCI CTCAE v 4.0 Grade >= 2 peripheral neuropathy; ECOG Performance Status of 2
- Measurable disease according to Response Evaluation Criteria in Solid Tumors v1.1
- Adequate hematologic and end-organ function

Exclusion Criteria:

- Significant cardiovascular disease
- Known clinically significant liver disease
- Any approved anti-cancer therapy, including chemotherapy or hormonal therapy, within 3 weeks prior to initiation of study treatment
- Prior treatment with CD137 or OX40 agonists, anti-cytotoxic T-lymphocyte-associated protein (CTLA4), anti-programmed death-1 (PD-1), anti- programmed death-ligand 1 (PD-L1), anti-CD-27, anti-glucocorticoid-induced tumor necrosis factor receptor (GITR) therapeutic antibody or pathway-targeting agents
- Untreated central nervous system (CNS) metastases or active (progressing or requiring corticosteroids for symptomatic control) CNS metastases
- Any history of leptomeningeal disease
- Malignancies other than UC within 5 years prior to Cycle 1, Day 1
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis, pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening chest computed tomography scan
- Active hepatitis B and C virus infection
- Positive HIV test at screening
- Active tuberculosis
- Prior allogeneic stem cell or solid organ transplantation