ForPatients
by Roche

Bladder CancerUrothelial Carcinoma

Study of Atezolizumab as Monotherapy and in Combination With Platinum-Based Chemotherapy in Participants With Untreated Locally Advanced or Metastatic Urothelial Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Completed	34 Countries	NCT02807636 2016-000250-35 WO30070

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, Multicenter, Randomized, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) as Monotherapy and in Combination With Platinum-Based Chemotherapy in Patients With Untreated Locally Advanced or Metastatic Urothelial Carcinoma

Trial Summary:

A Phase III, randomised study of atezolizumab alone and in combination with chemotherapy versus chemotherapy alone in participants with untreated advanced urothelial cancer.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02807636 2016-000250-35 WO30070
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Considered to be eligible to receive platinum-based chemotherapy, in the investigator's judgment
- Eastern Cooperative Oncology Group (ECOG) performance status of less than or equal to (</=) 2

- Histologically documented, locally advanced (T4b, any N; or any T, N2-3) or metastatic urothelial carcinoma (mUC) (M1, Stage IV) (also termed transitional cell carcinoma [TCC] or urothelial cell carcinoma [UCC] of the urinary tract; including renal pelvis, ureters, urinary bladder, and urethra)
- Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens in paraffin blocks (blocks preferred) or at least 15 unstained slides, with an associated pathology report, for central testing and determined to be evaluable for tumor PD-L1 expression prior to study enrollment; participants who have fewer than 15 unstained slides available at baseline (but no less than [<] 10) may be eligible following discussion with the Medical Monitor
- No prior chemotherapy for inoperable locally advanced or mUC
- For participants who received prior adjuvant/neoadjuvant chemotherapy or chemo-radiation for urothelial carcinoma, a treatment-free interval more than (>) 12 months between the last treatment administration and the date of recurrence is required in order to be considered treatment naive in the metastatic setting
- Prior local intravesical chemotherapy or immunotherapy is allowed if completed at least 4 weeks prior to the initiation of study treatment
- Measurable disease, as defined by RECIST v1.1
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 6 months after the last dose of carboplatin, cisplatin, or gemcitabine or for 5 months after the last dose of atezolizumab
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm

Exclusion Criteria:

- Any approved anti-cancer therapy, including chemotherapy or hormonal therapy, within 3 weeks prior to initiation of study treatment
- Treatment with any other investigational agent or participation in another clinical study with therapeutic intent within 28 days prior to enrolment
- Active or untreated CNS metastases as determined by computed tomography (CT) or magnetic resonance imaging evaluation during screening and prior radiographic assessments
- Participants with treated asymptomatic central nervous system (CNS) metastases are eligible, provided they meet all of the following criteria: * Evaluable or measurable disease outside the CNS * No metastases to midbrain, pons, medulla, or within 10 mm of the optic apparatus (optic nerves and chiasm) * No history of intracranial or spinal cord hemorrhage * No ongoing requirement for corticosteroid as therapy for CNS disease; anti-convulsants at a stable dose are allowed * No evidence of significant vasogenic edema * No stereotactic radiation, whole-brain radiation or neurosurgical resection within 4 weeks prior to Cycle 1, Day 1 * Radiographic demonstration of interim stability (i.e., no progression) between the completion of CNS-directed therapy and the screening radiographic study * Screening CNS radiographic study >/=4 weeks since completion of radiotherapy or surgical resection and >/=2 weeks since discontinuation of corticosteroids
- Prior treatment with CD137 agonists, anti-CTLA-4, anti-programmed death-1 (PD-1), or anti-PD-L1 therapeutic antibody or pathway-targeting agents
- Treatment with systemic corticosteroids or other systemic immunosuppressive medications (including but not limited to prednisone, dexamethasone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor [TNF] agents) within 2 weeks prior to Cycle 1, Day 1 or anticipated requirement for systemic immunosuppressive medications during the study
- Leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently)
- Uncontrolled tumour-related pain or hypercalcemia

- Significant cardiovascular disease including known left ventricular ejection fraction (LVEF) <40%
- Severe infections within 4 weeks before randomization or therapeutic oral or IV antibiotics within 2 weeks before randomization
- Major surgical procedure within 4 weeks prior to randomization or anticipation of need for a major surgical procedure during the course of the study other than for diagnosis
- Malignancies other than urothelial carcinoma within 5 years prior to Cycle 1, Day 1
- Life expectancy of <12 weeks
- Pregnant or lactating, or intending to become pregnant during the study
- Serum albumin <25 gram per liter (g/L)
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
- History of autoimmune disease
- Participants with prior allogeneic stem cell or solid organ transplantation
- History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia (i.e., bronchiolitis obliterans, cryptogenic organizing pneumonia), or evidence of active pneumonitis on screening chest CT scan
- Positive test for human immunodeficiency virus (HIV)
- Active hepatitis B or hepatitis C
- Active tuberculosis
- Administration of a live, attenuated vaccine within 4 weeks before Cycle 1, Day 1