ForPatients
by Roche

CarcinomaBladder Cancer

A Study of Atezolizumab Versus Observation as Adjuvant Therapy in Participants With High-Risk Muscle-Invasive Urothelial Carcinoma (UC) After Surgical Resection

Trial Status	Trial Runs In	Trial Identifier
Terminated	24 Countries	NCT02450331 2014-005603-25 WO29636

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, Multicenter, Randomized Study of Atezolizumab (Anti-PD-L1 Antibody) Versus Observation as Adjuvant Therapy in Patients With High-Risk Muscle-Invasive Urothelial Carcinoma After Surgical Resection

Trial Summary:

This Phase III, open-label, randomized, multicenter study is to evaluate the efficacy and safety of adjuvant treatment with atezolizumab compared with observation in participants with muscle-invasive UC who are at high risk for recurrence following resection. Eligible participants were randomized by a 1:1 ratio into atezolizumab group or control group.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02450331 2014-005603-25 WO29636
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically confirmed muscle-invasive UC (also termed transitional cell carcinoma) of the bladder or upper urinary tract (i.e., renal pelvis or ureters)

- For participants treated with prior neoadjuvant chemotherapy: tumor stage of ypT2-4a or ypN+ (ypT2-4 or ypN+ for participants with upper urinary tract UC) and M0
- For participants who have not received prior neoadjuvant chemotherapy: tumor stage of pT3-4a or pN+ (pT3-4 or pN+ for participants with upper urinary tract UC) and M0
- Representative formalin-fixed paraffin-embedded tumor specimens from surgical resection (i.e., radical cystectomy, nephroureterectomy, or lymph node dissection) 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 programmed death-ligand 1 (PD-L1) expression prior to study enrollment
- Absence of residual disease and absence of metastasis, as confirmed by a negative baseline computed tomography (CT) or magnetic resonance imaging scan of the pelvis, abdomen, and chest no more than 4 weeks prior to randomization
- Full recovery from cystectomy or nephroureterectomy within 14 weeks following surgery
- Eastern Cooperative Oncology Group performance status of less than or equal to (</=) 2
- Life expectancy greater than or equal to (>/=) 12 weeks
- Adequate hematologic and end-organ function
- For women who are not postmenopausal or surgically sterile: agreement to remain abstinent or use contraceptive methods that result in a failure rate of less than (<) 1 percent (%) per year during the treatment period and for at least 5 months after the last dose of atezolizumab

Exclusion Criteria:

- Any approved anti-cancer therapy within 3 weeks prior to initiation of study treatment
- Adjuvant chemotherapy or radiation therapy for UC following surgical resection
- Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 28 days or five half-lives of the drug prior to enrollment
- Malignancies other than UC within 5 years prior to Cycle 1, Day 1
- Pregnancy or breastfeeding
- Significant cardiovascular disease
- Severe infections within 4 weeks prior to Cycle 1, Day 1
- Major surgical procedure other than for diagnosis within 28 days prior to Cycle 1, Day 1
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
- History of autoimmune disease
- Prior allogeneic stem cell or solid organ transplant
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest CT scan
- Positive test for human immunodeficiency virus and/or active hepatitis B or hepatitis C or tuberculosis
- Administration of a live, attenuated vaccine within 4 weeks before Cycle 1 Day 1
- Prior treatment with cluster of differentiation 137 (CD137) agonists or immune checkpoint blockade therapies, including anti-CD40, anti-cytotoxic T-lymphocyte-associated protein 4 (anti-CTLA-4), anti-programmed death-1 (anti-PD-1), and anti-PD-L1 therapeutic antibodies