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Trial record **1 of 1** for: WO29636

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A Study of Atezolizumab Versus Observation as Adjuvant Therapy in Participants With High-Risk Muscle-Invasive Urothelial Carcinoma After Surgical Resection [IMvigor010]

This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2017 by *Hoffmann-La Roche*

Sponsor:
Hoffmann-La Roche

Information provided by (Responsible Party):
Hoffmann-La Roche

ClinicalTrials.gov Identifier:
NCT02450331

First received: May 19, 2015
Last updated: April 24, 2017
Last verified: April 2017
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

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 urothelial carcinoma (UC) who are at high risk for recurrence following resection. Eligible participants will be randomized by a 1:1 ratio into atezolizumab group or control group.

Condition	Intervention	Phase
Carcinoma, Transitional Cell	Drug: Atezolizumab	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: No masking
Primary Purpose: Treatment

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

Resource links provided by NLM:

Drug Information available for: Atezolizumab

Genetic and Rare Diseases Information Center resources: Transitional Cell Carcinoma

U.S. FDA Resources

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measures:

- Disease-Free Survival (DFS), as Assessed by Investigator [Time Frame: Randomization up to first occurrence of DFS event (assessed at screening/randomization, every 12 weeks after randomization in first 3 years, every 24 weeks for Years 4 and 5, and at Year 6)]

  DFS is defined as the time from randomization to the time of first occurrence of a DFS event. DFS events include: local (pelvic) recurrence of UC (including soft tissue and regional lymph nodes); urinary tract recurrence of UC (including all pathological stages and grades); distant metastasis of UC; or death from any cause. Tumor assessment will be performed using radiographic evaluations.

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: Randomization until death due to any cause (up to approximately 6.5 years)]
- Disease-Specific Survival (DSS), as Assessed by Investigator [Time Frame: Randomization until death due to UC (up to approximately 6.5 years)]

  DSS is defined as the time from randomization until the date of death from UC.

- Distant Metastasis-Free Survival (DMFS) [Time Frame: Randomization up to diagnosis of distant metastases or death from any cause (assessed at screening/randomization, every 12 weeks after randomization in first 3 years, every 24 weeks for Years 4 and 5, and at Year 6)]

  DMFS is defined as the time from randomization to the date of diagnosis of distant (that is, non-locoregional) metastases or death from any cause. Tumor assessment will be performed using radiographic evaluations.

- Non-Urinary Tract Recurrence-Free Survival (NURFS) [Time Frame: Randomization up to time of first occurrence of a NURFS event (assessed at screening/randomization, every 12 weeks after randomization in first 3 years, every 24 weeks for Years 4 and 5, and at Year 6)]

NURFS is defined as the time from randomization to the time of first occurrence of a NURFS event. NURFS events include: local (pelvic) recurrence of UC (including soft tissue and regional lymph nodes); distant metastasis of UC; or death from any cause. Tumor assessment will be performed using radiographic evaluations.

- Percentage of Participants with Adverse Events (AEs) [Time Frame: Screening up to approximately 1 year]
- Percentage of Participants With Anti-Therapeutic Antibodies (ATAs) to Atezolizumab [Time Frame: Pre-dose (Hour 0) on Day 1 of Cycles 1, 2, 3, 4, and every 8 cycles from Cycle 8; at treatment discontinuation (up to 1 year); 90 days after last dose (last dose = up to 1 year) (Cycle length = 21 days)]
- European Quality of Life (EuroQoL) Group 5-Dimension 5-Level (EQ-5D-5L) Self Report Questionnaire Health Utility Score [Time Frame: Day 1 of Cycle 1 up to 6 (detailed timeframe is provided in outcome description section)]

  Detailed timeframe: Day 1 of Cycles 1, 3, 5, 7, 9, 11, 13, 15, at treatment/observation period discontinuation (up to 1 year), thereafter every 12 weeks up to Year 3 and then every 24 weeks up to Year 5, at Year 6, additionally at 6, 12, 24 weeks after disease recurrence (any time up to 6 years) (Cycle length = 21 days)

- Minimum Observed Serum Atezolizumab Concentration (Cmin) [Time Frame: Pre-dose (Hour 0) on Day 1 of Cycles 1, 2, 3, 4, every 8 cycles from Cycle 8, at treatment discontinuation (up to 1 year), 120 days after treatment discontinuation (up to 1 year 4 months)]
- Maximum Observed Serum Atezolizumab Concentration (Cmax) [Time Frame: Pre-dose (Hour 0) and 0.5 hours after end of infusion on Day 1 of Cycle 1 (infusion duration = 60 minutes, Cycle length = 21 days)]

Estimated Enrollment:	700
Anticipated Study Start Date:	June 29, 2017
Estimated Study Completion Date:	April 30, 2022
Estimated Primary Completion Date:	June 30, 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Atezolizumab Participants will receive intravenous (IV) atezolizumab on Day 1 of each 21-day cycle for 16 cycles (up to 1 year).	Drug: Atezolizumab Atezolizumab will be administered at a dose of 1200 milligrams (mg). Other Name: Tecentriq; MPDL3280A
No Intervention: Observation Participants will undergo observation starting on Day 1 for 16 cycles (up to 1 year).	

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically confirmed muscle-invasive UC (also termed transitional cell carcinoma [TCC]) of the bladder or upper urinary tract (i.e., renal pelvis or ureters)
- Participants who have not received prior platinum-based neoadjuvant chemotherapy, have refused or are ineligible ("unfit") for cisplatin-based adjuvant chemotherapy
- Representative formalin-fixed paraffin-embedded (FFPE) 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 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 (MRI) 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 (ECOG) 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 (HIV) 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-programmed death-ligand 1 (anti-PD-L1) therapeutic antibodies

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02450331

Contacts

Contact: Reference Study ID Number: **WO29636** www.roche.com/about_roche/roche_worldwide.htm 888-662-6728 (U.S. and Canada) global-roche-genentech-trials@ge

Show 238 Study Locations

Sponsors and Collaborators

Hoffmann-La Roche

Investigators

Study Director: Clinical Trials Hoffmann-La Roche

More Information

Responsible Party:	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT02450331 History of Changes
Other Study ID Numbers:	**WO29636** 2014-005603-25 (EudraCT Number)
Study First Received:	May 19, 2015
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Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Carcinoma	Neoplasms
Carcinoma, Transitional Cell	Antibodies, Monoclonal
Neoplasms, Glandular and Epithelial	Immunologic Factors
Neoplasms by Histologic Type	Physiological Effects of Drugs

ClinicalTrials.gov processed this record on April 26, 2017