Protocol Title: Phase III, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study of Atezolizumab (Anti−PD-L1 Antibody) as Adjuvant Therapy in Patients with Renal Cell Carcinoma at High Risk of Developing Metastasis Following Nephrectomy

Target Population: Renal Cell Carcinoma

Summary: This is a Phase III, multicenter, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of atezolizumab versus placebo in participants with RCC who are at high risk of disease recurrence following nephrectomy.

Key Inclusion Criteria:
- Pathologically confirmed RCC with a component of clear cell histology or sarcomatoid histology that has not been treated in the adjuvant or neoadjuvant setting and classified as being at high risk of RCC recurrence.
- Radical or partial nephrectomy with lymphadenectomy in select participants.
- Absence of residual disease and absence of metastasis, as confirmed by a negative baseline CT of the pelvis, abdomen, and chest no more than 4 weeks prior to randomization.
- Absence of brain metastasis, as confirmed by a negative CT with contrast or MRI scan of the brain, no more than 4 weeks prior to randomization. Applicable only to metastasectomy participants.
- Full recovery from nephrectomy or metastasectomy within 12 weeks from randomization following surgery.

Key Exclusion Criteria:
- Bilateral synchronous tumors with inheritable forms of RCC including von Hippel-Lindau.
- 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 or five half-lives of the investigational agent, whichever is longer, prior to enrollment.
- Malignancies other than RCC within 5 years prior to Cycle 1, Day 1.
- Participants with prior allogeneic stem cell or solid organ transplantation.
- History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening chest CT scan.
- Participants with positive test for HIV, active Hepatitis B, active Hepatitis C, or active Tuberculosis.
- Severe infections within 4 weeks prior to randomization including but not limited to hospitalization for complications of infection, bacteremia, or severe pneumonia.
- 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.
- Administration of a live, attenuated vaccine within 4 weeks before Cycle 1, Day 1.
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the participant at high risk from treatment complications.
- Prior treatment with CD-137 agonists, anti-CTLA-4, anti-PD-1, anti-PD-L1 therapeutic antibody or pathway-targeting agents.
- Treatment with systemic immunostimulatory agents within 6 weeks or five half-lives of the drug, whichever is shorter, prior to randomization.
- Treatment with systemic immunosuppressive medications within 2 weeks prior to randomization or anticipated need for systemic immunosuppressive medications during the study.

Contacts:

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03024996

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