Protocol Title: A Phase 3, Open-label, Randomized Study of Nivolumab Combined with Ipilimumab, or with Standard of Care Chemotherapy, Versus Standard of Care Chemotherapy in Participants with Previously Untreated Unresectable or Metastatic Urothelial Cancer (CheckMate901)

Target Population: Metastatic or Inoperable Urothelial Cancer

Summary: The purpose of this study is to determine whether an investigational immunotherapy Nivolumab in combination with Ipilimumab or in combination with standard of care chemotherapy is more effective than standard of care chemotherapy alone in treating patients with previously untreated inoperable or metastatic urothelial cancer.

Key Inclusion Criteria:
- Metastatic or inoperable Urothelial Cancer.
- Must have at least 1 lesion with measurable disease.
- Must have full activity or, if limited, must be able to walk and carry out activities such as light house work or office work.
- No prior systemic chemotherapy treatment in the metastatic setting.

Key Exclusion Criteria:
- Patients with disease that is suitable for local therapy administered with curative intent.
- Patients with active brain metastases or leptomeningeal metastases.
- Patients with active, known or suspected autoimmune disease.
- Prior treatment with an anti-PD1, anti-PDL1, anti-PDL2, anti-CD137, or anti-CTLA4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03036098