A031901

DURATION OF IMMUNE CHECKPOINT THERAPY IN LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA: A RANDOMIZED PHASE 3 NON-INFERIORITY TRIAL (IMAGINE)

Commercial agents: Pembrolizumab, Nivolumab, Atezolizumab, Avelumab

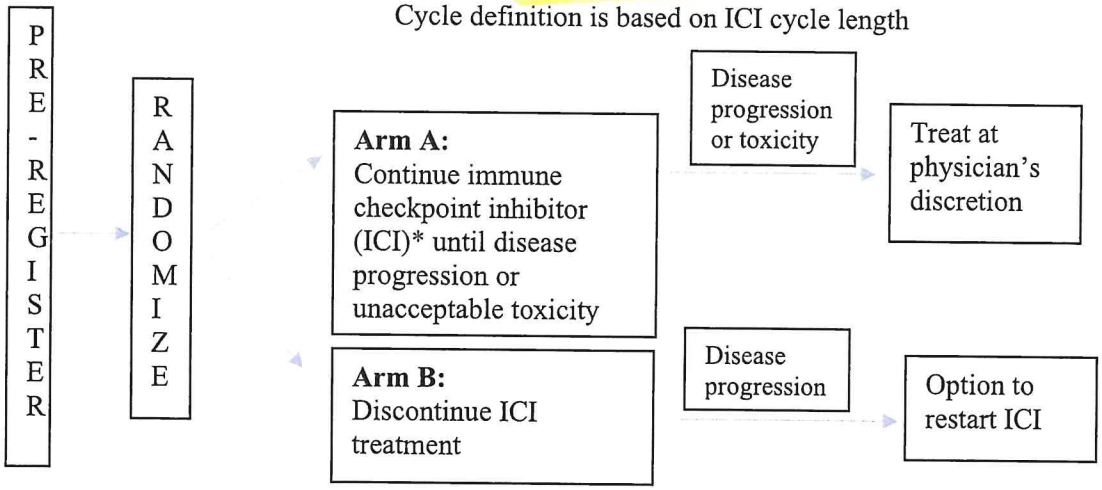
Pre- registration Eligibility Criteria
Histologic or cytologic confirmed urothelial carcinoma
Locally advanced or metastatic
At least 1 cycle of active treatment with standard of care ICI
At least one scan showing CR, PR or SD (no PD)
No history of allogeneic organ transplant

Registration Eligibility Criteria
No PD per RECIST v1.1 after 9-18 months of ICI
No ICI toxicity that makes treatment continuation unacceptable
Age ≥ 18 years
ECOG PS 0-2
CNS disease allowed if stable
No immunosuppressive medication exceeding 10 mg/day of prednisone or equivalent
Non-pregnant and non-nursing

Pre-reg and Reg Required Lab Values
Patients must have adequate bone marrow and organ function to continue PD-L1 ICI as judged by the treating physician. No specific parameters need to be met.

Schema

Cycle definition is based on ICI cycle length



* ICI agents include pembrolizumab, nivolumab, atezolizumab, and avelumab

Patients will be followed for 5 years or until death or withdrawal of consent, whichever occurs first.
Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.