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

Commercial agents: Pembrolizumab, Nivolumab, Atezolizumab, Durvalumab, Avelumab

Eligibility Criteria (see Section 3.0)

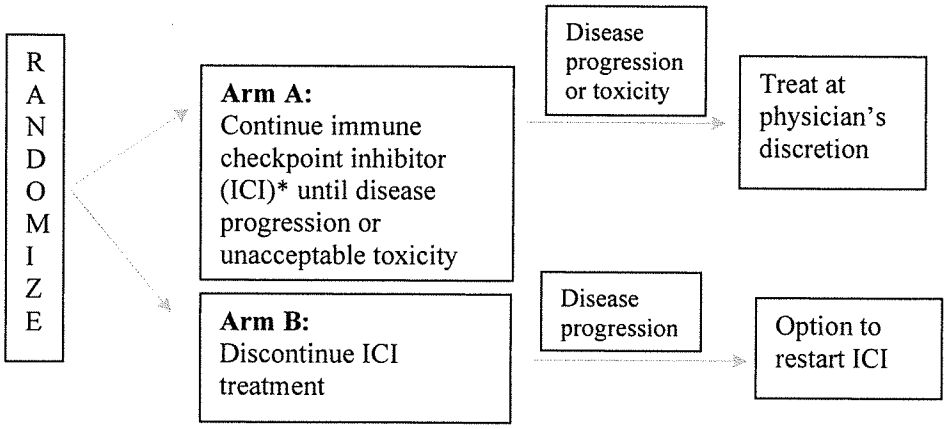
Histologic or cytologic confirmed urothelial carcinoma
Locally advanced or metastatic
On active treatment with standard of care ICI
Radiographic response without progression 12-15 months after starting ICI
No ICI toxicity that makes treatment continuation unacceptable.
Age ≥ 18 years
ECOG PS 0-2
CNS disease allowed if stable
No history of TB, active hep B/C or uncontrolled HIV
No history of allogeneic organ transplant
No immunosuppressive medication exceeding 10 mg/day of prednisone or equivalent
Non-pregnant and non-nursing

Required Initial Laboratory Values

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

Schema

Cycle definition is based on ICI cycle length



* ICI agents include pembrolizumab, nivolumab, atezolizumab, durvalumab 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.