There are limited treatment options for patients with metastatic urothelial carcinoma who have progressed following treatment with platinum (platinum or carboplatin)-based chemotherapy and/or immune checkpoint inhibitor therapy.

Approximately 200 patients will be enrolled in the ATLAS trial. Tumors will also be evaluated for expression of the immune regulatory protein PD-L1.

The ATLAS trial is enrolling biomarker unselected patients, with the goal of identifying and optimizing predictive biomarkers. Results from the analysis indicated that many urothelial tumors have high genomic LOH (see Table 2) and high BRCA1/2 mutant allele frequencies and alterations in genes associated with DNA repair and synthetic lethality.

At screening, patients must have an ECOG PS of 0–1, adequate organ function (e.g., creatinine clearance of ≥50 mL/min, or ≤1.5 × ULN if serum creatinine ≥1.5 × ULN), and an available tumor for analysis. Key eligibility criteria include:

- Patients with or without tumors associated with homologous recombination dysfunction (HRD) deficiency.
- Patients with or without tumors associated with homologous recombination deficiency (HRD) status.
- Tumor and/or archival tumor tissue.
- Adequate organ function.
- Simon Chowdhury, in all patients.
- Two interim analyses are planned after data are available for 60 and 120 patients.
- Collecting these samples also allows for the comprehensive characterization of tumor evolution.
- Microsatellite instability (MSI) and/or L1 expression.
- Cancer Res. 2018;78:47-55.