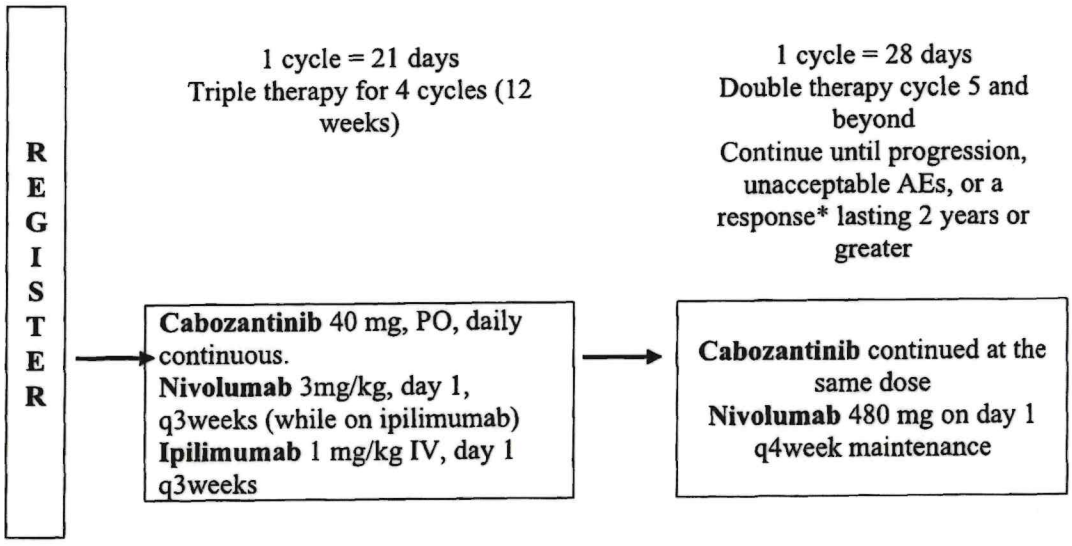
A PHASE II STUDY OF IPILIMUMAB, CABOZANTINIB, AND NIVOLUMAB IN RARE GENITOURINARY CANCERS (ICONIC)

Eligibility Criteria (For a complete listing of protocol eligibility criteria see Section 3.2)

Required Initial Laboratory Values

Absolute Neutrophil Count (ANC)	≥1,000/mcL
Platelet Count	≥75,000/mcL
Total Bilirubin	≤1.5 × ULN. For subjects with known Gilbert's disease or similar syndrome with slow conjugation of bilirubin, total bilirubin ≤ 3.0 mg/dL
AST/ALT	≤3.0 × institutional upper limit of normal (ULN) (or ≤5 x ULN for patients with liver metastases or Gilbert's disease)
Creatinine	≤ 1.5 x upper limit of normal (ULN) **OR**
creatinine clearance	≥ 40 mL/min/1.73 m^2 (calculated using the CKD-EPI equation or Cockroft-Gault formula) for patients with creatinine levels above institutional normal.
hemoglobin	≥9 g/dL (transfusion of PRBCs allowed)
serum albumin	≥3.2g/dL
lipase and amylase	≤2.0 × ULN and no radiologic (on baseline anatomical imaging) or clinical evidence of pancreatitis

Schema



*Response is defined as a complete or partial response or stable disease >9 months. Patients will be followed for a total of 5 years from the date of registration or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.