

A PHASE II STUDY OF <u>I</u>PILIMUMAB, <u>C</u>AB<u>O</u>ZANTINIB, AND <u>NI</u>VOLUMAB IN RARE GENITOURINARY <u>C</u>ANCERS (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 $\leq 3.0 \times \text{institutional upper limit of normal (ULN) (or } \leq 5 \times \text{ULN for}$

patients with liver metastases or Gilbert's disease)

Creatinine ≤ 1.5 x upper limit of normal (ULN)

OR

creatinine clearance $\geq 40 \text{ mL/min/1.73 m}^2$ (calculated using the CKD-EPI equation or

Cockroft-Gault formula) for patients with creatinine levels above

institutional normal.

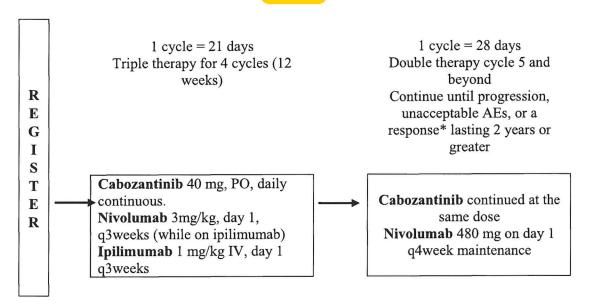
hemoglobin ≥9 g/dL (transfusion of PRBCs allowed)

serum albumin ≥3.2g/dL

lipase and amylase $\leq 2.0 \times \text{ULN}$ 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.