

**MAIN-CAV: PHASE III RANDOMIZED TRIAL OF MAINTENANCE CABOZANTINIB AND  
AVELUMAB VS MAINTENANCE AVELUMAB AFTER FIRST-LINE PLATINUM-BASED  
CHEMOTHERAPY IN PATIENTS WITH METASTATIC UROTHELIAL CANCER**

**Key Eligibility Criteria** (see [Section 3.2](#))

Histologically or cytologically-confirmed diagnosis of advanced or metastatic urothelial cancer, including N3 only disease CR, PR, or SD after 4-6 cycles of 1<sup>st</sup> line therapy, 3-10 weeks prior to randomization.

Prior treatment per [Section 3.2.2 and 3.2.3](#).

Age  $\geq$  18 years.

ECOG Performance Status: 0 or 1.

Not pregnant and not nursing. [Section 3.2.6](#).

No use of immunosuppressive medication within 7 days prior to randomization. However, certain exceptions are allowed per [Section 3.2.8](#).

HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial.

Patients with diabetes type I, vitiligo, psoriasis, or hypo or hyperthyroid disease not requiring immunosuppressive treatment are eligible.

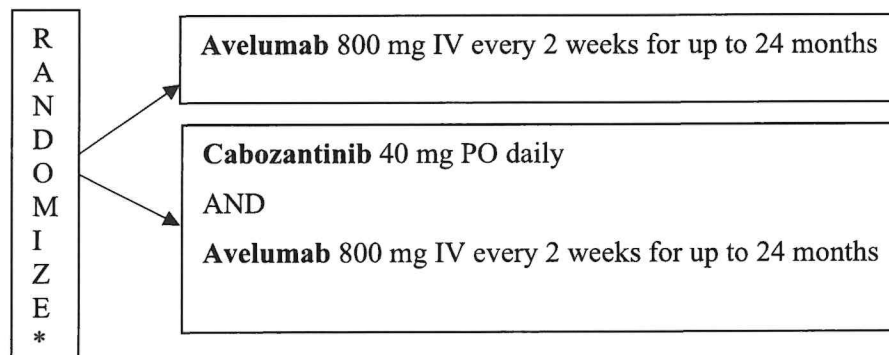
None of the criteria in [Section 3.2.11](#).

**Required Initial Laboratory Values**

ANC	$\geq 1000/\text{mm}^3$
Platelet count:	$\geq 100,000/\text{mm}^3$
Hemoglobin	$\geq 8 \text{ g/dL}$
Calc. creatinine	$\geq 30 \text{ mL/min}$
Clearance (using Cockcroft-Gault equation)	
Total serum bilirubin:	$\leq 1.5 \times \text{ULN}$
AST/ALT:	$\leq 2.5 \times \text{ULN}$ (or $\leq 5 \times \text{ULN}$ for patients with liver metastases or Gilbert's disease)
UPC Ratio	$\leq 1$ , or
24-urine protein	$< 1 \text{ g}$

**Schema**

1 Cycle = 28 Days



\*Randomization is to occur 3-10 weeks after last dose of 1st-line treatment

Stratification:

- Best response to 1st-line chemo (SD vs PR vs CR)
- Visceral metastases: present versus absent