

# NEW CLINICAL TRIAL OPEN FOR INCLUSION

## PROTOCOL TITLE

A randomized, open-label, phase 2/3 trial of izalontamab brengitecan versus platinum-based chemotherapy for metastatic urothelial cancer in participants with disease progression on or after an immunotherapy-based treatment.

## ALIAS

IZABRIGHT-BLADDER01

## CTO NUMBER

CTO25042BMS

## SPONSOR

Bristol Myers Squibb

## KEY INCLUSION CRITERIA

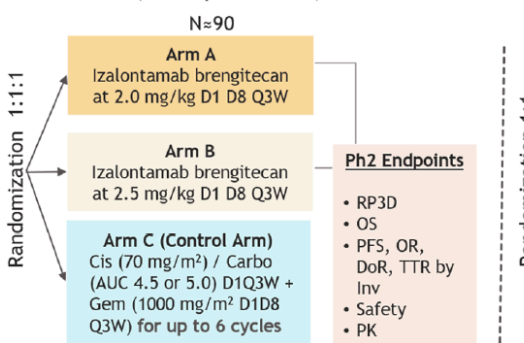
- Gemetastaseerd TCC van: pyelum, ureter, blaas, urethra
- Variante histologie toegestaan indien <50%
- Platinum-vrij interval  $\geq 12$  maanden
- Gearchiveerd tumorweefsel beschikbaar, maximaal 5 jaar oud

## KEY EXCLUSION CRITERIA

- Gevorderde of klinisch significante longziekte binnen de afgelopen 6 maanden
- Actieve infectie binnen 14 dagen vóór randomisatie
- Meer dan 2 voorgaande systemische behandelingen
- eGFR <30ml/min

## DESIGN

### Phase 2 (dose optimization)

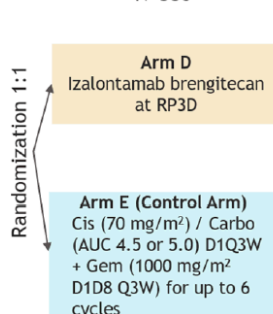


#### Stratification factors:

- Number of prior regimens of systemic therapy (1 vs 2) **Pause**
- Previous enfortumab vedotin (yes vs no)
- Liver metastases (present vs absent)

### Phase 3

N=380



### Phase 3 Endpoints

#### Dual Primary:

- PFS by BICR
- OS

#### Secondary:

- OR, DoR, TTR by BICR
- HRQoL (TDD in EORTC QLQ-C30)

#### Exploratory EPs:

- OR, DoR, PFS, TTR by Inv
- Safety
- PK (Phase 3) and IMG
- HRQoL (Additional EORTC QLQ-C30, EQ-5D, FACIT-GP5)
- Biomarkers

Treatment until progression, unacceptable toxicity, or a maximum of 6 cycles of PBC

Primary prophylaxis with pegylated G-CSF on Day 9 is mandated for all participants assigned to Arms A, B and D

## PRINCIPAL INVESTIGATOR

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