

## Supplemental Digital Content 7

**TABLE: Summary of Patient Analysis Sets**

Analysis Set	Definition
ITT	All randomized patients
Safety	All randomized patients who received $\geq 1$ dose of IV study drug
Safety evaluable	A subset of patients from the safety analysis set who received $\geq 72$ hours of study treatment <b>NB. Seven patients were excluded from the safety evaluable analysis set due to having received <math>&lt; 72</math> h of study treatment</b>
Micro-ITT	All randomized patients who had at least 1 Gram-negative baseline pathogen known to cause cUTI and no Gram-positive pathogen at baseline
Clinically evaluable <b>(CE)</b>	All patients in the micro-ITT analysis set with a confirmed diagnosis of cUTI who received an adequate course of treatment, had a valid clinical assessment and no protocol deviations or concomitant antibiotics that affected the assessment of efficacy <b>NB: clinically evaluable was defined separately for each visit; clinically evaluable at 72 hours, clinically evaluable at EOIV, clinically evaluable at EOT, clinically evaluable at TOC and clinically evaluable at LFU</b>
Microbiologically evaluable <b>(ME)</b>	All patients in the micro-ITT analysis set with a confirmed diagnosis of cUTI who received an adequate course of treatment, had an evaluable microbiological response that was not indeterminate, had at least 1 typical UTI pathogen from an adequate baseline culture that was susceptible to both ceftazidime-avibactam and cefepime, and had no protocol deviations or concomitant antibiotics that would affect the assessment of the microbiological responses <b>NB: Microbiologically evaluable was defined separately for each visit; microbiologically evaluable at EOIV, microbiologically evaluable at EOT, microbiologically evaluable at TOC and microbiologically evaluable at LFU</b>
Pharmacokinetic <b>(PK)</b>	A subset of patients from the safety analysis set who had $\geq 1$ ceftazidime and/or avibactam plasma measurement available

cUTI, complicated urinary tract infection; EOIV, end of IV; EOT, end of treatment; ITT, intent-to-treat; IV, intravenous; LFU, late follow-up; micro-ITT, microbiological intent-to-treat; TOC, test of cure.