Supplemental Digital Content 3

TABLE: Summary of Clinical Outcome Definitions at Each Study Visit

	Visit				
Clinical outcome	End of 72 hours	EOIV	EOT	TOC	LFU
Clinical improvement	Patients who improved but not enough to switch to oral therapy, and were still on IV study drug at end of 72 hours, with absence of new signs/symptoms and improvement in ≥1 sign/symptom from baseline with no worsening of any sign/symptom	Patients who switched to oral therapy, were afebrile (≤38.0°c) for ≥24 h, had no new or worsening baseline signs/symptoms and improvement to ≥1 baseline sign/symptom	NA	NA	NA
Clinical cure*	Resolution of all acute cUTI signs and symptoms or improvement to such an extent that no further antimicrobial therapy was required				Continued resolution of all acute signs/symptoms of cUTI requiring no further antimicrobial therapy
Clinical failure†	Patients who met ≥1 of the following criteria: Discontinuation of study drug due to insufficient therapeutic effect, including	Patients who met ≥1 of the following criteria: Discontinuation of study drug due to insufficient therapeutic effect, including persistence, incomplete clinical resolution or		Incomplete resolution or worsening of cUTI signs/symptoms or development of new signs/symptoms requiring	Reappearance or worsening of cUTI signs/symptoms requiring further

	persistence, incomplete resolution or worsening of cUTI signs/symptoms requiring alternative non-study antimicrobial therapy; discontinuation of study drug due to an AE requiring alternative non-study antimicrobial therapy for cUTI; death in which cUTI was contributory; improvement of ≥1 baseline sign/symptom, with no new or worsening signs/symptoms, but insufficient improvement to allow switch to oral therapy‡	worsening of cUTI signs/symptoms requiring alternative non-antimicrobial therapy; discontinuation of study drug due to an AE and requirement of alternative non-study antimicrobial therapy for cUTI; death in which cUTI was contributory	alternative non-study antimicrobial therapy, or death in which cUTI was contributory	antimicrobial therapy and/or surgery, or death after TOC were cUTI was contributory
Indeterminate	Study data unavailable for efficacy evaluation due to death in which cUTI is clearly non-contributory or extenuating circumstances that precluded classification as clinical cure or clinical failure (sustained clinical cure and relapse at LFU)			

*Sustained clinical cure at the LFU visit.

†Clinical relapse at the LFU visit.

‡Patient remained on IV study drug at the end of 72 hours.

End of 72 hours, >72 hours to 8 hours; EOIV, within 24 hours of completion of the last infusion of study drug; EOT, within 48 hours of completion of last dose of oral switch therapy or within 24 hours of the last infusion of study drug; TOC, 8–15 days after last dose of study drug; LFU, 20–35 days after the last dose of any study drug.

AE, adverse event; cUTI, complicated urinary tract infection; EOIV, end of intravenous treatment; EOT, end of treatment; LFU, late follow-up; TOC, test of cure; NA, not applicable.