Supplemental Digital Content 4

TABLE: Summary of Clinical Outcome Definitions at Each Study Visit

Clinical outcome	Visit				
	End of 72 hours	**EOIV**	**EOT**	**TOC**	**LFU**
Clinical improvement	Patients who improved ≥1 baseline sign/symptom with no new or worsening signs/symptoms, but had insufficient improvement to allow switch to oral therapy[†]	Patients who switched to oral therapy, were afebrile (≤38.0 °C) for ≥24 hours, had no new or worsening baseline signs/symptoms and improvement to ≥1 baseline sign/symptom	NA	NA	NA
Clinical cure[‡]	Resolution of all acute cIAI signs and symptoms or improvement to such an extent that no further antimicrobial therapy was required				Continued resolution of all acute signs/symptoms of cIAI 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 persistence, incomplete resolution or worsening of cIAI signs/symptoms requiring alternative non-study antimicrobial	Patients who met ≥1 of the following criteria: Discontinuation of study drug due to insufficient therapeutic effect, including persistence, incomplete clinical resolution or worsening of cIAI signs/symptoms requiring alternative non-antimicrobial therapy; discontinuation of study drug due to an AE and requirement of alternative non-study antimicrobial therapy for cIAI; death in which cIAI was contributory		Incomplete resolution or worsening of cIAI signs/symptoms or development of new signs/symptoms requiring alternative non-study antimicrobial therapy, or death in which cIAI was contributory	Reappearance or worsening of cIAI signs/symptoms requiring further antimicrobial therapy and/or surgery, or death after TOC in which cIAI was contributory

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	therapy; discontinuation of study drug due to an AE requiring alternative non-study antimicrobial therapy for cIAI; death in which cIAI was contributory; post-surgical wound infections‖ requiring additional antibiotics and/or non-routine wound care; improvement, but insufficient improvement to allow switch to oral therapy,†† and failure to show: absence of new signs and symptoms, and improvement to ≥1 baseline sign/symptom, and with no new or worsening signs/symptoms.				
Indeterminate	Study data unavailable for efficacy evaluation due to death in which cIAI is clearly non-contributory or extenuating circumstances which precluded classification as clinical cure or clinical failure (sustained clinical cure and relapse at LFU)				

†Patient remained on IV study drug at the end of 72 hours. ‡Sustained clinical cure at the LFU visit. §Clinical relapse at the LFU visit. ‖Post-surgical wound infections were defined as an open wound with signs of local infection; for example, purulent exudates, erythema or warmth. ††Patient remained on IV study drug at the end of 72 hours.

End of 72 hours, >72 hours of treatment and up to 8 hours later. 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 for those who did not receive oral switch therapy. TOC, 8–15 days after last dose of any study drug. LFU, 20–35 days after the last dose of any study drug.

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