Background. Carbapenem-resistant Enterobacterales and multidrug resistant 
*Pseudomonas aeruginosa* are global antimicrobial resistance threats. 
Cefepime-taniborbactam (FTB) is an investigational β-lactam/β-lactamase inhibitor 
combination that is active against Enterobacterales and *Pseudomonas aeruginosa* 
expressing serine and metallo-β-lactamases. CERTAIN-1 (Cefepime Rescue with 
Taniborbactam in cUTI) evaluated FTB efficacy and safety in the treatment of cUTI.

Methods. CERTAIN-1 was a randomized, double blind, double dummy, Phase 3 
study comparing FTB to meropenem (MEM) in adults hospitalized with cUTI. 
The primary endpoint was the composite (microbiologic and clinical) response at 
the test of cure (TOC) visit in the microITT population. Patients were randomized 2:1 to 
FTB 2.5g IV q8h or MEM 1g IV q8h for 7 days or up to 14 days in patients with bac-
teremia. The non-inferiority margin was -15.0% and a pre-specified test for superiority 
for the primary endpoint was performed following confirmation of non-inferior-
ity. The primary endpoint was defined as microbiologic and clinical response 
in 35.5% of FTB patients and 29.0% of MEM patients. Serious adverse events occurred 
in 13.1% of patients. Composite success was achieved in 70.0% and 58.0% of 
FTB and MEM patients, respectively (Figure). FTB was statistically superior to MEM 
for the primary endpoint at the TOC visit in the microITT population. Patients were randomized 2:1 to 
FTB 2.5g IV q8h or MEM 1g IV q8h for 7 days or up to 14 days in patients with bac-
teremia. The non-inferiority margin was -15.0% and a pre-specified test for superiority 
for the primary endpoint was performed following confirmation of non-inferior-
ity. The primary endpoint was defined as microbiologic and clinical response 
in 35.5% of FTB patients and 29.0% of MEM patients. Serious adverse events occurred 
in 2.0% and 1.8% of FTB and MEM patients, respectively. The most common TEAEs 
in 35.5% of FTB patients and 29.0% of MEM patients. Serious adverse events occurred 
in 2.0% and 1.8% of FTB and MEM patients, respectively. The most common TEAEs 
included Acute Pyelonephritis (AP) and 57.8% with cUTI.

Results. A total of 661 patients were randomized and 436 patients (66.0%) were 
included in the microITT population, including 62.2% with AP and 37.8% with cUTI. 
Patients ≥65 years represented 38.0% of the microITT population and bacteremia 
was present in 13.1% of patients. Composite success was achieved in 70.0% and 58.0% of 
FTB and MEM patients, respectively (Figure). FTB was statistically superior to MEM 
for the primary endpoint at the TOC (treatment difference [FTB-MEM], 11.9%; 95% 
CI, 2.4 to 21.6; p = 0.0136) and statistical superiority was sustained at the late follow up 
visit (LFU). Analyses of secondary endpoints and subgroups were consistent with the 
primary efficacy analysis. Treatment-emergent adverse events (TEAEs) were observed 
in 35.5% of FTB patients and 29.0% of MEM patients. Serious adverse events occurred 
in 2.0% and 1.8% of FTB and MEM patients, respectively. The most common TEAEs 
were headache (FTB 6.1%, MEM 3.7%) and diarrhea (FTB 4.1%, MEM 2.3%).

Conclusion. Following 7 days of therapy, FTB was statistically superior to MEM 
for the primary endpoint at the TOC. Composite success for FTB remained statistically 
superior to MEM at the LFU visit. FTB was safe and well-tolerated with a safety profile 
similar to MEM.

Disclosures. Paul C. McGovern, MD, Paratek Pharmaceuticals: Stocks/Bonds| 
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Figure: Composite Response Rate by Visit

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731. CERTAIN-1: A Phase 3 Study of Cefepime-Taniborbactam Efficacy and 
Safety in the Treatment of Complicated Urinary Tract Infections (cUTI), 
including Acute Pyelonephritis (AP)

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