Supplemental Digital Content 6

Sample Size Calculation

The sample size calculation was based on a 95% probability of observing a specific 'rare' adverse event (AE), with an underlying incidence rate assumed to be 3%, in ≥1 ceftazidime-avibactam-treated patient across 2 pediatric studies combined (this study, and a similarly designed study conducted in patients with complicated intra-abdominal infection; [Protocol number D4280C00015, NCT02475733]). The program aimed to include 120 patients treated with ceftazidime avibactam in the 2 studies combined. Target enrollment for the present study was 80 evaluable patients (that is, those who had received ≥72 hours of treatment [3 full days, ie, 9 doses if given 3 times daily, or 6 doses if given twice daily]) based on a 3:1 randomization ratio: 60 treated with ceftazidime-avibactam and 20 with cefepime.[1]

1. Mendes RE, Castanheira M, Woosley LN, et al. Molecular beta-lactamase characterization of Gram-negative pathogens recovered from patients enrolled in the ceftazidime-avibactam phase 3 trials (RECAPTURE 1 and 2) for complicated urinary tract infections: Efficacies analysed against susceptible and resistant subsets. *Int J Antimicrob Agents*. 2018;52:287–292.