Article:
Huang, DB, File, TM, Torres, A et al. (5 more authors) (2017) A Phase II Randomized, Double-Blind, Multicenter Study to Evaluate Efficacy and Safety of Intravenous Iclaprim Versus Vancomycin for the Treatment of Nosocomial Pneumonia Suspected or Confirmed to be Due to Gram-Positive Pathogens. Clinical Therapeutics, 39 (8). pp. 1706-1718. ISSN 0149-2918

https://doi.org/10.1016/j.clinthera.2017.07.007

Table 4: Safety Parameters by Treatment

Category	Iclaprim q12h (N=23)	Iclaprim q8h (N=24)	Vancomycin (N=23)
Death within 28 days from start of treatment	2 (8.7%)	3 (12.5%)	5 (21.7%)
Any drug-related TEAE	4 (17.4%)	3(12.5%)	7 (30.4%)
Any serious AE	5 (21.7%)	4 (16.7%)	10 (43.5%)
Discontinued medication due to AEs	0 (0.0%)	2 (8.3%)	3 (13.0%)
TEAE ≥ 12 in any treatment arm assessed as related to study medication			
Thrombocythemia	0	1 (4.2%)	2 (8.7%)
Sick sinus syndrome	0	0	1 (4.3%)
Aphthous stomatitis	0	1 (4.2%)	0
Diarrhea	0	0	2 (8.7%)
Candidiasis	1 (4.3%)	0	0
Alanine aminotransferase increased	0	0	1 (4.3%)
Aspartate aminotransferase increased	0	0	1 (4.3%)
Blood alkaline phosphatase increased	0	0	1 (4.3%)
Blood creatinine increased	0	0	1 (4.3%)
Blood urea nitrogen increased	0	0	1 (4.3%)
Prolonged QTc	2 (8.7%)	0	0
Liver function test abnormal	0	0	1 (4.3%)
Anorexia	1 (4.3%)	0	0
Dizziness	1 (4.3%)	0	0

Chronic Obstructive pulmonary disease	0	1 (4.2%)	0
Rash	0	1 (4.2%)	0

TEAE=treatment emergent adverse event; AE= Adverse event; N=Total number of patients in the population; SAE=serious adverse event