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Article:

Huang, DB, File, TM, Torres, A et al. (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

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1 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 \geq <u>12</u> in any treatment arm assessed as related to study medication			
Thrombocythemia	0	1 (4.2%)	2 (8.7%)
<u>Sick sinus syndrome</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Aphthous stomatitis</u>	<u>0</u>	<u>1 (4.2%)</u>	<u>0</u>
Diarrhea	0	0	2 (8.7%)
<u>Candidiasis</u>	<u>1 (4.3%)</u>	<u>0</u>	<u>0</u>
<u>Alanine aminotransferase increased</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Aspartate aminotransferase increased</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Blood alkaline phosphatase increased</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Blood creatinine increased</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Blood urea nitrogen increased</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Prolonged QTc</u>	<u>2 (8.7%)</u>	<u>0</u>	<u>0</u>
<u>Liver function test abnormal</u>	<u>0</u>	<u>0</u>	<u>1 (4.3%)</u>
<u>Anorexia</u>	<u>1 (4.3%)</u>	<u>0</u>	<u>0</u>
<u>Dizziness</u>	<u>1 (4.3%)</u>	<u>0</u>	<u>0</u>

<u>Chronic Obstructive pulmonary disease</u>	<u>0</u>	<u>1 (4.2%)</u>	<u>0</u>
<u>Rash</u>	<u>0</u>	<u>1 (4.2%)</u>	<u>0</u>

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3 TEAE=treatment emergent adverse event; AE= Adverse event; N=Total number of patients in

4 the population; SAE=serious adverse event