P0901
Paper Poster Session
New treatments for skin infection

Treatment of acute bacterial skin and skin structure infection (ABSSSI) with single-dose dalbavancin in an outpatient setting

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Background: To describe the demographics and outcomes for patients with ABSSSI treated in the outpatient setting in a phase 3 clinical trial evaluating the efficacy of a single 1500mg dose of dalbavancin relative to the approved two-dose regimen.

Material/methods: This study was a double-blind, single-dummy trial in patients with ABSSSI who were randomized to receive dalbavancin 1500 mg as a single IV infusion over 30 minutes *or* 1000 mg IV on Day 1 followed one week later by 500 mg IV. The primary endpoint was the proportion of patients in each arm with ≥20% reduction in the erythema associated with the infection 48-72 hours after start of treatment. Clinical outcome based on a composite of clinical measures was assessed on Days 14 and 28. In this analysis, we compared outcomes for patients treated entirely in the outpatient setting with those for patients admitted to a hospital for the treatment of ABSSSI.

Results: Patients treated in the outpatient setting were more likely to be younger and be enrolled in North America versus those admitted to the hospital for the treatment of the ABSSSI. More outpatients had major abscess and traumatic wound infection as the type of infection relative to inpatients who were more likely to have cellulitis as the type of ABSSSI.

TABLE 1: Efficacy at various time-points for outpatients and inpatients

Timing	Outcome measure	Outpatients		Inpatients	
		Dalbavancin Single-Dose n/N (%)	**Dalbavancin Two-dose n/N (%)**	**Dalbavancin Single-Dose n/N (%)**	**Dalbavancin Two-dose n/N (%)**
48-72 hours	Treatment response (ITT)	156 /190 (82.1)	162 /196 (82.7)	128 /159 (80.5)	132 /153 (86.3)
	95% CI	-0.5 (-8.3, 7.1)		-5.8 (-14.1, 2.6)	
Day 14	Clinical success (CE)	142 /162 (87.7)	151 /169 (89.3)	125 /140 (89.3)	119 /133 (89.5)
	95% CI	-1.7 (-8.8, 5.3)		-0.2 (-7.7, 7.5)	
Day 28	Clinical success (CE)	139 /150 (92.7)	136 /150 (90.7)	108 /117 (92.3)	114 /121 (94.2)
	95% CI	2.0 (-4.5, 8.6)		-1.9 (-9.0, 4.8)	

Conclusions: Outcome rates at 48-72 hours, Day 14 and Day 28 were similar between patients treated in the outpatient or inpatient setting with either a single dose of dalbavancin or the two-dose dalbavancin regimen. Based on this experience, there is a subset of patients with ABSSSI who can be successfully treated with dalbavancin in an ambulatory setting.