O152
Oral Session
New antibiotics in clinical trials

A single dose of oritavancin (ORI) compared to 7-10 days of vancomycin (VAN): clinical response across different lesion types in the SOLO non-inferiority studies

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Objectives: ORI is a lipoglycopeptide with rapid bactericidal activity against Gram-positive bacteria including MRSA. The recently completed Phase 3 SOLO studies evaluated the clinical response rates of single 1200 mg infusion of ORI compared to twice-daily VAN for 7-10 days in ABSSSI patients with either major cutaneous abscess, cellulitis or wound infections.
Methods: SOLO I and SOLO II were Phase 3, multicenter, double-blind, randomized studies of identical design. Adults with ABSSSI requiring IV therapy received either a single 1200 mg IV dose of ORI, or IV VAN for 7 to 10 days (1 g or 15 mg/kg twice daily); from the second day the VAN dose could be adjusted based on patient's clinical status, renal function or vancomycin plasma concentrations. Three efficacy endpoints were tested: 1) primary composite endpoint at 48 to 72 h, (cessation of spreading or reduction in size of the baseline lesion, absence of fever, and no rescue antibiotic); 2) investigator-assessed clinical cure 7 to 14 days after end of treatment; and 3) >=20% reduction in lesion area at 48 to 72 h. Patients with confirmed ABSSSI with a major cutaneous abscess, cellulitis or wound infections of >=75 cm^2 were enrolled in the studies.
Results: In the combined studies 1959 patients were enrolled. All pre-specified endpoints met the 10% non-inferiority margin in each SOLO study. In the sub group analysis similar results were seen between treatment groups for the individual lesion types for all three endpoints (Table). There were more patients with confirmed MRSA in the major cutaneous abscess subgroup (50.6%) compared to cellulitis (18.0%) and wound infection (31.4%). The incidence of AEs was similar across the different lesion types [Major cutaneous abscess (56.8% vs. 57.3%), Cellulitis (57.7% vs. 59.0%) and wound infection (50.5% vs. 53.4%) in ORI and VAN groups, respectively].
Conclusions: A single 1200 mg dose of ORI was non-inferior to 7 to 10 days of VAN in treating ABSSSI, with a similar safety profile. The clinical response rates for ORI were similar to VAN irrespective of lesion type and the results in the subgroup analysis are concordant with the results from the main analysis population. ORI provides a single-dose alternative to multi-dose therapies for ABSSSI.

	Early Clinical Response at ECE *		>=20% Reduction in Lesion Size at ECE *		Investigator Assessed Clinical Cure at PTE #	
	ORI (n=978) n (%)	VAN (n=981) n (%)	ORI (n=978) n (%)	VAN (n=981) n (%)	ORI (n=978) n (%)	VAN (n=981) nN (%)
Wound Infection	249/283 (88.0)	239/281 (85.1)	243/283 (85.9)	232/281 (82.6)	236/283 (83.4)	220/281 (78.3)
Cellulitis	294/387 (76.0)	302/400 (75.5)	320/387 (82.7)	320/400 (80.0)	127/167 (76.0)	315/400 (78.8)
Major Cutaneous Abscess	251/308 (81.5)	253/300 (84.3)	282/308 (91.6)	273/300 (91.0)	264/308 (85.7)	252/300 (84.0)

* Early Clinical Evaluation (ECE) endpoints occurred at 48-72 hours after the first infusion
\# Post Therapy Evaluation (PTE) endpoint occurred at 7-14 days after the end of therapy