ORAL ABSTRACTS

1331. The SOLO Studies: A Single-Dose of Oritavancin (ORI) Compared to 7-10 Days of Vancomycin (VAN) in the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

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Background. ORI is a lipoglycopeptide with rapid bactericidal activity against gram-positive bacteria including MRSA. Its concentration-dependent activity and long half- life allow for single dose administration.

Methods. SOLO I and SOLO II were identical Phase 3, multicenter, double-blind, randomized studies. Adults with ABSSSI requiring IV therapy received either a single 1200 mg IV dose of ORI, or VAN for 7 to 10 days (1 g or 15mg/kg BID). Three efficacy endpoints were tested for non-inferiority: 1) primary composite end point 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. Safety was measured to Day 60.

Results. All pre-specified endpoints met the 10% non-inferiority margin in SOLO I and II. In the combined studies, 978 and 981 patients comprised the modified intent to treat (mITT) population for ORI and VAN, respectively. For the combined studies, efficacy outcomes were as follows: primary composite end point: ORI, 81.2%; VAN, 80.9%; investigator-assessed clinical cure: ORI, 81.2%; VAN, 80.2%; proportion of patients attaining ≥20% reduction in lesion area: ORI, 86.4%; VAN, 84.1% (table). More MRSA patients treated with ORI attained > 20% reduction in lesion size compared to VAN (ORI 93.1%, VAN 87.1%; difference 6.1%; p = 0.032). Overall, safety profiles were similar: 55.3% of ORI patients and 56.9% of VAN patients reported at least one adverse event.

Efficacy outcomes in the SOLO trials (n [%])

Timepoint	Endpoint	ORI (n = 978)	VAN (n = 981)
ECE	Cessation of spread, absence of fever, no rescue antibiotics	794 (81.2%)	794 (80.9%)
	≥20% reduction of lesion area	845 (86.4%)	825 (84.1%)
PTE	Investigator-assessed clinical cure	794 (81.2%)	787 (80.2%)

Conclusion. A single 1200 mg dose of ORI was non-inferior to 7 to 10 days of VAN in treating ABSSSI caused by gram-positive pathogens. In summary ORI provides a single-dose alternative to multi-dose VAN for the treatment of ABSSSI.

Disclosures. **R. Corey**, The Medicines Company: Investigator, Grant recipient **M. Wikler**, The Medicines Company: Employee, Salary **G. Moeck**, The Medicines Company: Employee, Salary **H. Jiang**, The Medicines Company: Employee, Salary **S. Good**, The Medicines Company: Employee, Salary

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