A phase-3 randomized, double-blind, multi-centre study to compare the safety and efficacy of oral omadacycline to oral linezolid for treating adult subjects with ABSSSI (OASIS-2 study)

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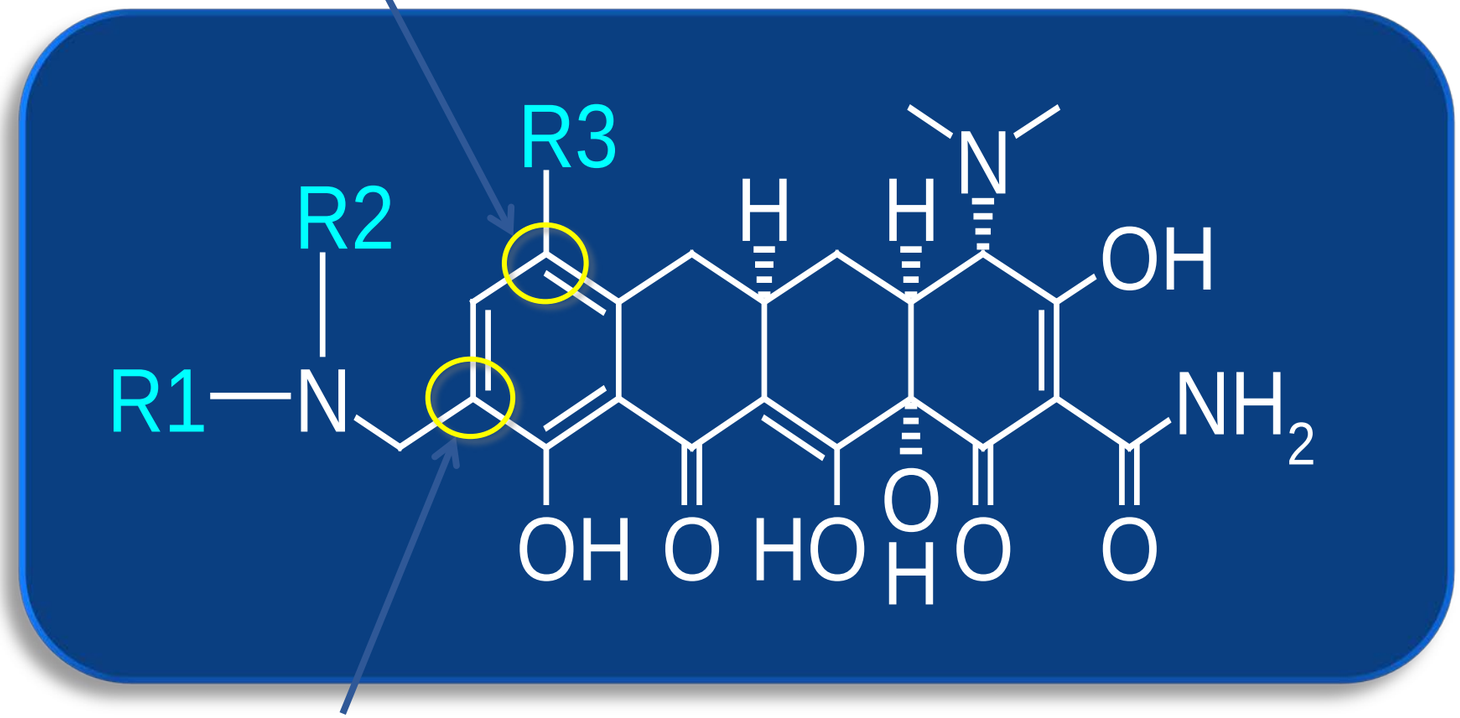
Omadacycline – Investigational Product Overview

Restoring Tetracycline Activity by Overcoming Resistance

Aminomethylcycline

7-Position Modification:
Overcomes Efflux Pump



9-Position Modification:
Overcomes Ribosomal Protection

Key Product Attributes

- Safety and efficacy demonstrated in ABSSSI and CABP
- In-vitro activity against important community pathogens
- Two once-daily formulations – intravenous and oral
- IV and oral doses with equivalent exposure (AUC[1])

[1] AUC = Area Under the Curve

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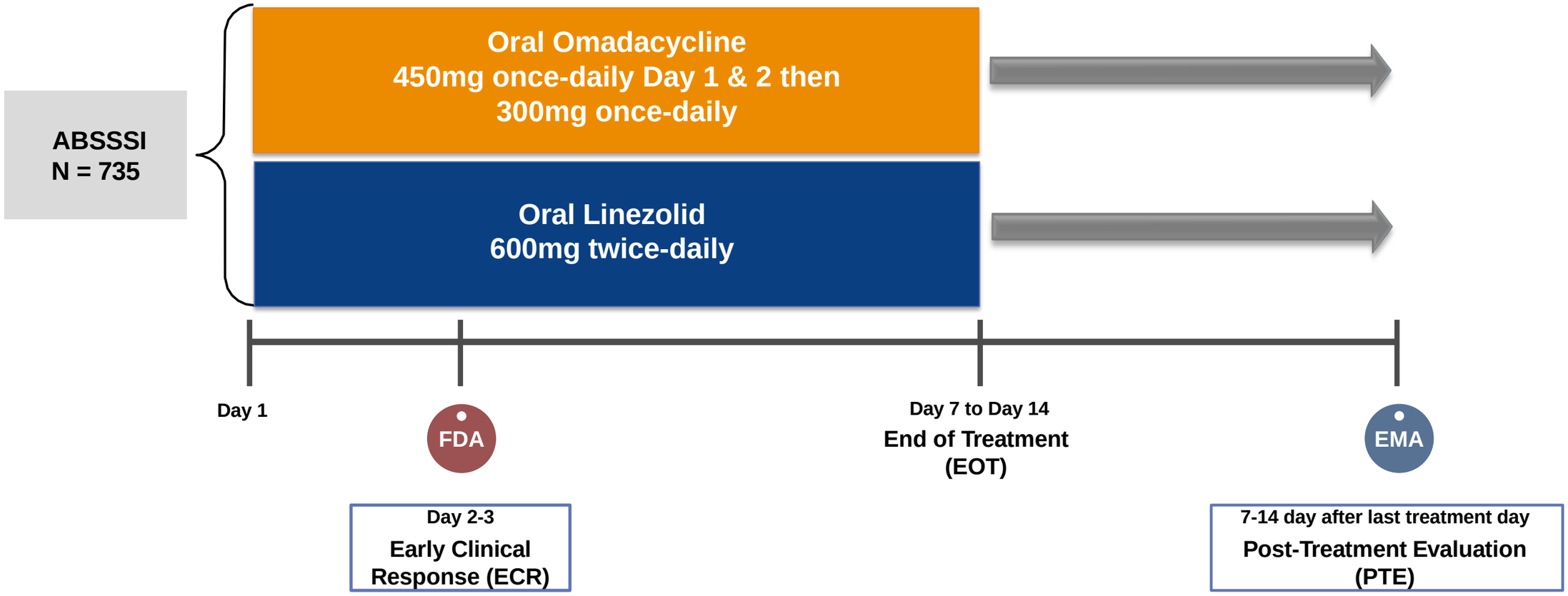
Design of the Phase 3 OASIS-2 Study

Once-Daily Oral Omadacycline vs Twice-Daily Oral Linezolid (1:1)



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Demographic Characteristics
Balanced Demographics Between Treatment Arms

Characteristics	Omadacycline	Linezolid
Gender[a] n (%)		
Female	126 (34.2)	147 (40.1)
Male	242 (65.8)	220 (59.9)
Age[a] (years)		
Mean (SD)	42.8 (12.72)	44.5 (13.11)
BMI[a,b] (kg/m^2)		
Mean (SD)	27.91 (6.472)	27.93 (6.556)
Lesion area[c] (cm^2)		
Mean (range)	422 (75-2601)	396 (75-2243)
Type of Primary Infection[c] n (%)		
Wound Infection	210 (58.3)	214 (59.4)
Cellulitis/erysipelas	86 (23.9)	84 (23.3)
Major Abscess	64 (17.8)	62 (17.2)

[a] Safety Population (OMC 368; LZD 367); [b] BMI = body mass index; [c] mITT Population (OMC 360; LZD 360)

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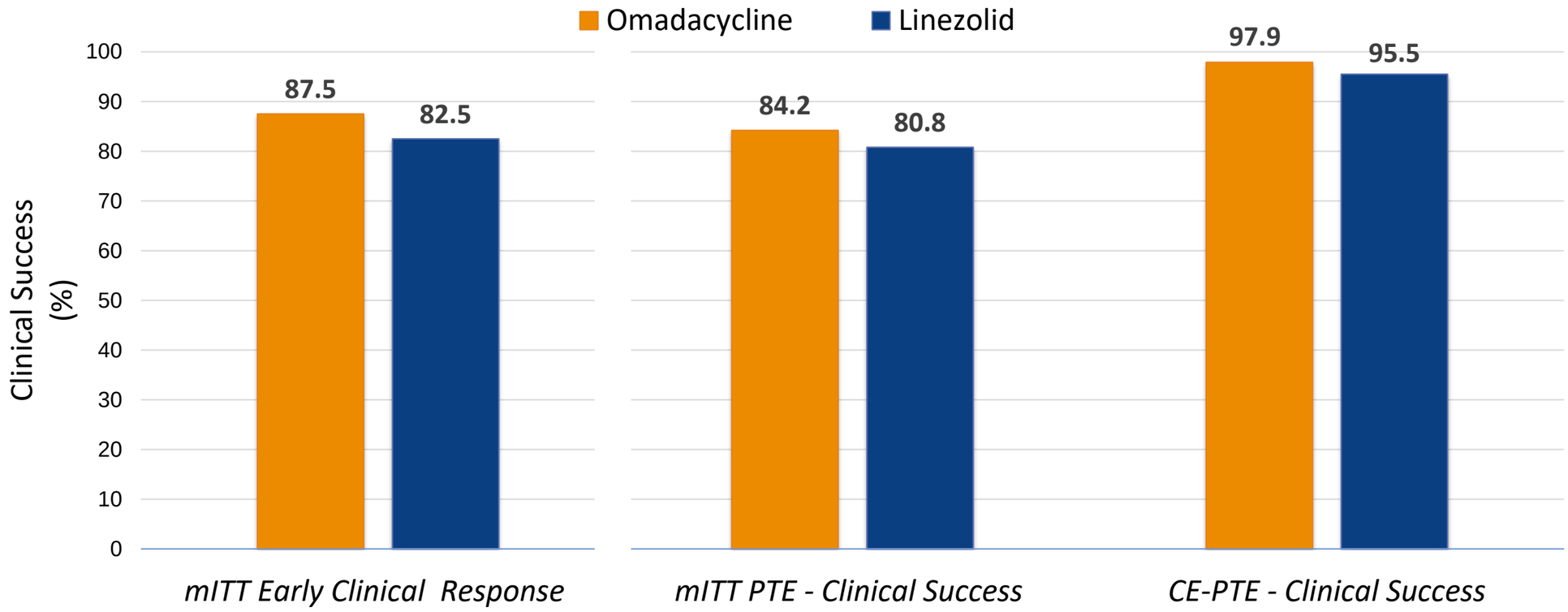
Oral Omadacycline Effective in ABSSSI

Met Non-Inferiority for Both FDA and EMA Efficacy Endpoints



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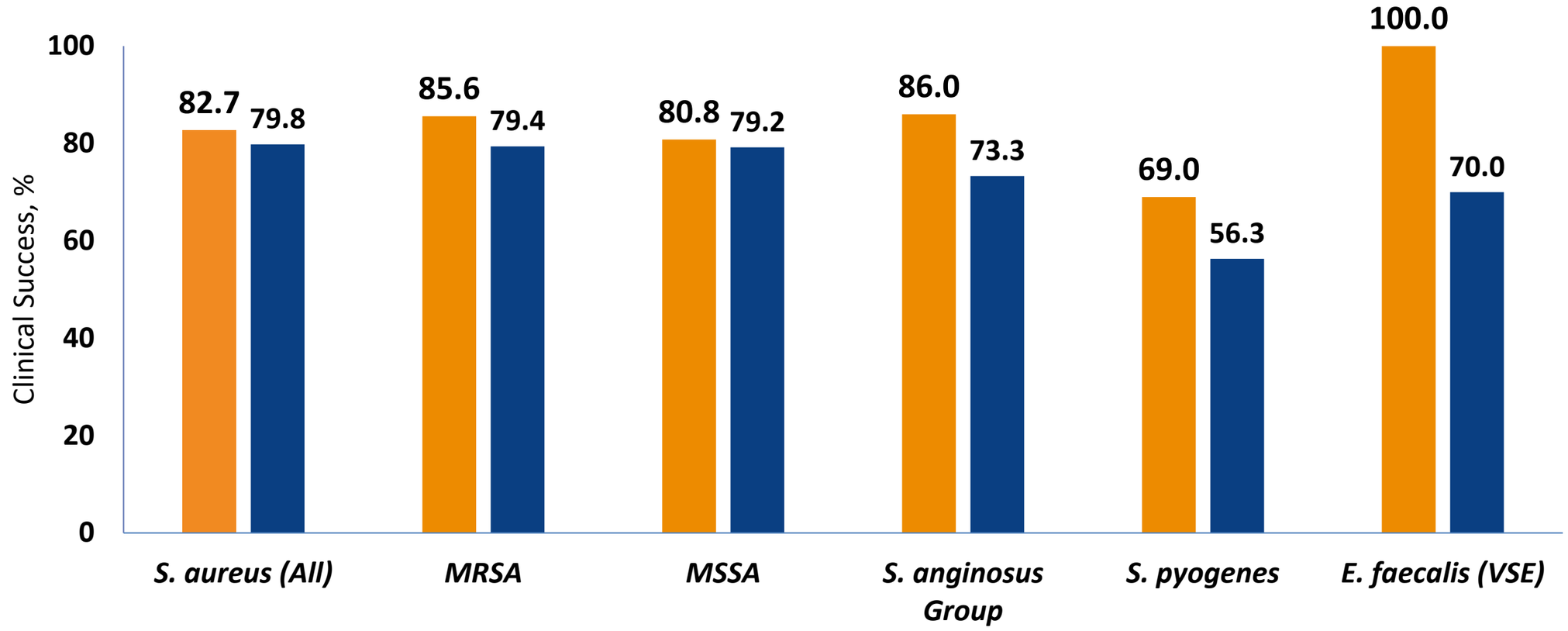
Clinical Response by Pathogen at PTE - micro-mITT Population

Microbiological Responses Consistent with Clinical Responses



OMC, n	220	104	120	57	29	7
LZD, n	233	107	130	45	16	10

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Overview of Adverse Events – Safety Population

Omadacycline Was Safe and Generally Well Tolerated

Parameter	Omadacycline N= 368 n(%)	Linezolid N= 367 n(%)
Subjects with at Least One		
Treatment-Emergent Adverse Event (TEAE)[a]	197 (53.5)	137 (37.3)
Severe TEAE	6 (1.6)	7 (1.9)
Serious TEAE	5 (1.4)	5 (1.4)
TEAE leading to premature discontinuation of test article[b]	6 (1.6)	3 (0.8)
Most Frequent TEAEs[a] (>2% omadacycline arm)		
Nausea	111 (30.2) [c]	28 (7.6)
Vomiting	62 (16.8) [c]	11 (3.0)
Wound Infection	22 (6.0)	17 (4.6)
ALT Increased	19 (5.2)	11 (3.0)
AST Increased	17 (4.6)	12 (3.3)
Diarrhea	15 (4.1)	10 (2.7)
Headache	13 (3.5)	8 (2.2)
Cellulitis	12 (3.3)	9 (2.5)
Abdominal Pain Upper	10 (2.7)	4 (1.1)

[a] TEAE is defined as an AE occurring after first dose of active test article; [b] 1 omadacycline subject discontinued due to nausea / vomiting
[C] Day 1 & 2 nausea (25.3%) and vomiting (12.5%), Day 3 through EOT nausea (4.1%) and vomiting (4.1%)

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OASIS-2 Study Conclusions

- In the phase 3 OASIS-2 trial, omadacycline was clinically effective and non-inferior to linezolid for treatment of ABSSSI
  - ✓ Met **both** FDA and EMA primary endpoints
  - ✓ High clinical response rates for the most common ABSSSI pathogens, including MRSA
- Omadacycline was safe and generally well-tolerated
  - ✓ Nausea and vomiting TEAEs were more frequent during the first two days of the OASIS-2 oral study, when the subjects received a “loading dose” of OMC (450 mg)

Oral Omadacycline Is Clinically Effective as a Once-daily Oral Antibiotic With Activity Against the Most Common ABSSSI Pathogens Including MRSA

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