HEALTH-RELATED QUALITY-OF-LIFE OUTCOMES IN OPTIC-2: A RANDOMIZED, CONTROLLED, PHASE 3B TRIAL OF OMADACYCLINE VS MOXIFLOXACIN IN COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA

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Financial Disclosure

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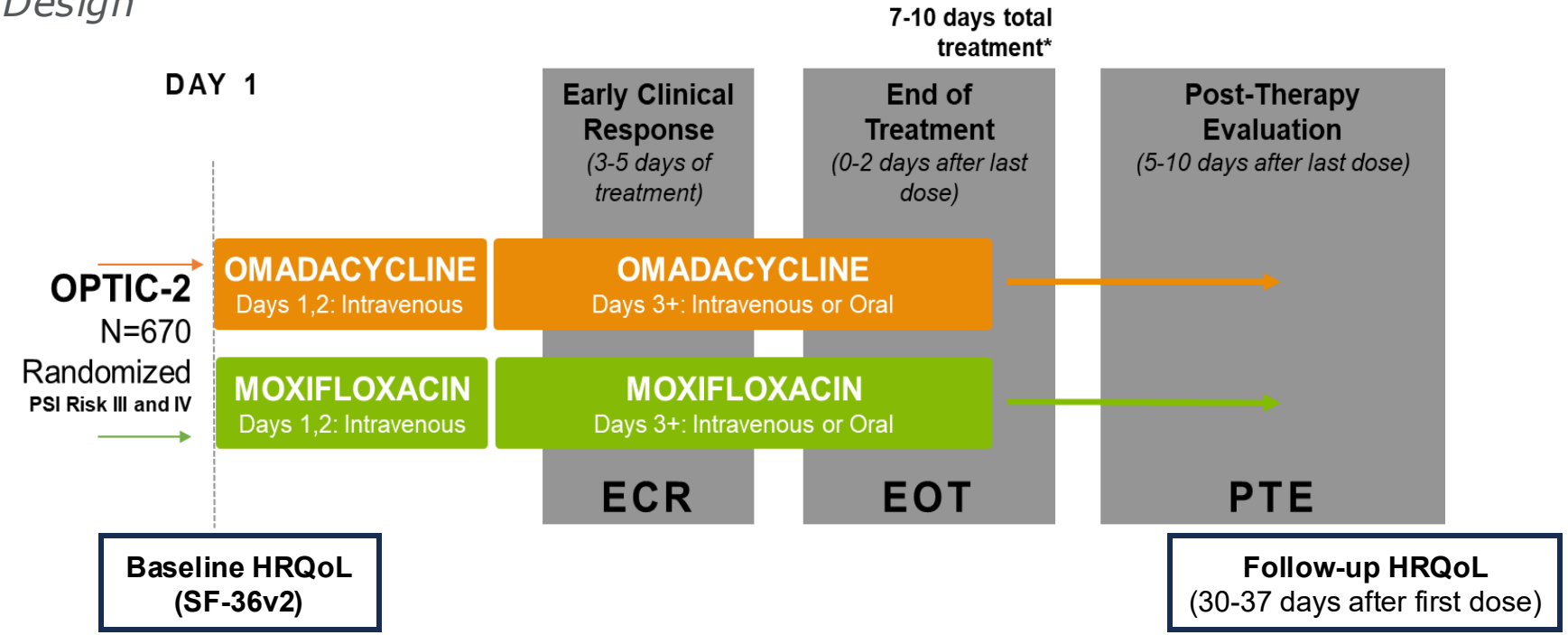
Background & Objective

- Omadacycline is a once-daily oral and IV aminomethylcycline antibiotic approved for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections in adults
- OPTIC-2 was a phase 3b, double-blind study that compared omadacycline and moxifloxacin for the treatment of CABP in adults, and included a comparison of health-related quality-of-life (HRQoL) outcomes between the treatment groups

CABP, community-acquired bacterial pneumonia; HRQoL, health-related quality-of-life; IV, intravenous

OPTIC-2

Trial Design



ClinicalTrials.gov Registration: NCT04779242

*If participants had bacteremia at baseline, total treatment duration was up to 14 days

CABP, community-acquired bacterial pneumonia; ECR, early clinical response; EOT, end of treatment; HRQoL, health-related quality-of-life; ITT, intent-to-treat; PSI, Pneumonia Severity Index; PTE, post-therapy evaluation; SF-36v2, 36-Item Short Form Survey version 2

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Methods

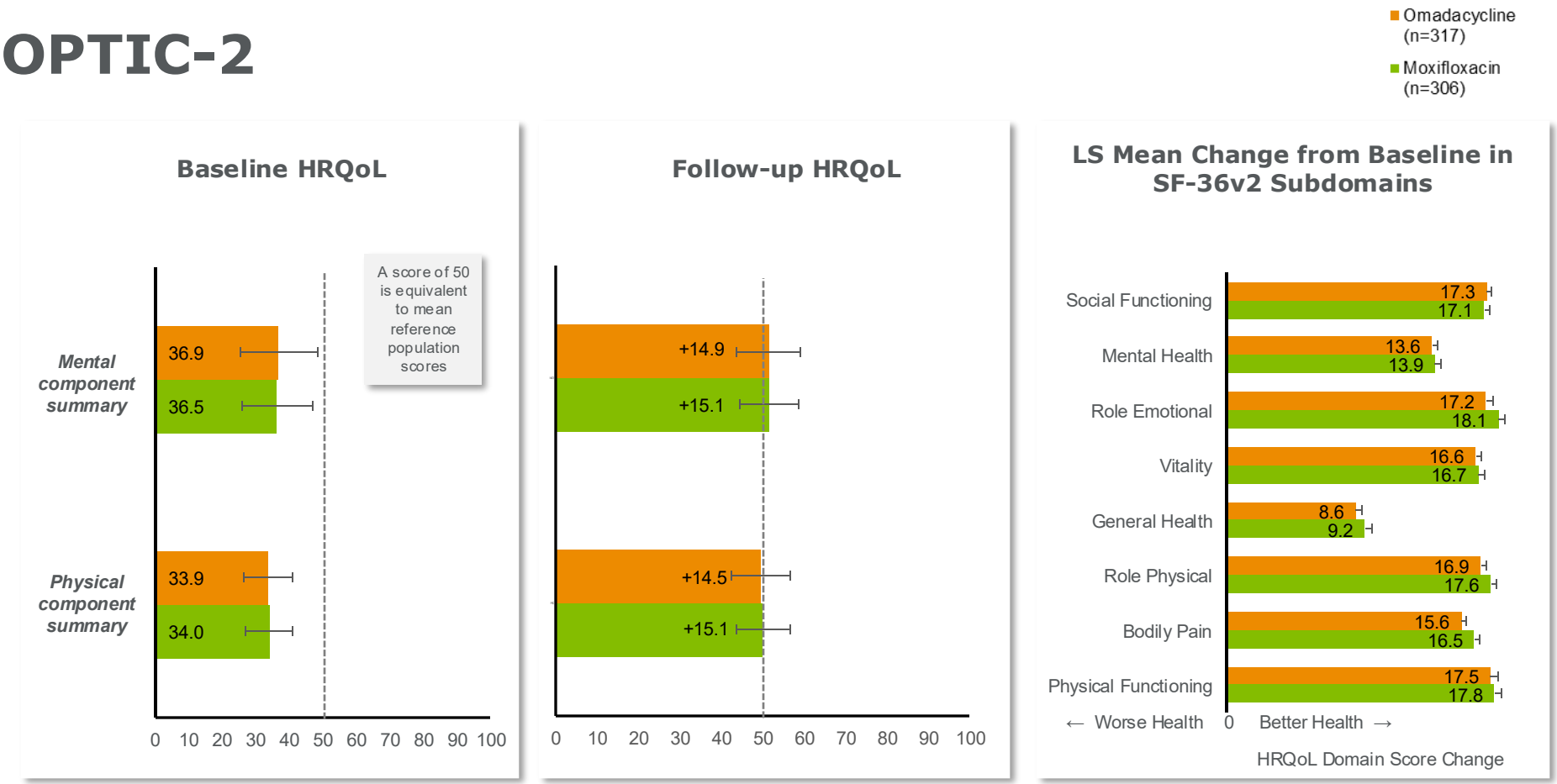
- Patients completed the 36-Item Short Form Survey (SF-36v2) at baseline and 30–37 days after the first dose
- Scores were normalized to a scale of 0–100
  - **Higher scores indicate better health**
- Change from baseline was analyzed using an ANCOVA model with treatment group as a fixed effect and baseline scaled score as a covariate

HRQoL Components

- Physical component summary
- Mental component summary
- General health
- Mental health
- Physical functioning
- Role emotional
- Role physical
- Social functioning
- Vitality
- Bodily pain

ANCOVA, analysis of covariance; SF-36v2, 36-Item Short Form Survey version 2

OPTIC-2



All within-group changes were statistically significant ($P < .0001$); between-group differences were not statistically significant. Error bars show standard deviation for baseline and follow-up HRQoL and standard error LS mean change from baseline.

HRQoL, health-related quality of life; SF-36v2, 36-Item Short Form Survey version 2

Omadacycline In CABP: Conclusions from OPTIC-2

- Patients with CABP in OPTIC-2 who received omadacycline or moxifloxacin had similar changes from baseline, including improvements, in HRQoL domains
- Effective treatment of CABP is associated with better HRQoL

CABP, community-acquired bacterial pneumonia; HRQoL, health-related quality-of-life

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OPTIC-2

Baseline Characteristics

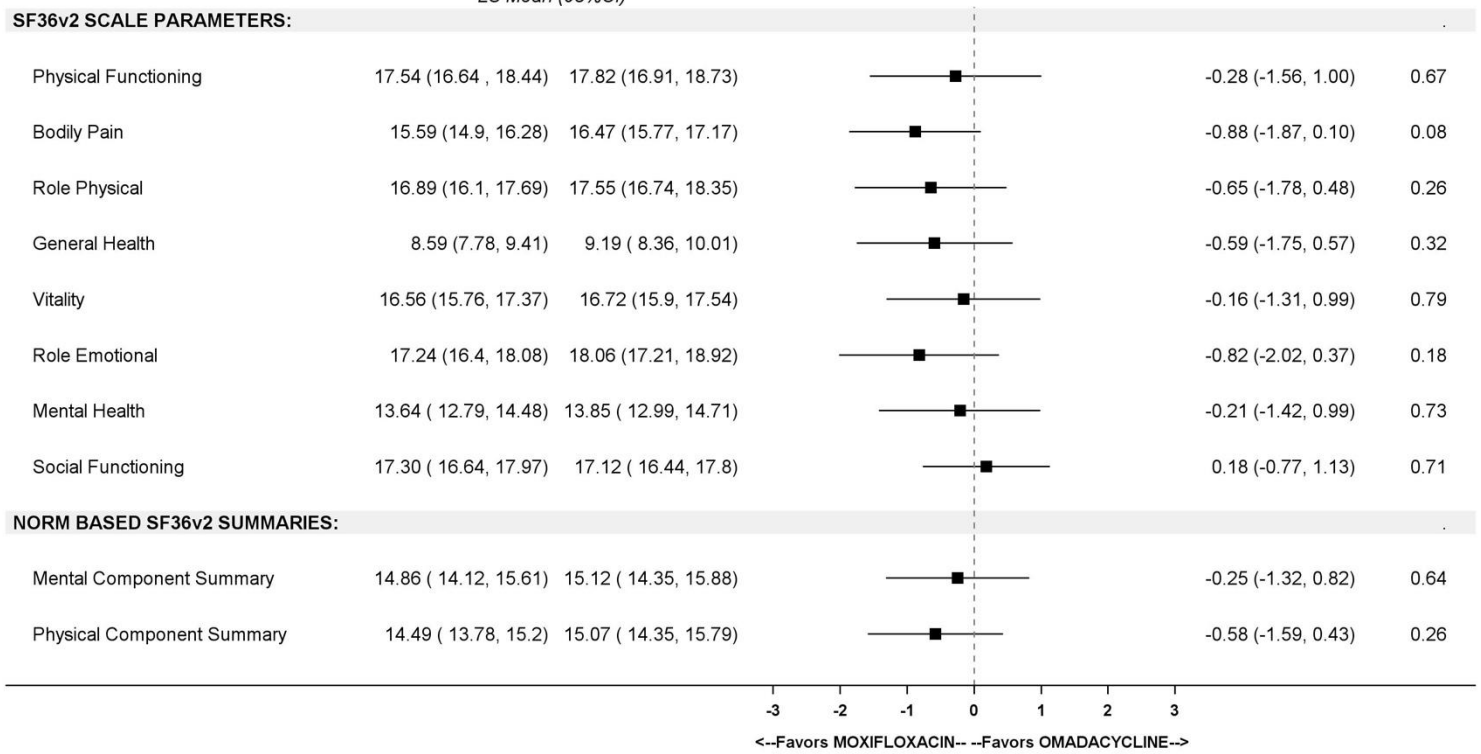
OPTIC-2 Demographics and Baseline Characteristics, ITT Population (unless otherwise stated)	Omadacycline (n=336)	Moxifloxacin (n=334)	All Patients (N=670)
Male, n (%)	178 (53.0)	168 (50.3)	346 (51.6)
Race, n (%)			
White	335 (99.7)	333 (99.7)	668 (99.7)
Asian	1 (0.3)	1 (0.3)	2 (0.3)
Geographic region, Eastern Europe, n (%)	336 (100)	334 (100)	670 (100)
Age, years; mean (SD)	63.3 (14.4)	62.2 (15.4)	62.8 (14.9)
>65 years; n (%)	160 (47.6)	163 (48.8)	323 (48.2)
Body mass index, kg/m^2; mean (SD)	27.0 (5.2)	27.0 (4.7)	27.0 (4.9)
Past medical history, n (%)			
Heart disease	58 (17.3)	43 (12.9)	101 (15.1)
Diabetes mellitus	66 (19.6)	63 (18.9)	129 (19.3)
Mild/moderate asthma or COPD	40 (11.9)	40 (12.0)	80 (11.9)
Renal impairment	166 (49.4)	146 (43.7)	312 (46.6)
Mild	123 (36.6)	103 (30.8)	226 (33.7)
Moderate	43 (12.8)	43 (12.9)	86 (12.8)
PSI classification, n (%)			
Class III	257 (76.5)	256 (76.6)	513 (76.6)
Class IV	79 (23.5)	78 (23.4)	157 (23.4)
Bacteremia, n (%)	12 (3.6)	14 (4.2)	27 (4.0)
Baseline pathogen identified, microITT, n (%)	202 (60.1)	174 (52.1)	376 (56.1)

COPD, chronic obstructive pulmonary disease; ITT, intent-to-treat; microITT, microbiological ITT; PSI, Pneumonia Severity Index; SD, standard deviation

OPTIC-2

Treatment effect at the end of the treatment period in the ITT population

QOL OUTCOME	OMADACYCLINE LS Mean (95%CI)	MOXIFLOXACIN LS Mean (95%CI)	Difference (95% CI)	PValue
SF36v2 SCALE PARAMETERS:				
Physical Functioning	17.54 (16.64 , 18.44)	17.82 (16.91, 18.73)	-0.28 (-1.56, 1.00)	0.67
Bodily Pain	15.59 (14.9, 16.28)	16.47 (15.77, 17.17)	-0.88 (-1.87, 0.10)	0.08
Role Physical	16.89 (16.1, 17.69)	17.55 (16.74, 18.35)	-0.65 (-1.78, 0.48)	0.26
General Health	8.59 (7.78, 9.41)	9.19 (8.36, 10.01)	-0.59 (-1.75, 0.57)	0.32
Vitality	16.56 (15.76, 17.37)	16.72 (15.9, 17.54)	-0.16 (-1.31, 0.99)	0.79
Role Emotional	17.24 (16.4, 18.08)	18.06 (17.21, 18.92)	-0.82 (-2.02, 0.37)	0.18
Mental Health	13.64 (12.79, 14.48)	13.85 (12.99, 14.71)	-0.21 (-1.42, 0.99)	0.73
Social Functioning	17.30 (16.64, 17.97)	17.12 (16.44, 17.8)	0.18 (-0.77, 1.13)	0.71
NORM BASED SF36v2 SUMMARIES:				
Mental Component Summary	14.86 (14.12, 15.61)	15.12 (14.35, 15.88)	-0.25 (-1.32, 0.82)	0.64
Physical Component Summary	14.49 (13.78, 15.2)	15.07 (14.35, 15.79)	-0.58 (-1.59, 0.43)	0.26



CI, confidence interval; ITT, intent-to-treat; LS mean, least square mean; QOL, quality of life; SF-36v2, 36-Item Short Form Survey version 2