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In vitro Antibacterial Activity of Omadacycline and Comparators against Key Respiratory, Skin and Skin Structure, and Urinary Tract Pathogens Collected from the United States and Europe during the 2016 SENTRY Antimicrobial Surveillance Program

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AMENDED ABSTRACT

Background: Omadacycline (OMC) is a broad-spectrum aminomethylcycline in late-stage clinical development for acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia. OMC has excellent *in vitro* activity against bacterial pathogens commonly associated with ABSSSI and respiratory tract infections (RTI), including drug-resistant isolates.

Methods: A total of 16,958 clinical isolates representing multiple infection types were collected during the 2016 SENTRY Antimicrobial Surveillance Program, including only 1 isolate/patient infection episode. Organism identification and drug susceptibility testing was performed in a central laboratory using CLSI broth microdilution methodology and interpreted using CLSI/EUCAST breakpoints.

Results: OMC showed potent *in vitro* activity against ABSSSI pathogens that included *Staphylococcus aureus* (31.8% MRSA), β-haemolytic streptococci, and *Enterococcus* spp. with MIC_{90} values ≤0.25 μg/mL. OMC was equally active (MIC_{90} 0.25 μg/mL) against *S. aureus* isolates (36.3% MRSA) obtained from pneumonia specimens. OMC was highly active against RTI isolates composed of *Streptococcus pneumoniae* (including penicillin-, tetracycline-, and macrolide-resistant strains) and *Moraxella catarrhalis* with MIC_{90} values of 0.12 and 0.25 μg/mL, respectively. The $MIC_{50/90}$ for *Haemophilus influenzae* was 1/1 μg/mL. OMC activity encompassed *Enterobacteriaceae* ($MIC_{50/90}$ 1/8 μg/mL) obtained from urinary tract infections (UTI), including *Escherichia coli* ($MIC_{50/90}$ 0.5/2 μg/mL) and ESBL-phenotype *E. coli* ($MIC_{50/90}$ 1/2 μg/mL).

Organism (no. of isolates)	Infection type	Omadacycline (μg/mL)		
		MIC_{50}	MIC_{90}	MIC range
S. aureus (1,891)	ABSSSI	0.12	0.25	0.03-4
β-haemolytic streptococci (386)	ABSSSI	0.06	0.12	0.03-0.5
Enterococcus spp. (254)	ABSSSI	0.12	0.25	≤0.015-1
S. aureus (968)	RTI	0.12	0.25	≤0.015-8
S. pneumoniae (1,127)	RTI	0.06	0.12	≤0.015-1
H. influenzae (772)	RTI	1	1	0.12-16
M. catarrhalis (405)	RTI	0.25	0.25	0.06-0.5
Enterobacteriaceae (2,067)	UTI	1	8	0.12->32
E. coli (1,178)	UTI	0.5	2	0.12-16

Conclusion: OMC was highly active against key bacterial pathogens (including drug-resistant isolates) responsible for ABSSSI (MIC_{90} 0.12-0.25 μg/mL) and RTI (MIC_{90} 0.12-1 μg/mL) and was also active against *Enterobacteriaceae* responsible for UTI. These data support continued clinical evaluation of OMC, especially where drug-resistant pathogens may be encountered.

INTRODUCTION

- Omadacycline is a broad-spectrum aminomethylcycline protein synthesis inhibitor in late-stage clinical development (oral and intravenous formulations) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP)
- The spectrum of activity of omadacycline includes a broad range of gram-positive (staphylococci, streptococci, and enterococci) and gram-negative bacterial pathogens (*Haemophilus influenzae* and *Moraxella catarrhalis*) commonly associated with ABSSSI and CABP
- Omadacycline is highly active against bacterial clinical isolates expressing common tetracycline-, penicillin/oxacillin-, fluoroquinolone-, and macrolide-resistance mechanisms that include staphylococci, streptococci (*Streptococcus pneumoniae* and β-haemolytic streptococci), and enterococci
- The *in vitro* susceptibility results for omadacycline and comparator agents against 16,958 gram-positive and -negative bacterial clinical isolates collected from patients in medical centers in the United States (US) and Europe participating in a global surveillance program during 2016 are presented

MATERIALS AND METHODS

- A total of 16,958 (non-duplicate) gram-positive and gram-negative bacterial isolates were collected from patients with multiple infection types in medical centers in the US, Europe, and Israel during 2016 and represented only 1 isolate per patient/infection episode
- Bacterial isolates were initially identified by the submitting laboratories and confirmed by JMI Laboratories using a matrix-assisted laser desorption/ionization-time of flight mass spectrometry (Bruker Daltonics, Bremen, Germany)
- Susceptibility testing was performed according to CLSI (M07-A10, 2015) reference broth microdilution methodology and results were interpreted using CLSI (M100-S27, 2017) and EUCAST (2017) breakpoint interpretive criteria
  - CLSI quality control (QC) reference strains (M100-S27, 2017) were tested concurrently and included *S. aureus* ATCC 29213; *Enterococcus faecalis* ATCC 29212; *Escherichia coli* ATCC 25922 and ATCC 35218; *Klebsiella pneumoniae* ATCC 700603; *S. pneumoniae* ATCC 49619; *H. influenzae* ATCC 49247; and *Pseudomonas aeruginosa* ATCC 27853

RESULTS

- Cumulative percent inhibition data for omadacycline against key gram-positive and gram-negative pathogens collected from patients in the US, Europe, and Israel with multiple infection types are presented in Table 1
- Omadacycline demonstrated potent *in vitro* activity against gram-positive isolates with $MIC_{50/90}$ values of ≤0.12/≤0.25 μg/mL against *S. aureus* (4,215), methicillin-resistant *S. aureus* (MRSA; 1,438), *Streptococcus agalactiae* (358), *S. pyogenes* (448), *S. pneumoniae* (1,314), and enterococci (1,067; Table 1)
- Omadacycline was equally active against *S. aureus* isolates from ABSSSI ($MIC_{50/90}$ 0.12/0.25 μg/mL; Table 2) and respiratory tract infections (RTI) ($MIC_{50/90}$ 0.12/0.25 μg/mL; Table 3) and retained a high level of activity against isolates displaying tetracycline- (doxycycline and tetracycline), fluoroquinolone- (levofloxacin), macrolide- (erythromycin), lincosamide- (clindamycin), and/or oxacillin-resistance phenotypes
  - Corresponding resistance rates were 0.2%-2.4% for doxycycline, 4.1%-6.3% for tetracycline, 23.4%-32.1% for levofloxacin, 34.0%-45.9% for erythromycin, 8.3%-12.9% for clindamycin, and 31.8%-36.3% for oxacillin (Tables 2 and 3)
- Against MRSA from ABSSSI, omadacycline (MIC_{90} 0.25 μg/mL) was 4-fold more active than doxycycline (MIC_{90}, 1 μg/mL) and 32-fold more active than tetracycline (MIC_{90}, 8 μg/mL; Table 2)
- MRSA isolates from RTI were also susceptible to omadacycline, whereas doxycycline and tetracycline were ≥4-fold less active (MIC_{90} values, 1 and 2 μg/mL, respectively; Table 3)
- Omadacycline was very active against β-haemolytic streptococci from ABSSSI, including *Streptococcus agalactiae* and *S. pyogenes* (omadacycline and tigecycline MIC_{90} values, 0.12-0.25 and 0.06 μg/mL, respectively; Table 2)
  - These isolates were susceptible (100.0%) to all agents tested except for tetracycline (13.2%-84.0% susceptible), clindamycin (69.0%-96.1% susceptible), erythromycin (53.1%-87.9% susceptible), and levofloxacin (99.2% susceptible; Table 2)
- Omadacycline was 2-fold more active against *E. faecium* ($MIC_{50/90}$ 0.06/0.12 μg/mL) compared to *E. faecalis* ($MIC_{50/90}$, 0.12/0.25 μg/mL), and its activity was unchanged against *E. faecium* isolates displaying resistance to vancomycin (Tables 1 and 2)
- *S. pneumoniae* isolates from RTI, including penicillin-resistant strains, were highly susceptible to omadacycline ($MIC_{50/90}$, 0.06/0.12 μg/mL), whereas 20.5% of *S. pneumoniae* isolates were resistant to tetracycline ($MIC_{50/90}$, ≤0.25/>8 μg/mL; Table 3)
- *Haemophilus influenzae* isolates from RTI were inhibited by omadacycline ($MIC_{50/90}$, 1/1 μg/mL), as were *M. catarrhalis* RTI isolates (omadacycline $MIC_{50/90}$, 0.25/0.25 μg/mL; Table 3)
- *Escherichia coli* isolates (including ESBL phenotype and isolates from UTI) were susceptible to omadacycline ($MIC_{50/90}$, 0.5-1/2 μg/mL); corresponding doxycycline and tetracycline MIC_{90} values were >8 μg/mL (Table 1 and Figures 1 and 2)

Table 1 Antimicrobial activity of omadacycline against key gram-positive and -negative pathogens collected from patients in medical centers in the US and Europe during 2016

Organisms (no. tested)	No. of isolates at MIC (μg/mL; cumulative %) [a]													MIC_{50}	MIC_{90}
	≤0.004	0.008	0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	>		
Staphylococcus aureus (4,215)	2 <0.1	71 1.7	1,260 31.6	2,020 79.5	**722** **96.7**	80 98.6	37 99.5	19 99.9	3 >99.9	1 100.0				0.12	0.25
MRSA (1,438)	0 0.0	28 1.9	437 32.3	632 76.3	**232** **92.4**	53 96.1	33 98.4	19 99.7	3 99.9	1 100.0				0.12	0.25
Streptococcus agalactiae (358)	0 0.0	9 2.5	82 25.4	231 89.9	**34** **99.4**	2 100.0								0.12	0.25
S. pyogenes (448)	0 0.0	17 3.8	370 86.4	**54** **98.4**	7 100.0									0.06	0.12
Streptococcus pneumoniae (1,314)	20 1.5	255 20.9	902 89.6	**133** **99.7**	2 99.8	1 99.9	1 100.0							0.06	0.12
Enterococcus faecalis (677)	4 0.6	28 4.7	200 34.3	292 77.4	**134** **97.2**	18 99.9	1 100.0							0.12	0.25
E. faecium (390)	4 1.0	34 9.7	200 61.0	**132** **94.9**	8 96.9	6 98.5	5 99.7	0 99.7	0 99.7	1 100.0				0.06	0.12
Haemophilus influenzae (803)				0 0.0	1 0.1	16 2.1	349 45.6	**381** **90.9**	71 99.4	4 99.9	0 99.9	1 100.0	1 100.0	1	1
Moraxella catarrhalis (408)				0 0.0	5 1.2	189 47.5	**205** **97.8**	9 100.0						0.25	0.25
Enterobacteriaceae (8,345)				0 0.0	9 0.1	337 4.1	2,119 29.5	2,501 59.5	1,676 79.6	704 88.0	**401** **92.8**	598 100.0	1	8	
E. coli (3,541)				0 0.0	8 0.2	305 8.8	1,707 57.0	984 84.8	**384** **95.7**	116 99.0	30 99.8	7 100.0	0.5	2	
E. coli ESBL phenotype (733)				0 0.0	1 0.1	30 4.2	217 33.8	261 69.4	**165** **92.0**	44 98.0	13 99.7	2 100.0	1	2	

[a] MIC_{50} values are underlined; MIC_{90} values are bold

Figure 1 Cumulative % inhibition of omadacycline, doxycycline, and tetracycline against 2,067 *Enterobacteriaceae* isolates from UTI

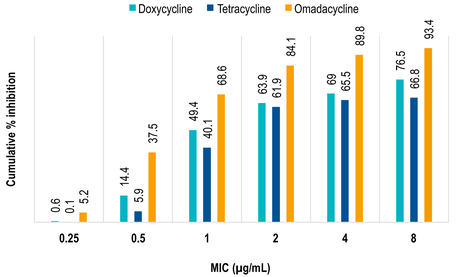

Table 2 Antimicrobial activity of omadacycline and comparators against ABSSSI pathogens collected from medical centers in the US and Europe during 2016

Organism (no. tested) / antimicrobial agent	MIC_{50}	MIC_{90}	Range	CLSI %S	CLSI %R	EUCAST %S	EUCAST %R
Staphylococcus aureus (1,891)							
Omadacycline	**0.12**	**0.25**	**0.03 — 4**	—	—	—	—
Doxycycline	≤0.06	0.12	≤0.06 — >8	98.2	0.5	95.9	2.2
Tetracycline	≤0.5	≤0.5	≤0.5 — >8	94.3	5.1	93.2	6.3
Tigecycline	0.06	0.12	≤0.015 — 0.5	100.0	0.0	100.0	0.0
Oxacillin	0.5	>2	≤0.25 — >2	68.2	31.8	68.2	31.8
Levofloxacin	0.25	>4	0.06 — >4	75.8	23.4	75.8	24.2
Erythromycin	0.25	>8	≤0.06 — >8	61.2	34.0	61.6	36.2
Clindamycin	≤0.25	≤0.25	≤0.25 — >2	91.5	8.3	91.4	8.5
Linezolid	1	1	0.25 — 2	100.0	0.0	100.0	0.0
Daptomycin	0.5	0.5	≤0.12 — 1	100.0	0.0	100.0	0.0
Vancomycin	0.5	1	0.25 — 2	100.0	0.0	100.0	0.0
MRSA (601)							
Omadacycline	**0.12**	**0.25**	**0.03 — 4**	—	—	—	—
Doxycycline	≤0.06	1	≤0.06 — >8	95.3	1.3	91.7	5.7
Tetracycline	≤0.5	8	≤0.5 — >8	89.2	9.7	87.4	11.6
Tigecycline	0.06	0.12	≤0.015 — 0.5	100.0	0.0	100.0	0.0
Levofloxacin	4	>4	0.12 — >4	35.6	62.9	35.6	64.4
Erythromycin	>8	>8	≤0.06 — >8	23.1	73.2	23.1	75.2
Clindamycin	≤0.25	>2	≤0.25 — >2	76.9	22.8	76.9	23.1
Linezolid	1	1	0.25 — 2	100.0	0.0	100.0	0.0
Daptomycin	0.5	0.5	≤0.12 — 1	100.0	0.0	100.0	0.0
Vancomycin	0.5	1	0.25 — 2	100.0	0.0	100.0	0.0
Streptococcus agalactiae (129)							
Omadacycline	**0.12**	**0.25**	**0.03 — 0.5**	—	—	—	—
Tetracycline	>8	>8	≤0.25 — >8	13.2	85.3	13.2	86.8
Tigecycline	0.06	0.06	0.015 — 0.12	100.0	0.0	100.0	0.0
Levofloxacin	0.5	1	0.25 — >4	99.2	0.8	99.2	0.8
Erythromycin	0.06	>32	≤0.015 — >32	53.1	45.3	53.1	45.3
Clindamycin	≤0.25	>2	≤0.25 — >2	69.0	29.5	70.5	29.5
Linezolid	1	1	0.25 — 2	100.0	0.0	100.0	0.0
Daptomycin	0.25	0.25	≤0.06 — 0.5	100.0	0.0	100.0	0.0
Vancomycin	0.5	0.5	0.25 — 0.5	100.0	0.0	100.0	0.0
Streptococcus pyogenes (257)							
Omadacycline	**0.06**	**0.12**	**0.03 — 0.25**	—	—	—	—
Tetracycline	≤0.25	>8	≤0.25 — >8	84.0	15.6	83.6	16.0
Tigecycline	0.03	0.06	0.015 — 0.12	100.0	0.0	100.0	0.0
Levofloxacin	0.5	1	0.12 — >4	99.2	0.4	99.2	0.8
Erythromycin	0.03	2	≤0.015 — >32	87.9	11.7	87.9	11.7
Clindamycin	≤0.25	≤0.25	≤0.25 — >2	96.1	3.9	96.1	3.9
Linezolid	1	1	0.5 — 2	100.0	0.0	100.0	0.0
Daptomycin	≤0.06	0.12	≤0.06 — 0.5	100.0	0.0	100.0	0.0
Vancomycin	0.25	0.5	0.12 — 1	100.0	0.0	100.0	0.0
Enterococcus faecalis (179)							
Omadacycline	**0.12**	**0.25**	**≤0.015 — 1**	—	—	—	—
Tetracycline	>16	>16	≤0.12 — >16	24.6	74.9	—	—
Tigecycline	0.06	0.12	≤0.015 — 0.12	100.0	0.0	100.0	0.0
Ampicillin	1	2	≤0.5 — 2	100.0	0.0	100.0	0.0
Levofloxacin	1	>4	≤0.03 — >4	74.9	24.0	76.0	24.0
Linezolid	1	2	0.25 — 2	100.0	0.0	100.0	0.0
Vancomycin	1	2	0.25 — >16	98.3	1.7	98.3	1.7
E. faecium (75)							
Omadacycline	**0.06**	**0.12**	**0.03 — 1**	—	—	—	—
Tetracycline	>16	>16	≤0.12 — >16	38.7	58.7	—	—
Tigecycline	0.03	0.06	≤0.015 — 0.25	—	—	100.0	0.0
Ampicillin	>16	>16	≤0.5 — >16	9.3	90.7	8.0	90.7
Levofloxacin	>4	>4	1 — >4	6.7	92.0	8.0	92.0
Linezolid	1	1	0.5 — 2	100.0	0.0	100.0	0.0
Vancomycin	1	>16	0.25 — >16	58.7	41.3	58.7	41.3

Figure 2 Cumulative % inhibition of omadacycline, doxycycline, and tetracycline against 1,178 *Escherichia coli* isolates from UTI

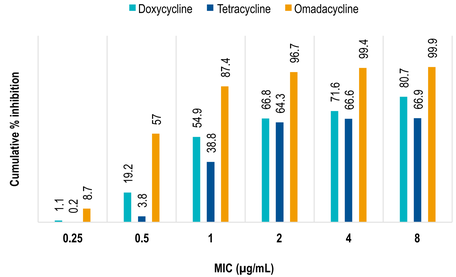

Table 3 Antimicrobial activity of omadacycline and comparators against RTI pathogens collected from medical centers in the US and Europe during 2016

Organism (no. tested) / antimicrobial agent	MIC_{50}	MIC_{90}	Range	CLSI %S	CLSI %R	EUCAST %S	EUCAST %R
Staphylococcus aureus (968)							
Omadacycline	**0.12**	**0.25**	**≤0.015 — 8**	—	—	—	—
Doxycycline	≤0.06	0.25	≤0.06 — >8	98.7	0.2	96.4	2.4
Tetracycline	≤0.5	≤0.5	≤0.5 — >8	95.1	4.1	92.9	5.9
Tigecycline	0.06	0.12	0.03 — 0.5	100.0	0.0	100.0	0.0
Oxacillin	0.5	>2	≤0.25 — >2	63.7	36.3	63.7	36.3
Levofloxacin	0.25	>4	≤0.03 — >4	66.9	32.1	66.9	33.1
Erythromycin	0.25	>8	≤0.06 — >8	50.6	42.5	51.2	45.9
Clindamycin	≤0.25	>2	≤0.25 — >2	87.1	12.5	87.0	12.9
Linezolid	1	1	≤0.12 — 4	100.0	0.0	100.0	0.0
Daptomycin	0.5	0.5	≤0.12 — 1	100.0	0.0	100.0	0.0
Vancomycin	0.5	1	0.25 — 2	100.0	0.0	100.0	0.0
MRSA (351)							
Omadacycline	**0.12**	**0.25**	**0.03 — 8**	—	—	—	—
Doxycycline	≤0.06	1	≤0.06 — >8	96.9	0.6	94.6	3.7
Tetracycline	≤0.5	2	≤0.5 — >8	92.6	6.6	88.9	8.8
Tigecycline	0.06	0.12	0.03 — 0.5	100.0	0.0	100.0	0.0
Levofloxacin	>4	>4	0.12 — >4	22.2	76.6	22.2	77.8
Erythromycin	>8	>8	0.12 — >8	16.2	76.9	17.1	80.6
Clindamycin	≤0.25	>2	≤0.25 — >2	69.8	29.3	69.8	30.2
Linezolid	1	1	0.25 — 4	100.0	0.0	100.0	0.0
Daptomycin	0.5	0.5	≤0.12 — 1	100.0	0.0	100.0	0.0
Vancomycin	0.5	1	0.25 — 2	100.0	0.0	100.0	0.0
Streptococcus pneumoniae (1,127)							
Omadacycline	**0.06**	**0.12**	**≤0.015 — 1**	—	—	—	—
Tetracycline	≤0.25	>8	≤0.25 — >8	79.0	20.5	79.0	20.5
Tigecycline	0.03	0.06	0.015 — 0.25	99.3	0.0	—	—
Levofloxacin	1	1	0.25 — >4	98.5	1.2	98.5	1.5
Penicillin	0.03	2	≤0.004 — >8	67.0	12.3 [a]	67.0	33.0 [b]
				67.0	33.0 [c]	67.0	4.9 [c]
Ceftriaxone	0.03	1	≤0.015 — >2	86.5	3.3	86.5	0.5
Erythromycin	0.06	>32	≤0.015 — >32	65.9	33.5	65.9	33.5
Clindamycin	≤0.25	>2	≤0.25 — >2	84.6	15.2	84.8	15.2
Linezolid	1	2	0.25 — 2	100.0	0.0	100.0	0.0
Haemophilus influenzae (772)							
Omadacycline	**1**	**1**	**0.12 — 16**	—	—	—	—
Tetracycline	0.5	1	0.12 — >8	99.7	0.3	99.5	0.3
Tigecycline	0.12	0.25	0.06 — 1	96.0	0.0	—	—
Amoxicillin-clavulanic acid	1	2	0.12 — >8	99.4	0.6	93.9	6.1
Ampicillin	1	>8	0.12 — >8	65.0	26.0	65.0	35.0
Azithromycin	0.5	1	0.12 — >32	99.0	0.0	99.0	1.0
Ceftriaxone	0.004	0.015	≤0.001 — 0.5	100.0	0.0	99.5	0.5
Levofloxacin	0.015	0.03	0.008 — >2	99.7	0.0	98.2	1.8
Trimethoprim-sulfamethoxazole	0.12	>4	≤0.06 — >4	64.5	32.8	64.5	34.8
Moraxella catarrhalis (405)							
Omadacycline	**0.25**	**0.25**	**0.06 — 0.5**	—	—	—	—
Tetracycline	0.25	0.5	0.12 — 0.5	100.0	0.0	100.0	0.0
Tigecycline	0.06	0.06	≤0.015 — 0.12	—	—	—	—
Ceftriaxone	0.25	0.5	0.002 — 2	100.0	0.0	99.8	0.0
Amoxicillin-clavulanic acid	0.12	0.25	≤0.06 — 0.5	100.0	0.0	100.0	0.0
Levofloxacin	0.06	0.06	0.015 — 1	100.0	0.0	100.0	0.0
Azithromycin	0.015	0.03	0.008 — 1	99.7	0.0	99.7	0.3
Trimethoprim-sulfamethoxazole	0.12	0.25	≤0.06 — 2	96.8	0.0	96.8	0.7

[a] Using oral breakpoints
[b] Using parenteral breakpoints
[c] Using parenteral, meningitis breakpoints
[d] Using non-meningitis breakpoints

CONCLUSIONS

- Omadacycline was highly active against *S. aureus* and MRSA that included isolates from ABSSSI and RTI ($MIC_{50/90}$ values, 0.12/0.25 μg/mL) as well as strains displaying resistance to tetracyclines (doxycycline and/or tetracycline), fluoroquinolones (levofloxacin), macrolides (erythromycin), and lincosamides (clindamycin)
- Streptococci, including β-haemolytic streptococci (*S. agalactiae* and *S. pyogenes*) from ABSSSI and *S. pneumoniae* from RTI were inhibited by low levels of omadacycline ($MIC_{50/90}$ values of ≤0.12/≤0.25 μg/mL)
- Omadacycline remained highly active against tetracycline-resistant *S. pneumoniae* (20.5% tetracycline-resistant), *S. agalactiae* (85.3%-86.8% tetracycline-resistant), and *S. pyogenes* (15.6%-16.0% tetracycline-resistant) isolates
- Omadacycline exhibited potent *in vitro* activity against *E. faecalis* ($MIC_{50/90}$, 0.12/0.25 μg/mL) and vancomycin-susceptible and -resistant isolates of *E. faecium* ($MIC_{50/90}$, 0.06/0.12 μg/mL)
  - Tetracycline demonstrated little utility against *E. faecalis* and *E. faecium* isolates (MIC_{90} values >16 μg/mL)
- *Haemophilus influenzae* and *M. catarrhalis* isolates from RTI were susceptible to omadacycline with MIC_{90} values of 1 and 0.25 μg/mL, respectively
- *Escherichia coli* isolates (including ESBL phenotype and UTI isolates) were susceptible to omadacycline (MIC_{90}, 2 μg/mL), whereas doxycycline and tetracycline were not active (MIC_{90}, >8 μg/mL)
- Results of this surveillance study support continued omadacycline development, especially in infections where resistant pathogens are likely to be encountered, including ABSSSI, CABP, and UTI

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