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Lefamulin Activity Against Respiratory Tract Pathogens Collected in the 2017 Global SENTRY Antimicrobial Surveillance Program

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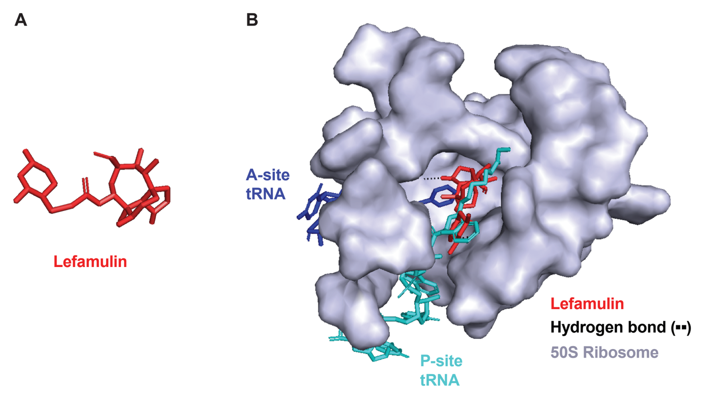
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INTRODUCTION

- Community-acquired bacterial pneumonia (CABP) is a common infection-related cause of hospitalization and/or death in older adults in Europe, Latin America, Asia-Pacific, and North America[1-5]
- Annual CABP care costs an estimated €10.1 billion[1] in Europe and >$17 billion in the United States[5]
- Increasing rates of antibiotic resistance among CABP-causing pathogens and safety concerns around available antibiotics drive a worldwide need for new CABP treatment options[6]
- Lefamulin (LEF) is a first-in-class pleuromutilin antibiotic in phase 3 clinical development for intravenous (IV) and oral treatment of CABP[7,8]
 - LEF selectively inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit at the A- and P-sites in the peptidyl transferase center[7,8] **(Figure 1)**
- LEF was noninferior to moxifloxacin in two phase 3 trials (one IV-to-oral switch study and one oral-only study) in adults with CABP[7,9]
- The objective of this study was to evaluate the in vitro activity of LEF and comparators against a contemporary global set of respiratory tract pathogens

Figure 1. (A) Structure of Lefamulin and (B) Lefamulin in the Peptidyl Transferase Center Overlapping With A- and P-site tRNA


A
B
Lefamulin
A-site tRNA
Lefamulin
Hydrogen bond (••)
50S Ribosome
P-site tRNA

METHODS

- As part of the 2017 global SENTRY Antimicrobial Surveillance Program, 3190 unique isolates (1 per patient) were collected from patients with community-acquired respiratory tract infections (77.2%) or hospitalized patients with pneumonia (22.8%)
- Isolates were collected from 109 sites in 33 countries
 - 40.3% of isolates were collected from the United States, 41.1% from Europe, 10.3% from Asia Pacific, and 8.2% from Latin America
- Minimum inhibitory concentration (MIC) for LEF and comparators was determined using Clinical and Laboratory Standards Institute (CLSI) broth microdilution[10]; susceptibility was evaluated using the CLSI (2019) breakpoints[11]

RESULTS

- LEF showed potent antibacterial activity against all tested CABP pathogens and its activity was not affected by resistance to other antibiotic classes **(Table 1)**

Streptococcus pneumoniae

- *S. pneumoniae* isolates showed resistance to macrolides (35.8% resistant to erythromycin), penicillin (14.4%), trimethoprim-sulfamethoxazole (18.4%), and tetracycline (24.9%), whereas they were largely susceptible (≥84%) to the tested cephalosporins and fluoroquinolones **(Table 2)**
- LEF inhibited 99.5% of *S. pneumoniae* isolates at ≤0.25 µg/mL, with $MIC_{50/90}$ values of 0.06/0.12 µg/mL for multidrug-resistant and penicillin-resistant subsets and 0.12/0.25 µg/mL for the macrolide-resistant subset **(Table 3)**

Staphylococcus aureus

- *S. aureus* isolates overall, and particularly methicillin-resistant *S. aureus* (MRSA) strains, were resistant to macrolides (40.2% and 70.2%, respectively, resistant to erythromycin) and fluoroquinolones (26.4% and 67.5%, respectively, resistant to moxifloxacin; **Table 4**)
- LEF showed potent activity against *S. aureus* as well as MRSA, with $MIC_{50/90}$ values of 0.06/0.12 µg/mL for both **(Table 4)**

Haemophilus influenzae

- *H. influenzae* isolates were largely susceptible to all antimicrobial agents except ampicillin (27.6% resistant) and trimethoprim-sulfamethoxazole (33.1% resistant; **Table 5**)
- LEF inhibited *H. influenzae* isolates **(Table 5)**, including the β-lactamase–positive subset (*n*=144; data not shown), with $MIC_{50/90}$ values of 0.5/2 µg/mL for both

Haemophilus parainfluenzae

- *H. parainfluenzae* isolates were largely susceptible to all antimicrobial agents except ampicillin (15.2% resistant), clarithromycin (8.7% resistant), and trimethoprim-sulfamethoxazole (16.3% resistant; **Table 5**)
- LEF inhibited *H. parainfluenzae* isolates at $MIC_{50/90}$ values of 1/2 µg/mL **(Table 5)**

Moraxella catarrhalis

- *M. catarrhalis* isolates included a substantial proportion of β-lactamase producers (96.9%) and were largely susceptible to all tested antimicrobial agents **(Table 5)**
- LEF inhibited *M. catarrhalis* isolates at concentrations of ≤0.12 µg/mL ($MIC_{50/90}$ values of 0.06/0.06 µg/mL; **Table 5**)

β-hemolytic and viridans group streptococci

- LEF showed potent activity against both β-hemolytic and viridans group streptococci, with $MIC_{50/90}$ values of 0.03/0.03 µg/mL and 0.06/2 µg/mL, respectively **(Table 1)**
- β-hemolytic and viridans group streptococcal isolates showed resistance to clindamycin (11.1% and 23.1%, respectively), erythromycin (33.3% and 46.2%, respectively), and levofloxacin (5.6% and 7.7%, respectively; data not shown)

Table 1. Activity of Lefamulin and Comparators Against CABP Pathogens

		$MIC_{50/90}$, µg/mL					
Organism	*n*	Lefamulin	Amoxicillin-clavulanic acid	Azithromycin	Ceftriaxone	Moxifloxacin	Tigecycline
S. pneumoniae	1862	0.12/0.25	≤0.03/2	0.06/>4	0.03/1	0.12/0.25	0.06/0.06
Penicillin resistant*	268	0.06/0.12	2/>4	>4/>4	1/2	0.12/0.25	0.06/0.12
Macrolide resistant†	667	0.12/0.25	0.5/>4	>4/>4	0.5/2	0.12/0.25	0.06/0.06
Multidrug resistant‡	162	0.06/0.12	4/>4	>4/>4	1/2	0.12/0.25	0.06/0.12
S. aureus	428	0.06/0.12	–	0.5/>32	0.25/1§	≤0.06/>4	0.12/0.12
MRSA	151	0.06/0.12	–	>32/>32	1/2§	2/>4	0.12/0.25
H. influenzae	550	0.5/2	1/2	1/2	0.004/0.015	0.03/0.06	0.25/0.5
H. parainfluenzae	92	1/2	0.5/1	0.5/2	0.004/0.06	0.06/>2	0.25/0.5
M. catarrhalis	227	0.06/0.06	≤0.25/≤0.25	0.015/0.03	0.25/1	0.06/0.06	0.06/0.06
β-hemolytic *Streptococcus* spp.¶	18	0.03/0.03	–	0.03/8‖	0.06/0.06	0.12/0.25	0.06/0.06
Viridans group *Streptococcus* spp.^	13	0.06/2	–	0.03/>16‖	0.12/0.5	0.12/0.25	0.06/0.12

CABP=community-acquired bacterial pneumonia; CLSI=Clinical and Laboratory Standards Institute; MIC=minimum inhibitory concentration; MIC_{50}=minimum concentration at which 50% of isolates were inhibited; MIC_{90}=minimum concentration at which 90% of isolates were inhibited; MRSA=methicillin-resistant *S. aureus*.
*Applying oral CLSI breakpoint of ≥2 µg/mL. †Using erythromycin breakpoint. ‡Resistant to oral penicillin, erythromycin, and tetracycline. §Ceftaroline tested instead of ceftriaxone. ¶Organisms include: *Streptococcus pyogenes* (*n*=8) and *S. agalactiae* (*n*=10). ‖Erythromycin tested instead of azithromycin. ^Organisms include: *Streptococcus anginosus* (*n*=1), *S. anginosus* group (*n*=1), *S. gallolyticus* (*n*=2), *S. mitis* group (*n*=7), *S. parasanguinis* (*n*=1), *S. salivarius/vestibularis* (*n*=1).

Table 2. Activity of Lefamulin and Comparators Against *S. pneumoniae*

	µg/mL			CLSI*		
Antimicrobial Agent	MIC_{50}	MIC_{90}	Range	%S	%I	%R
***S. pneumoniae* (*n*=1862)**						
Lefamulin	**0.12**	**0.25**	**≤0.008–1**	**[100.0]†**		
Amoxicillin-clavulanic acid	≤0.03	2	≤0.03–>4	93.1	2.2	4.8
Azithromycin	0.06	>4	≤0.03–>4	63.7	0.6	35.7
Ceftaroline	≤0.008	0.12	≤0.008–>1	99.9	–	–
Ceftriaxone	0.03	1	≤0.015–>2	83.8‡ 94.9§	11.2 4.1	5.1 1.0
Clindamycin	≤0.25	>2	≤0.25–>2	80.8	0.4	18.8
Erythromycin	0.03	>16	≤0.015–>16	63.7	0.4	35.8
Levofloxacin	1	2	0.25–>4	98.0	0.3	1.7
Moxifloxacin	0.12	0.25	≤0.03–>4	98.4	1.1	0.4
Penicillin	0.03	2	≤0.008–>4	64.9¶ 64.9‖ 94.0^	20.7 – 5.3	14.4 35.1 0.6
Tetracycline	0.5	>4	0.06–>4	74.8	0.3	24.9
Tigecycline	0.06	0.06	0.015–0.25	93.7#	–	–
Trimethoprim-sulfamethoxazole	0.25	>4	≤0.12–>4	71.4	10.2	18.4

CLSI=Clinical and Laboratory Standards Institute; I=intermediate; MIC=minimum inhibitory concentration; MIC_{50}=minimum concentration at which 50% of isolates were inhibited; MIC_{90}=minimum concentration at which 90% of isolates were inhibited; R=resistant; S=susceptible.
*Criteria as published by CLSI 2019. †Percentage inhibited at proposed lefamulin breakpoint of ≤1 µg/mL for *S. pneumoniae* shown for reference. ‡Using meningitis breakpoints. §Using nonmeningitis breakpoints. ¶Using oral breakpoints. ‖Using parenteral, meningitis breakpoints. ^Using parenteral, nonmeningitis breakpoints. #US Food and Drug Administration breakpoints accessed February 2018.

Table 3. Activity of Lefamulin and Comparators Against Drug-Resistant *S. pneumoniae*

	µg/mL			CLSI*		
Antimicrobial Agent	MIC_{50}	MIC_{90}	Range	%S	%I	%R
Penicillin-resistant† *S. pneumoniae* (*n*=268)						
Lefamulin	**0.06**	**0.12**	**0.015–0.5**	**[100.0]‡**		
Amoxicillin-clavulanic acid	2	>4	1–>4	51.7	15.0	33.3
Azithromycin	>4	>4	≤0.03–>4	15.7	0.7	83.6
Ceftaroline	0.12	0.25	0.03–>1	99.3	–	–
Ceftriaxone	1	2	0.25–>2	5.2§ 66.0¶	60.8 27.6	34.0 6.3
Clindamycin	>2	>2	≤0.25–>2	46.3	0.7	53.0
Erythromycin	>16	>16	≤0.015–>16	15.7	0.0	84.3
Levofloxacin	1	2	0.5–>4	96.6	0.0	3.4
Moxifloxacin	0.12	0.25	0.06–>4	97.4	1.1	1.5
Penicillin	2	4	2–>4	0.0‖ 0.0^ 58.6#	0.0 – 36.9	100.0 100.0 4.5
Tetracycline	>4	>4	0.25–>4	38.4	0.0	61.6
Tigecycline	0.06	0.12	0.015–0.12	89.6**	–	–
Trimethoprim-sulfamethoxazole	>4	>4	≤0.12–>4	24.3	11.2	64.6
Macrolide-resistant†† *S. pneumoniae* (*n*=667)						
Lefamulin	**0.12**	**0.25**	**0.015–1**	**[100.0]‡**		
Amoxicillin-clavulanic acid	0.5	>4	≤0.03–>4	83.8	5.6	10.7
Azithromycin	>4	>4	≤0.03–>4	0.6	0.9	98.5
Ceftaroline	0.06	0.12	≤0.008–>1	99.7	–	–
Ceftriaxone	0.5	2	≤0.015–>2	62.0§ 86.2¶	24.2 11.3	13.8 2.6
Clindamycin	>2	>2	≤0.25–>2	46.5	1.2	52.3
Erythromycin	>16	>16	1–>16	0.0	0.0	100.0
Levofloxacin	1	2	0.5–>4	97.8	0.3	1.9
Moxifloxacin	0.12	0.25	≤0.03–>4	98.4	0.9	0.7
Penicillin	0.5	4	≤0.008–>4	28.0‖ 28.0^ 85.5#	38.1 – 12.7	33.9 72.0 1.8
Tetracycline	>4	>4	0.12–>4	39.7	0.1	60.1
Tigecycline	0.06	0.06	0.015–0.25	92.4**	–	–
Trimethoprim-sulfamethoxazole	1	>4	≤0.12–>4	49.5	17.3	33.2
Multidrug-resistant‡‡ *S. pneumoniae* (*n*=162)						
Lefamulin	**0.06**	**0.12**	**0.015–0.25**	**[100.0]‡**		
Amoxicillin-clavulanic acid	4	>4	1–>4	42.9	18.6	38.5
Azithromycin	>4	>4	1–>4	0.0	1.2	98.8
Ceftaroline	0.12	0.25	0.06–0.5	100.0	–	–
Ceftriaxone	1	2	0.5–>2	4.3§ 50.6¶	46.3 41.4	49.4 8.0
Clindamycin	>2	>2	≤0.25–>2	21.0	1.2	77.8
Erythromycin	>16	>16	1–>16	0.0	0.0	100.0
Levofloxacin	1	2	0.5–>4	95.7	0.0	4.3
Moxifloxacin	0.12	0.25	0.06–>4	96.9	1.9	1.2
Penicillin	4	4	2–>4	0.0‖ 0.0^ 45.1#	0.0 – 48.8	100.0 100.0 6.2
Tetracycline	>4	>4	>4–>4	0.0	0.0	100.0
Tigecycline	0.06	0.12	0.015–0.12	85.8**	–	–
Trimethoprim-sulfamethoxazole	>4	>4	≤0.12–>4	18.5	13.6	67.9

CLSI=Clinical and Laboratory Standards Institute; I=intermediate; MIC=minimum inhibitory concentration; MIC_{50}=minimum concentration at which 50% of isolates were inhibited; MIC_{90}=minimum concentration at which 90% of isolates were inhibited; R=resistant; S=susceptible.
*2019 CLSI criteria. †Penicillin MIC ≥2 µg/mL using the oral breakpoint. ‡Percentages inhibited at proposed lefamulin breakpoint of ≤1 µg/mL for *S. pneumoniae* shown for reference. §Using meningitis breakpoint. ¶Using nonmeningitis breakpoint. ‖Using oral breakpoint. ^Using parenteral, meningitis breakpoints. #Using parenteral, nonmeningitis breakpoints. **US Food and Drug Administration breakpoints accessed February 2018. ††Using erythromycin breakpoint. ‡‡Resistant to oral penicillin, erythromycin, and tetracycline.

Table 4. Activity of Lefamulin and Comparators Against *S. aureus*

	µg/mL			CLSI*		
Antimicrobial Agent	MIC_{50}	MIC_{90}	Range	%S	%I	%R
***S. aureus* (*n*=428)**						
Lefamulin	**0.06**	**0.12**	**0.015–1**	**[99.5]†**		
Azithromycin	0.5	>32	0.06–>32	56.8	0.0	43.2
Ceftaroline	0.25	1	≤0.06–4	92.5‡	7.5	0.0
Clindamycin	0.06	>2	≤0.03–>2	81.3	0.0	18.7
Doxycycline	0.12	1	≤0.06–>8	95.1	3.0	1.9
Erythromycin	0.25	>8	≤0.06–>8	56.3	3.5	40.2
Gentamicin	≤1	>8	≤1–>8	88.3	0.7	11.0
Levofloxacin	0.25	>4	0.12–>4	69.9	0.2	29.9
Linezolid	1	2	0.25–4	100.0	–	0.0
Moxifloxacin	≤0.06	>4	≤0.06–>4	70.3	3.3	26.4
Oxacillin	0.5	>2	0.25–>2	64.7	–	35.3
Tigecycline	0.12	0.12	≤0.015–0.5	100.0§	–	–
Trimethoprim-sulfamethoxazole	≤0.5	≤0.5	≤0.5–>16	97.9	–	2.1
Vancomycin	1	1	0.5–2	100.0	0.0	0.0
MRSA (*n*=151)						
Lefamulin	**0.06**	**0.12**	**0.03–0.25**	**[98.6]†**		
Azithromycin	>32	>32	0.12–>32	26.5	0.0	73.5
Ceftaroline	1	2	0.25–4	78.8‡	21.2	0.0
Clindamycin	0.06	>2	≤0.03–>2	53.6	0.0	46.4
Doxycycline	0.12	8	≤0.06–>8	86.8	8.6	4.6
Erythromycin	>8	>8	≤0.06–>8	26.5	3.3	70.2
Gentamicin	≤1	>8	≤1–>8	76.8	2.0	21.2
Levofloxacin	>4	>4	0.12–>4	24.5	0.0	75.5
Linezolid	1	2	0.5–2	100.0	–	0.0
Moxifloxacin	2	>4	≤0.06–>4	25.2	7.3	67.5
Oxacillin	>2	>2	>2–>2	0.0	–	100.0
Tigecycline	0.12	0.25	0.03–0.5	100.0§	–	–
Trimethoprim-sulfamethoxazole	≤0.5	≤0.5	≤0.5–>16	95.4	–	4.6
Vancomycin	1	1	0.5–2	100.0	0.0	0.0

CLSI=Clinical and Laboratory Standards Institute; I=intermediate; MIC=minimum inhibitory concentration; MIC_{50}=minimum concentration at which 50% of isolates were inhibited; MIC_{90}=minimum concentration at which 90% of isolates were inhibited; MRSA=methicillin-resistant *S. aureus*; R=resistant; S=susceptible.
*2019 CLSI criteria. †Percentages inhibited at proposed lefamulin breakpoint of ≤0.5 µg/mL for *S. aureus* shown for reference. ‡Intermediate interpreted as susceptible-dose dependent. §US Food and Drug Administration breakpoints accessed February 2018.

Table 5. Activity of Lefamulin and Comparators Against *H. influenzae*, *H. parainfluenzae*, and *M. catarrhalis*

	µg/mL			CLSI*		
Antimicrobial Agent	MIC_{50}	MIC_{90}	Range	%S	%I	%R
***H. influenzae* (*n*=550)**						
Lefamulin	**0.5**	**2**	**0.015–4**	**[100.0]†**		
Amoxicillin-clavulanic acid	1	2	≤0.06–16	98.9	–	1.1
Ampicillin	0.5	>8	≤0.12–>8	67.3	5.1	27.6
Azithromycin	1	2	≤0.12–>8	99.1	–	–
Cefepime	0.12	0.25	≤0.015–>2	99.8	–	–
Ceftriaxone	0.004	0.015	≤0.002–0.25	100.0	–	–
Ciprofloxacin	0.015	0.015	0.008–>1	98.9	–	–
Clarithromycin	8	16	≤0.12–>16	80.5	17.6	1.8
Moxifloxacin	0.03	0.06	≤0.008–>2	99.1	–	–
Tetracycline	0.5	1	0.12–>8	98.4	0.2	1.5
Tigecycline	0.25	0.5	0.03–2	86.2‡	–	–
Trimethoprim-sulfamethoxazole	0.12	>4	≤0.06–>4	62.9	4.0	33.1
***H. parainfluenzae* (*n*=92)**						
Lefamulin	**1**	**2**	**≤0.008–8**	**[100.0]†**		
Amoxicillin-clavulanic acid	0.5	1	≤0.06–8	98.9	–	1.1
Ampicillin	0.5	>8	≤0.12–>8	81.5	3.3	15.2
Azithromycin	0.5	2	≤0.12–>8	95.7	–	–
Cefepime	0.06	2	≤0.015–>2	96.7	–	–
Ceftriaxone	0.004	0.06	≤0.002–>2	98.9	–	–
Ciprofloxacin	0.015	>1	≤0.004–>1	88.0	–	–
Clarithromycin	8	16	0.5–>16	68.5	22.8	8.7
Moxifloxacin	0.06	>2	≤0.008–>2	85.7	–	–
Tetracycline	0.5	1	0.25–>8	92.4	0.0	7.6
Tigecycline	0.25	0.5	0.06–1	–	–	–
Trimethoprim-sulfamethoxazole	≤0.06	4	≤0.06–>4	79.3	4.3	16.3
***M. catarrhalis* (*n*=227)**						
Lefamulin	**0.06**	**0.06**	**≤0.008–0.12**	**[100.0]†**		
Amoxicillin-clavulanic acid	≤0.25	≤0.25	≤0.25–2	100.0	–	0.0
Azithromycin	0.015	0.03	≤0.004–0.06	100.0	–	–
Ceftriaxone	0.25	1	≤0.002–>2	99.6	–	–
Clarithromycin	≤0.12	≤0.12	≤0.12–0.5	100.0	–	–
Moxifloxacin	0.06	0.06	0.015–0.12	–	–	–
Tetracycline	0.25	0.5	≤0.06–>8	99.1	0.0	0.9
Tigecycline	0.06	0.06	≤0.015–0.12	–	–	–
Trimethoprim-sulfamethoxazole	0.25	0.5	≤0.06–2	94.7	5.3	0.0

CLSI=Clinical and Laboratory Standards Institute; I=intermediate; MIC=minimum inhibitory concentration; MIC_{50}=minimum concentration at which 50% of isolates were inhibited; MIC_{90}=minimum concentration at which 90% of isolates were inhibited; R=resistant; S=susceptible.
*2019 CLSI criteria. †Percentages inhibited at proposed lefamulin breakpoints of ≤4 µg/mL for *H. influenzae*, ≤8 µg/mL for *H. parainfluenzae*, and ≤0.5 µg/mL for *M. catarrhalis* shown for reference. ‡US Food and Drug Administration breakpoints accessed February 2018.

CONCLUSIONS

- LEF demonstrated potent in vitro activity against this contemporary (2017) collection of community-acquired bacterial pathogens collected worldwide from patients with respiratory tract infections and hospitalized patients with pneumonia compared with the most potent comparator agents used to treat CABP
- LEF activity was unaffected by resistance to other antibiotic classes, including macrolides, fluoroquinolones, and tetracyclines
- These in vitro data suggest that LEF may offer an important empiric monotherapy treatment option for CABP, in particular, where resistance to antimicrobials commonly used for CABP is high

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