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Activity of Ceftaroline Against the Leading Community-acquired Respiratory Tract Infection Pathogens in Europe and the Mediterranean Region, 2011

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Amended Abstract

Objective: To monitor the spectrum and potency of ceftaroline (CPT) against the leading community-acquired respiratory tract infection (CARTI) pathogens in Europe and the Mediterranean region (EMR). CPT, the active form of ceftaroline fosamil, a novel, parenteral cephalosporin with bactericidal activity against Gram-positive and common Gram-negative organisms, was approved for clinical use in the European Union in 2012 for the treatment of community-acquired pneumonia and complicated skin and soft tissue infections.

Methods: 2,288 non-duplicate, clinically relevant isolates of *Staphylococcus aureus* (SA), *Streptococcus pneumoniae* (SPN), *Haemophilus influenzae* (HI), and *H. parainfluenzae* (HP) from 41 medical centres in 16 countries from SENTRY as part of the 2011 AWARE ceftaroline surveillance programme were evaluated to determine susceptibility (S) profiles against CPT and commonly used comparator agents. S testing was performed by CLSI broth microdilution methodology. S interpretations were as published in CLSI and EUCAST guidelines.

Results: CPT was active against SA (90.3% susceptible overall), 31.6% of which were methicillin-resistant (MRSA; 69.4% susceptible). The CPT $MIC_{50/90}$ for MRSA was 1/2 compared to 0.25/0.25 mg/L for methicillin-susceptible SA (MSSA). For SPN, the CPT $MIC_{50/90}$ was at ≤0.015/0.12 mg/L; 99.3% of isolates were S. There were only three strains (0.2%) at the highest MIC value of 1 mg/L from Poland, Romania and Turkey. CPT activity against penicillin-resistant (Pen-R) and –intermediate SPN was at $MIC_{50/90}$, 0.25/1 and 0.12/0.25 mg/L, respectively, but activity was lower than seen against penicillin-susceptible isolates. CPT was 16-fold more active than ceftriaxone ($MIC_{50/90}$, 4/>8 mg/L) and >32-fold more active than amoxicillin/clavulanic acid ($MIC_{50/90}$, >8/>8 mg/L) against the Pen-R strains. All Pen-R SPN strains and 21.7% of all SPN were non-susceptible to ceftriaxone. CPT was active against 591 beta-lactamase (BL) negative and 90 BL positive HI isolates with $MIC_{50/90}$, ≤0.015/0.03 mg/L. Activity was also demonstrated for CPT against 39 HP ($MIC_{50/90}$, ≤0.015/0.06 mg/L).

Conclusions: CPT demonstrated *in vitro* activity against the leading CARTI pathogens SA including MRSA, SPN and *Haemophilus* spp. in this recent (2011) collection of pathogens from EMR. The activity of CPT against MDR SPN strains merits further study.

Introduction

Ceftaroline fosamil is a cephalosporin with bactericidal activity *in vitro* against Gram-positive and common Gram-negative pathogens causing community-acquired respiratory tract infections (CARTI), including methicillin-resistant *Staphylococcus aureus* (MRSA), multidrug-resistant (MDR) *Streptococcus pneumoniae* and β-lactamase-producing *Haemophilus influenzae*. Ceftaroline fosamil is a prodrug which is rapidly hydrolyzed *in vivo* to release the active form of the drug, ceftaroline.

Ceftaroline fosamil was approved in 2010 by the United States Food and Drug Administration (USA-FDA) for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). Ceftaroline fosamil also recently received marketing authorization in the European Union (EU; August 2012) for use in the treatment of complicated skin and soft tissue infections (cSSTI) and community-acquired pneumonia (CAP). In this study we evaluated the activity of ceftaroline against bacterial isolates collected from patients with CARTI in Europe and the Mediterranean region (EMR) during 2011 from SENTRY as part of the **A**ssessing **W**orldwide **A**ntimicrobial **R**esistance **E**valuation (AWARE) Programme, a global ceftaroline surveillance study.

Materials and Methods

Non-duplicate, unique isolates were collected in 41 medical centres in 16 countries; 14 EU countries, including (no. of medical centres) Belgium (1), Czech Republic (2), France (5), Germany (3), Greece (1), Italy (3), Poland (3), Portugal (1), Romania (3), Russia (3), Slovenia (1), Spain (3), Sweden (2) and the United Kingdom (UK; 2), plus Turkey (5) and Israel (3). A total of 2,288 organisms were evaluated, including 196 *S. aureus* (31.6% MRSA), 1,372 *S. pneumoniae* (1.5% penicillin-resistant [MIC, ≥8 mg/L] and 21.7% ceftriaxone-non-susceptible; European Committee on Antimicrobial Susceptibility Testing [EUCAST] interpretive criteria), 681 *H. influenzae* (13.2% β-lactamase-positive), and 39 *H. parainfluenzae*.

Reference broth microdilution tests were conducted according to the Clinical and Laboratory Standards Institute (CLSI) methods. The antimicrobial susceptibility of ceftaroline and comparator antimicrobials used to treat CARTI were determined. Validated MIC panels were manufactured by ThermoFisher Scientific® (formerly TREK Diagnostics®; Cleveland, Ohio, USA). *S. aureus* strains were tested in cation-adjusted Mueller-Hinton broth (CA-MHB), *S. pneumoniae* were tested in CA-MHB supplemented with 2.5–5% lysed horse blood, and *Haemophilus* spp. strains were tested in Haemophilus test medium according to CLSI document M07-A9 (2012). β-lactamase testing for *Haemophilus* spp. was performed using the Remel Nitrocephin Disk (Remel, Lenexa, Kansas, USA).

Quality control (QC) strains included: *S. aureus* ATCC 29213, *S. pneumoniae* ATCC 49619 and *H. influenzae* 49247. Susceptibility percentages and validation of QC results were based on the CLSI guidelines (M100-S23) and susceptibility breakpoints were used to determine susceptibility/resistance rates (CLSI and EUCAST, 2013).

Table 1. *Summary of ceftaroline activity tested against pathogens associated with CARTI in EMR (2011)*

	Cumulative % inhibited at ceftaroline MIC (mg/L) of:										
Organism (no. tested)	**≤0.015**	**0.03**	**0.06**	**0.12**	**0.25**	**0.5**	**1**	**2**	**4**	**MIC_{50}**	**MIC_{90}**
S. aureus (196)	0.5	0.5	0.5	12.2	67.4	78.6	90.3	100.0	–	0.25	1
MSSA (134)	0.8	0.8	0.8	17.9	98.5	100.0	–	–	–	0.25	0.25
MRSA (62)	–	–	–	–	–	32.3	69.4	100.0	–	1	2
S. pneumoniae (1,372)	64.7	70.7	79.7	95.6	99.3	99.8	100.0	–	–	≤0.015	0.12
penicillin-susceptible (MIC, ≤2 mg/L) (1,263)[a]	70.2	76.8	85.7	99.1	100.0	–	–	–	–	≤0.015	0.12
penicillin-intermediate (MIC, 4 mg/L) (89)[a]	–	–	11.2	66.3	98.9	100.0	–	–	–	0.12	0.25
penicillin-resistant (MIC, ≥8 mg/L) (20)[a]	–	–	–	–	55.0	85.0	100.0	–	–	0.25	1
H. influenzae (681)	86.8	97.7	99.6	100.0	–	–	–	–	–	≤0.015	0.03
beta-lactamase negative (591)	88.8	98.5	99.8	100.0	–	–	–	–	–	≤0.015	0.03
beta-lactamase positive (90)	73.3	92.2	97.8	100.0	–	–	–	–	–	≤0.015	0.03
H. parainfluenzae (39)	84.6	89.7	92.3	97.4	97.4	97.4	97.4	97.4	100.0	≤0.015	0.06

[a]Criteria as published by the CLSI for 'Penicillin parenteral non-meningitis' (S≤2, I=4, R≥8 mg/L)

Table 2. *Activity of ceftaroline and comparator antimicrobial agents when tested against pathogens associated with CARTI in EMR (2011)*

Organism group (no. tested)/ antimicrobial agent	**MIC_{50}**	**MIC_{90}**	**Range**	**CLSI[a] %S / %I / %R**	**EUCAST[a] %S / %I / %R**
S. aureus (196)					
Ceftaroline	0.25	1	≤0.015 – 2	90.3 / 9.7 / 0.0	90.3 / 0.0 / 9.7
Oxacillin	0.5	>2	≤0.25 – >2	68.4 / 0.0 / 31.6	68.4 / 0.0 / 31.6
Ceftriaxone	4	>8	0.5 – >8	68.4 / 0.0 / 31.6	68.4 / 0.0 / 31.6
Erythromycin	0.25	>16	≤0.12 – >16	63.3 / 2.5 / 34.2	63.3 / 0.0 / 36.7
Clindamycin	≤0.25	≤0.25	≤0.25 – >2	91.8 / 0.0 / 8.2	91.8 / 0.0 / 8.2
Vancomycin	1	1	0.5 – 2	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Linezolid	1	1	0.5 – 2	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Tetracycline	≤0.25	>8	≤0.25 – >8	87.2 / 0.0 / 12.8	86.7 / 0.0 / 13.3
Tigecycline[b]	0.06	0.12	≤0.03 – 0.5	100.0 / – / –	100.0 / 0.0 / 0.0
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – >4	98.5 / 0.0 / 1.5	98.5 / 0.0 / 1.5
Daptomycin	0.25	0.5	≤0.06 – 0.5	100.0 / – / –	100.0 / 0.0 / 0.0
MSSA (134)					
Ceftaroline	0.25	0.25	≤0.015 – 0.5	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Ceftriaxone	4	4	0.5 – 8	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Erythromycin	0.25	>16	≤0.12 – >16	85.1 / 2.2 / 12.7	85.1 / 0.0 / 14.9
Clindamycin	≤0.25	≤0.25	≤0.25 – >2	98.5 / 0.0 / 1.5	98.5 / 0.0 / 1.5
Vancomycin	1	1	0.5 – 2	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Linezolid	1	2	0.5 – 2	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Tetracycline	≤0.25	0.5	≤0.25 – >8	91.8 / 0.0 / 8.2	91.0 / 0.0 / 9.0
Tigecycline[b]	0.06	0.06	≤0.03 – 0.5	100.0 / – / –	100.0 / 0.0 / 0.0
Levofloxacin	≤0.12	0.5	≤0.12 – >4	93.3 / 0.7 / 6.0	93.3 / 0.7 / 6.0
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – >4	99.3 / 0.0 / 0.7	99.3 / 0.0 / 0.7
Daptomycin	0.25	0.5	≤0.06 – 0.5	100.0 / – / –	100.0 / 0.0 / 0.0
MRSA (62)					
Ceftaroline	1	2	0.5 – 2	69.4 / 30.6 / 0.0	69.4 / 0.0 / 30.6
Ceftriaxone	>8	>8	>8	0.0 / 0.0 / 100.0	0.0 / 0.0 / 100.0
Erythromycin	>16	>16	≤0.12 – >16	16.1 / 3.3 / 80.6	16.1 / 0.0 / 83.9
Clindamycin	≤0.25	>2	≤0.25 – >2	77.4 / 0.0 / 22.6	77.4 / 0.0 / 22.6
Vancomycin	1	1	0.5 – 2	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Linezolid	1	1	0.5 – 2	100.0 / 0.0 / 0.0	100.0 / 0.0 / 0.0
Tetracycline	≤0.25	>8	≤0.25 – >8	77.4 / 0.0 / 22.6	77.4 / 0.0 / 22.6
Tigecycline[b]	0.06	0.25	≤0.03 – 0.25	100.0 / – / –	100.0 / 0.0 / 0.0
Levofloxacin	>4	>4	≤0.12 – >4	9.7 / 0.0 / 90.3	9.7 / 0.0 / 90.3
Trimethoprim/sulfamethoxazole	≤0.5	≤0.5	≤0.5 – >4	96.8 / 0.0 / 3.2	96.8 / 3.2
Daptomycin	0.25	0.5	0.12 – 0.5	100.0 / – / –	100.0 / 0.0 / 0.0
S. pneumoniae (1,372)					
Ceftaroline	≤0.015	0.12	≤0.015 – 1	99.8 / – / –	99.3 / 0.0 / 0.7
Ceftriaxone	≤0.06	1	≤0.06 – >8	92.4 / 6.0 / 1.6	78.3 / 20.1 / 1.6
Penicillin[c]	≤0.06	2	≤0.06 – 8	92.1 / 6.4 / 1.5	– / – / –
Penicillin[d]	≤0.06	2	≤0.06 – 8	64.1 / 16.9 / 19.0	64.1 / 28.0 / 7.9
Amoxicillin/clavulanate	≤1	2	≤1 – >8	90.0 / 4.8 / 5.2	– / – / –
Cefuroxime	≤0.5	8	≤0.5 – >16	74.9 / 2.1 / 23.0	71.0 / 3.9 / 25.1
Erythromycin	≤0.12	>16	≤0.12 – >16	66.0 / 0.5 / 33.5	66.0 / 0.5 / 33.5
Clindamycin	≤0.25	>2	≤0.25 – >2	76.4 / 0.3 / 23.3	76.7 / 0.0 / 23.3
Levofloxacin	1	1	≤0.12 – >4	99.1 / 0.0 / 0.9	99.1 / 0.0 / 0.9
Trimethoprim/sulfamethoxazole	≤0.5	>4	≤0.5 – >4	67.1 / 12.5 / 20.4	76.2 / 3.4 / 20.4
Tetracycline	0.5	>8	≤0.25 – >8	72.1 / 0.6 / 27.3	71.5 / 0.6 / 27.9

Table 2. *(Cont)*

Organism group (no. tested)/ antimicrobial agent	**MIC_{50}**	**MIC_{90}**	**Range**	**CLSI[a] %S / %I / %R**	**EUCAST[a] %S / %I / %R**
S. pneumoniae, penicillin-resistant (20)					
Ceftaroline	0.25	1	0.25 – 1	85.0 / – / –	55.0 / 0.0 / 45.0
Ceftriaxone	4	>8	1 – >8	5.0 / 25.0 / 70.0	0.0 / 30.0 / 70.0
Amoxicillin/clavulanate	>8	>8	4 – >8	0.0 / 5.0 / 95.0	– / – / –
Cefuroxime	>16	>16	8 – >16	0.0 / 0.0 / 100.0	0.0 / 0.0 / 100.0
Erythromycin	>16	>16	8 – >16	0.0 / 0.0 / 100.0	0.0 / 0.0 / 100.0
Clindamycin	>2	>2	≤0.25 – >2	10.0 / 0.0 / 90.0	10.0 / 0.0 / 90.0
Levofloxacin	1	1	0.5 – >4	90.0 / 0.0 / 10.0	90.0 / 0.0 / 10.0
Trimethoprim/sulfamethoxazole	>4	>4	1 – >4	0.0 / 5.0 / 95.0	5.0 / 0.0 / 95.0
Tetracycline	>8	>8	0.5 – >8	10.0 / 0.0 / 90.0	10.0 /0.0 / 90.0
H. influenzae (681)					
Ceftaroline	≤0.015	0.03	≤0.015 – 0.12	100.0 / – / –	97.7 / 0.0 / 2.3
Amoxicillin/clavulanate	≤1	2	≤1 – 8	99.9 / 0.0 / 0.1	89.9 / 0.0 / 10.1
Ceftriaxone	≤0.06	≤0.06	≤0.06 – 0.12	100.0 / – / –	100.0 / 0.0 / 0.0
Cefuroxime	≤0.5	2	≤0.5 – 8	99.6 / 0.4 / 0.0	78.6 / 16.0 / 5.4
Tetracycline	0.5	0.5	≤0.12 – >16	97.9 / 0.2 / 1.9	97.5 / 0.4 / 2.1
Trimethoprim/sulfamethoxazole	≤0.5	>4	≤0.5 – >4	72.0 / 3.9 / 24.1	72.0 / 1.3 / 26.7
Azithromycin	1	2	≤0.03 – >4	99.6 / – / –	0.9 / 98.7 / 0.4
Clarithromycin	8	8	≤0.12 – >16	92.8 / 6.0 / 1.2	1.9 / 98.1 / 0.0
Levofloxacin	≤0.12	≤0.12	≤0.12 – >4	99.9 / – / –	99.9 / 0.0 / 0.1
H. parainfluenzae (39)					
Ceftaroline	≤0.015	0.06	≤0.015 – 4	– / – / –	– / – / –
Amoxicillin/clavulanate	≤1	≤1	≤1 – 2	100.0 / 0.0 / 0.0	– / – / –
Ceftriaxone	≤0.06	0.12	≤0.06 – 0.5	100.0 / – / –	– / – / –
Cefuroxime	≤0.5	1	≤0.5 – 16	97.4 / 0.0 / 2.6	– / – / –
Tetracycline	0.5	16	0.25 – >16	82.1 / 0.0 / 17.9	– / – / –
Trimethoprim/sulfamethoxazole	≤0.5	>4	≤0.5 – >4	74.4 / 7.7 / 17.9	– / – / –
Azithromycin	1	2	0.12 – 2	100.0 / – / –	– / – / –
Clarithromycin	8	8	1 – >16	92.3 / 5.1 / 2.6	– / – / –
Levofloxacin	≤0.12	≤0.12	≤0.12 – >4	97.4 / – / –	– / – / –

[a]Criteria as published by the CLSI (2013) and EUCAST (2013). [b]USA-FDA breakpoints were applied when available (Tygacil Package Insert, 2012). [c]Criteria as published by the CLSI (2012) for 'Penicillin parenteral (non-meningitis)'. [d]Criteria as published by the CLSI (2012) for 'Penicillin (oral penicillin V)'

Results

- Ceftaroline was very active against *S. aureus* overall ($MIC_{50/90}$, 0.25/1 mg/L; 90.3% susceptible; Tables 1 and 2). When tested against oxacillin (methicillin)-susceptible strains (MSSA), ceftaroline (MIC_{50} and MIC_{90}, 0.25 mg/L) was 16-fold more active than ceftriaxone (MIC_{50} and MIC_{90}, 4 mg/L) and 4- to 8-fold more active than linezolid ($MIC_{50/90}$, 1/2 mg/L). The highest ceftaroline MIC value among MSSA strains was only 0.5 mg/L (Tables 1 and 2).
- Ceftaroline MIC values ranged from 0.5 to 2 mg/L ($MIC_{50/90}$, 1/2 mg/L; 69.4% susceptible) when tested against MRSA (Tables 1 and 2). Ceftaroline was considerably more active than other cephalosporins against MRSA; ceftaroline MIC values were slightly higher (2- to 4-fold) among MRSA compared to MSSA (Tables 1 and 2).
- The overall MRSA rate was 31.6% and MRSA strains exhibited high rates of resistance to erythromycin (80.6 and 83.9% according to CLSI and EUCAST breakpoint criteria, respectively), clindamycin (22.6%) and levofloxacin (90.3% [CLSI and EUCAST]; Table 2).
- Ceftaroline was the most active of all β-lactams tested against *S. pneumoniae* strains ($MIC_{50/90}$, ≤0.015/0.12 mg/L; Tables 1 and 2). The highest ceftaroline MIC value observed was 1 mg/L. A total of 99.3% of isolates were susceptible by EUCAST breakpoint criteria (≤0.25 mg/L) and 99.8% susceptible by CLSI breakpoint criteria (≤0.5 mg/L; M100-S23).
- Ceftaroline activity ($MIC_{50/90}$, 0.25/1 mg/L) against penicillin-resistant *S. pneumoniae* (penicillin MIC ≥8 mg/L, penicillin-resistant by CLSI breakpoint for penicillin parenteral, non-meningitis) was ≥8-fold more active than ceftriaxone ($MIC_{50/90}$, 4/>8 mg/L; 0.0% susceptible [EUCAST criteria]), and amoxicillin/clavulanate ($MIC_{50/90}$, >8/>8 mg/L; 0.0% susceptible [CLSI criteria]; Table 2). Ceftaroline MIC values ranged from 0.25 to 1 mg/L and 55.0% were inhibited at a ceftaroline MIC of ≤0.25 µg/mL (EUCAST breakpoint); 85.0% at MIC of ≤0.5 mg/L (CLSI breakpoint; Table 1).
- The highest ceftaroline MIC value among *H. influenzae* was 0.12 mg/L (0.4%) and ceftaroline activity against *H. influenzae* was not adversely affected by β-lactamase production (Tables 1 and 2). 100.0/97.7% of *H. influenzae* were susceptible to ceftaroline (CLSI/EUCAST) and most comparator agents exhibited good activity (>97% susceptibility, CLSI criteria) against *H. influenzae*, except clarithromycin ($MIC_{50/90}$, 8/8 mg/L; 92.8% susceptibility [CLSI] and 1.9% susceptibility [EUCAST]) and trimethoprim/sulfamethoxazole (TMP/SMX; $MIC_{50/90}$, ≤0.5/>4 mg/L; 72.0% susceptibility [CLSI and EUCAST interpretive criteria]).
- Ceftaroline was highly active against *H. parainfluenzae* ($MIC_{50/90}$, ≤0.015/0.06 mg/L; Tables 1 and 2).

Conclusions

- Ceftaroline demonstrated *in vitro* activity against the leading community-acquired respiratory tract pathogens *S. aureus* (including MRSA), *S. pneumoniae* including penicillin-resistant strains, and *Haemophilus* spp. in this recent (2011) collection of pathogens from EMR.
- The activity of ceftaroline against MDR bacteria including MDR *S. pneumoniae* strains merits further study.
- There is currently insufficient clinical evidence to confirm efficacy of ceftaroline fosamil against CAP due to MRSA.

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