reactions were rash (4), hives (3), anaphylaxis (2), red man syndrome (2), renal failure (2), and general malaise (1). Six patients had at least 1 additional subjective drug allergy. The various infections treated included cellulitis/abscess (8), osteomyelitis (1), and bacteremia (2). Most patients received 1500mg (2 received 1125mg) of dalbavancin in 300-500mL of dextrose 5% in water infused at either 600 or 1000mL/hr via a peripheral (6) or central (4) intravenous line. All patients tolerated the infusion with no adverse events reported and no receipt of premedication before administration.

Conclusion. Dalbavancin may be a reasonable treatment option in vancomycin allergic patients, despite possible cross-sensitivity. Further investigation into cross-sensitivity between vancomycin, dalbavancin, and other glycopeptide class agents is warranted.

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1057. Tebipenem *In vitro* Activity Against a Collection of Pathogens Responsible for Urinary Tract Infections in the US

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Session: P-61. Novel Agents

Background. *Enterobacterales* (ENT)—especially *Escherichia coli* (EC), *Klebsiella pneumoniae* (KPN), and *Proteus mirabilis* (PM)—are widely implicated in urinary tract infections (UTIs). Many oral agents are used to manage UTIs, but their usefulness has been compromised by the increased prevalence of extended-spectrum β-lactamases (ESBL) and presence of co-resistance to trimethoprim-sulfamethoxazole (TMP/SMX) and quinolones. Tebipenem (TBP) is an oral carbapenem in clinical development for treating complicated UTIs and acute pyelonephritis. This study assessed the *in vitro* activity of TBP and comparator agents against ENT responsible for UTIs in the US during 2019-2020.

Methods. A total of 3,576 ENT recovered from urine samples during the 2019-2020 STEWARD Surveillance Program were included in the study. Isolates were collected from medical centers in all 9 US Census Regions and were centrally tested for susceptibility by reference broth microdilution method. MIC interpretation was performed based on CLSI criteria.

Results. EC comprised 65.6% of all ENT pathogens, followed by KPN (14.3%), PM (6.6%), and other species (13.7%). TBP (MIC_{90}, 0.015-0.06 mg/L) and ertapenem (ERT; MIC_{90}, 0.03 mg/L) showed similar MIC_{90} results against ENT, EC, and KPN (Table). Ceftazidime (CAZ; MIC_{90}, 8-16 mg/L) had elevated MIC_{90} values and suboptimal susceptibility results (86.1-89.3%) against ENT, EC, and KPN. The oral agents, cefuroxime, amoxicillin-clavulanate, TMP-SMX, and levofloxacin showed susceptibility rates ranging from 63.1% to 87.1% against ENT, EC, and KPN. TBP ($MIC_{50/90}$, 0.12/0.12 mg/L) inhibited all PM at ≤0.25 mg/L. PM isolates were susceptible to ERT (100.0%), CAZ (98.7%), cefuroxime (94.4%), and amoxicillin/clavulanate (96.6%), whereas susceptibility rates of 71.8-76.8% were noted for TMP-SMX and levofloxacin.

Conclusion. TBP displayed potent activity against ENT UTI pathogens recovered from patients in the US. TBP demonstrated *in vitro* activity against these UTI pathogens similar to that of ERT. In addition, these data showed compromised activity of intravenous and oral agents used for treating UTI. This data supports the development of tebipenem as an oral option for management of UTI in the US.

	MICs50/MIC90 in mg/L (% susceptible; CLSI)						
Organism (no. tested)	Tebipenem[a]	Ertapenem	Ceftazidime	Cefuroxime[a]	A/C	TMP-SMX	Levofloxacin
All (3,567)	0.015-0.06	≤0.008/0.03 (98.5)	0.25/8 (88.1%)	4/>64 (63.5)	4/32 (76.1)	≤0.12/>4 (73.9)	0.06/16 (79.4)
E. coli (2,339)	0.015/0.015	≤0.008/0.03 (99.6)	0.25/8 (89.3)	4/>64 (63.1)	4/16 (80.8)	≤0.12/>4 (69.2)	0.03/16 (75.7)
K. pneumoniae (511)	0.015/0.03	≤0.008/0.03 (96.3)	0.25/16 (86.1)	4/>64 (75.3)	2/16 (86.7)	≤0.12/>4 (79.8)	0.06/1 (87.1)
P. mirabilis (235)	0.12/0.12	0.015/0.015 (100.0)	0.06/0.12 (98.7)	1/4 (94.4)	1/1 (96.6)	≤0.12/>4 (76.8)	0.06/16 (71.8)

A/C, amoxicillin/clavulanate; TMP-SMX, trimethoprim-sulfamethoxazole.
[a] Breakpoint not available.
[b] Percent susceptible based on the oral breakpoint.

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1058. *In Vitro* and *In Vivo* Antibacterial Activity of Cefiderocol against *Burkholderia* spp.

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Session: P-61. Novel Agents

Background. *Burkholderia* spp. is an opportunistic pathogen associated with respiratory infections. Cefiderocol (CFDC), a siderophore cephalosporin approved in US and EU, is active *in vitro* against carbapenem-resistant Gram-negative bacteria including *Burkholderia* spp. This study examined *in vitro* and *in vivo* activity of CFDC against *Burkholderia* spp.

Methods. MICs of CFDC and 13 marketed antibacterial drugs against 462 clinical isolates of *Burkholderia* spp. collected in 2014 - 2019 in 13 countries were determined by broth microdilution method according to CLSI guidelines. Only for CFDC, iron-depleted CAMHB was used. In a rat lung infection model, *B. cepacia* ATCC 25416 (CFDC MIC: ≤ 0.031 µg/mL, MEM MIC: 4 µg/mL) was used. Male CD (SD, immunocompetent, n=4-5) rats were infected by intrabronchial inoculation of the bacterial suspension including 1% nutrient agar. The humanized PK in plasma by administration of CFDC 2 g every 8 h (3-h infusion) and MEM 1 g every 8 h (0.5-h infusion) were recreated via the continuous intravenous infusion for 4 days, and the viable cfu in lungs were counted.

Results. Against 462 strains, including 185 MEM non-susceptible isolates, CFDC showed MIC_{50}/MIC_{90} of ≤ 0.031/1 µg/mL, which was the lowest among the tested antibiotics. Among 185 MEM non-susceptible isolates, 94% of the isolates exhibited ≤ 4 µg/mL of CFDC MIC. In a rat lung infection model, CFDC and MEM showed bactericidal activity with 2.8 and 2.4 $\log_{10}$ CFU/lung decrease compared with non-treated control, respectively. By recreating the humanized PK exposure in this model, 100% and ca.35% of *f*T >MIC of CFDC and MEM in plasma has been achieved, respectively. The bactericidal activities of both compounds vs *B. cepacia* ATCC 25416 would be reasonable because the *f*T >MIC achieved in this model exceeds the target *f*T >MIC (75% for CFDC and 26% for MEM against *Acinetobacter baumannii*, respectively) required to cause 1 $\log_{10}$ reduction in murine thigh infection models[1,2].

1) M. Sabet. 2019. AAC 2) R. Nakamura. 2019. AAC

In vitro activity of CFDC and comparator agents against Burkholderia spp.

Drug	MIC against *Burkholderia* spp. (µg/mL)							
	Total strains				Carbapenem non-susceptible strains*			
	N	MIC range	MIC_{50}	MIC_{90}	N	MIC range	MIC_{50}	MIC_{90}
Cefiderocol	462	≤ 0.03 - > 64	≤ 0.03	1	185	≤ 0.03 - > 64	≤ 0.03	1
Ampicillin-sulbactam	188	≤ 2 - > 64	> 64	> 64	104	4 - > 64	> 64	> 64
Aztreonam-avibactam	110	1 - > 8	4	8	28	2 - > 8	4	8
Cefepime	462	≤ 0.06 - > 16	8	> 16	185	≤ 0.06 - > 16	1	> 64
Ceftazidime-avibactam	462	0.25 - > 16	4	8	185	0.25 - > 16	4	16
Ceftolozane-tazobactam	274	≤ 0.06 - > 64	2	32	81	0.5 - > 64	8	> 64
Ciprofloxacin	462	≤ 0.12 - > 8	1	> 8	185	≤ 0.12 - > 8	2	8
Colistin	462	≤ 0.25 - > 8	> 8	> 8	185	≤ 0.25 - > 8	> 8	> 8
Imipenem-relebactam	188	0.06 - > 16	0.5	4	104	0.25 - > 16	1	4
Meropenem	462	0.12 - > 16	4	16	185	8 - > 16	8	16
Meropenem-vaborbactam	298	0.12 - > 16	1	4	132	0.5 - > 16	2	4
Minocycline	188	≤ 0.25 - > 8	2	> 8	104	0.5 - > 8	2	> 8
Tigecycline	188	≤ 0.12 - > 4	1	> 4	104	0.25 - > 4	2	> 4
Trimethoprim-sulfamethoxazole	188	≤ 0.25 - > 8	1	8	104	≤ 0.25 - > 8	1	8

*: meropenem MIC >= 8 µg/mL

Conclusion. CFDC has potential for treating respiratory tract infections caused by *Burkholderia* spp. In critically ill patients, the recommended dosing regimen achieves 100% of *f*T >MIC of ≤ 4 ug/mL[3].3) N. Kawaguchi. 2021. AAC

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1059. *In vitro* Activity of Exebacase (CF-301) against *Staphylococcus aureus* Causing Bacteremia in the United States, Including Multidrug-resistant Subsets

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Session: P-61. Novel Agents

Background. Exebacase (CF-301) is a lysin (peptidoglycan hydrolase enzyme) with anti-staphylococcal activity. CF-301 is in Phase 3 of clinical development for the treatment of *Staphylococcus aureus* (SA) bacteremia (SAB), including right-sided infective endocarditis (IE), used in addition to standard-of-care antibiotics. CF-301 *in vitro* activity was determined against SA isolates reflecting the Phase 3 target patient SAB population, including IE.

Methods. 666 SA recovered from blood (3% from known IE) of patients hospitalized in 29 centers located in 9 Census regions were included as part of the SENTRY Antimicrobial Surveillance Program for 2020. Identification was confirmed by MALDI-TOF. Susceptibility to 12 comparators used reference broth microdilution (BMD), whereas CF-301 used a modified BMD method with cation-adjusted Mueller-Hinton broth (CAMHB) supplemented with 25% horse serum and 0.5 mM DL-dithiothreitol according to CLSI. MIC interpretation for comparator agents used CLSI criteria, including determination of multidrug-resistant (MDR) phenotype (non-susceptible to ≥3 classes of antibiotics).

Results. Against all SA tested CF-301 had an MIC range of 0.06-1 mg/L, with MIC_{50}, MIC_{90} and modal MIC values of 0.5 mg/L. CF-301 MIC results ($MIC_{50/90}$, 0.5/0.5 mg/L) against methicillin-susceptible (MSSA) and -resistant (MRSA; 38.6% of all SA) SA were identical. Many comparators had activity against MSSA; among drugs indicated for treating SAB caused by MRSA, daptomycin and vancomycin were active (100% susceptible) against all isolates. A total of 62.3% of MRSA isolates were categorized as MDR, and CF-301 showed equal MIC_{50} and MIC_{90} results against MDR ($MIC_{50/90}$, 0.5/0.5 mg/L) and non-MDR ($MIC_{50/90}$, 0.5/0.5 mg/L) populations. Daptomycin and vancomycin were active (100% susceptible) against MDR MRSA isolates.

Conclusion. CF-301 was uniformly active against contemporary SA isolates responsible for bloodstream infections in the US in 2020. CF-301 activity was consistent, regardless of resistance phenotype (MSSA, MRSA, including MDR isolates). Surveillance data presented here further support the clinical development of CF-301 as a promising option for treatment of SAB, including those caused by MDR MRSA isolates.

S. aureus/Phenotype (No. tested)	MIC_{50}/MIC_{90} in mg/L (% susceptible by CLSI M100 criteria)		
	CF-301	VAN	DAP
All (666)	0.5/0.5 (-)	1/1 (100)	0.25/0.5 (100)
MSSA (409)	0.5/0.5 (-)	1/1 (100)	0.25/0.5 (100)
MRSA (257)	0.5/0.5 (-)	1/1 (100)	0.25/0.5 (100)
MDR (160)	0.5/0.5 (-)	1/1 (100)	0.25/0.5 (100)
Non-MDR (97)	0.5/0.5 (-)	1/1 (100)	0.25/0.5 (100)

MSSA, methicillin-susceptible *S. aureus*; MRSA, methicillin-resistant *S. aureus*; MDR, multidrug-resistant; VAN, vancomycin; DAP, daptomycin; (-) No breakpoint available.

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