1081. Antimicrobial Activity of Ceftibuten-Avibactam against Clinical Isolates of *Enterobacterales* Producing Clinically Relevant Beta-Lactamases

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Session: P-61. Novel Agents

Background. Ceftibuten (CTB) is an oral cephalosporin active against *Enterobacterales* approved by the US Food and Drug Administration in 1995. Avibactam (AVI) is a potent inhibitor of extended-spectrum β-lactamases (ESBLs), serine carbapenemases and AmpC that can be administered orally. We evaluated the *in vitro* activity of CTB-AVI against molecularly characterized *Enterobacterales* that produced the most common β-lactamases (BLs) and assessed the AVI concentration to be combined with CTB for susceptibility testing.

Methods. The organism collection (n=71) included *Enterobacterales* producing ESBLs (28; CTX-M, SHV, and TEM), KPCs (8), MBLs (7; NDM, VIM, and IMP), AmpC derepressed (3), plasmid AmpC (3), OXA-48-like (2), and SME (2) as well as isolates with porin alterations (5) and wild-type organisms (13). Resistance mechanisms were evaluated by whole genome sequencing. MIC values were determined by broth microdilution of CTB with fixed concentrations (2, 4, and 8 mg/L) and ratios (1:1 and 2:1) of AVI.

Results. The fixed AVI concentration of 4 mg/L best separated CTB-AVI-susceptible from CTB-AVI-resistant isolates. CTB-AVI (fixed 4 mg/L) was very active against *Enterobacterales* producing ESBL ($MIC_{50/90}$, 0.03/0.12 mg/L), including CTX-M-15 ($MIC_{50/90}$, 0.03/0.12 mg/L), KPC (MIC_{50}, 0.06 mg/L), derepressed AmpC (MIC range, 1-2 mg/L), plasmidic AmpC (MIC range, 0.12-0.5 mg/L), SME (MIC range, 0.06-0.12 mg/L), and OXA-48-like (MIC range, 0.5-4 mg/L), but it showed limited activity against MBL-producers (MIC_{50}, >128 mg/L) and isolates with porin alterations (MIC_{50}, 32 mg/L; Table). CTB was very active against SME-producers (MIC, 0.12-0.25 mg/L) and showed some activity against KPC-producers (MIC_{50}, 4 mg/L; MIC range, 2-16 mg/L) and ESBL-producers ($MIC_{50/90}$, 4/64 mg/L), but it exhibited very limited activity against MBL, AmpC derepressed, plasmidic AmpC, and OXA-48-like producers (MIC_{50} values of 128 to >128 mg/L).

Conclusion. CTB-AVI showed potent *in vitro* activity against *Enterobacterales* producing most clinically relevant BLs, including ESBLs, KPCs, OXA-48-like, and AmpC, for which limited oral treatment options are available. These *in vitro* results support further clinical development of CTB-AVI.

Resistance mechanism	No. and cumulative % of isolates inhibited at CTB-AVI (fixed 4 mg/L) MIC (mg/L) of:												
(no. of isolates)	≤0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	16	32	>128
ESBL (28)	6 (21.4)	8 (50.0)	6 (71.4)	8 (100.0)									
CTX-M-15 (12)	3 (25.0)	4 (58.3)	3 (83.3)	2 (100.0)									
KPC (8)		1 (12.5	3 (50.0)	2 (75.0)	2 (100.0)								
MBL (7)										1 (14.3)			6 (100.0)
AmpC derepressed (3)							1 (33.3)	2 (100.0)					
Plasmid AmpC (3)				2 (66.7)	0 (66.7)	1 (100.0)							
SME (2)			1 (50.0)	1 (100.0)									
OXA-48-like (2)						1 (50.0)	0 (50.0)	0 (50.0)	1 (100.0)				
Porin alterations (5)									1 (20.0)	0 (20.0)	1 (40.0)	1 (60.0)	2 (100.0)
Wild type (13)	8 (61.5)	0 (61.5)	3 (84.6)	0 (84.6)	1 (92.3)	1 (100.0)							

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1082. Real-World Experience with Omadacycline for Nontuberculous Mycobacterial Infections: A Multicenter Evaluation

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Session: P-61. Novel Agents

Background. Nontuberculous mycobacteria (NTM) are resistant to numerous antibiotics and lead to significant morbidity and mortality. Omadacycline (OMC) is an aminomethylcycline antibiotic that is Food and Drug Administration-approved for acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia. Furthermore, OMC has shown *in vitro* activity against NTM. Given that real-world evidence is lacking, our primary objective was to evaluate the clinical success and tolerability of OMC when used for a variety of NTM infections.

Methods. This was a multicenter, retrospective, observational study conducted from January 2020 to June 2021. We included all patients ≥ 18 years of age that received OMC of any indication for *Mycobacterium* spp. The primary outcome was clinical success, defined as a lack of all-cause mortality, lack of persistence or re-emergence of infection during or after therapy, and lack of alteration of OMC. Incidence of adverse effects potentially attributable to OMC and reasons for OMC utilization were also analyzed.

Results. A total of 31 patients were included from 12 geographically distinct academic health systems (median age: 57 (IQR, 45-63) years; 45% male; 81% Caucasian). The majority of isolated pathogens were *Mycobacterium abscessus* complex (84%) and of those with subspeciation performed (54%), the majority (86%) were subsp. *abscessus*. The primary infections were of pulmonary origin (67%) and the median (IQR) duration of OMC therapy was 5.3 (3.2-9.4) months. Most isolates did not have OMC susceptibility conducted (87%), while the majority did for tigecycline (90%). Clinical success was reported in 81% of the population. Most patients were on combination antimicrobial therapy, and 39% of patients reported an adverse effect while on OMC (58% gastrointestinal distress). The majority of patients were prescribed OMC due to ease of administration (61%) and antimicrobial resistance to previous antibiotics (42%).

Conclusion. OMC may be a potential option for the therapy of NTM infections. Prospective, randomized clinical trials are needed to confirm our preliminary findings.

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1083. Phase 1b Results of Pharmacokinetics, Pharmacodynamics, and Safety for LBP-EC01, a CRISPR-Cas3 Enhanced Bacteriophage Cocktail Targeting *Escherichia coli* that Cause Urinary Tract Infections

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Session: P-61. Novel Agents

Background. LBP-EC01 is the first CRISPR-engineered bacteriophage product to successfully complete Phase 1b testing in a clinical program designed to address infections caused by E. coli initially targeting urinary tract infections (UTIs). Thirty-six subjects were enrolled in this randomized, double blind study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of LBP-EC01 in patients with lower urinary tract colonization caused by E. coli.

Methods. N/A

Results. No drug-related Treatment Emergent Adverse Events (TEAEs) were observed. All nondrug related TEAEs were Grade 2 or below and there were no tolerability signals associated with LBP-EC01.A modified ITT (mITT) population was defined to assess PK in subjects treated with LBP-EC01 (n=17). Subjects were removed from the PK analysis who had missing or insufficient colonization at baseline (n=3), were exposed to antibiotics during screening or study conduct (n=3) or exhibited a non-drug related SAE (n=1). Of these subjects, 12 were found to be sensitive to LBP-EC01 and of these, 10 (83%) showed phage amplification. A PD analysis compared the mITT populations of LBP-EC01 vs. placebo (n=6) and showed that the LBP-EC01 arm had a decrease in E. coli that was greatest within 24 hours of initial treatment and remained below baseline across the entire treatment period. The placebo arm showed increased levels of E. coli and higher variability over the treatment period. An average difference of 2-3 log (100x to 1,000x) existed in urine E. coli concentration (CFU/mL) between the LBP-EC01 and placebo arms across the duration of the treatment period.

Conclusion. LBP-EC01 has proved to be safe and well-tolerated in this Phase 1b study of subjects colonized by E. coli. In addition, phage amplification was observed in patients with E. coli isolates sensitive to LBP-EC01, demonstrating a clear proof of mechanism. Finally, the apparent difference in PD effect between LBP-EC01 and placebo which was irrespective of MDR status, provides promise that LBP-EC01 may someday be an excellent option for patients suffering from UTIs caused by E. coli, especially in strains that are resistant to conventional antibiotics.

Disclosures. **Dave ousterout, PhD**, **InceptorBio** (Advisor or Review Panel member, Shareholder)**Locus Biosciences** (Employee, Shareholder)

1084. Comparative Outcomes Among Patients Receiving Varying Daptomycin Dosing Regimens in Hemodialysis

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Session: P-62. PK/PD Studies

Background. Daptomycin (DAP) has become an appealing treatment option for gram-positive infections, which are common in patients receiving hemodialysis (HD), due to frequent access and manipulation. The approved DAP dosing of 4 to 6 mg/kg every 48 hours (q48h) quickly becomes desynchronized from the patient's HD schedule and requires the burden of additional IV access. Previous pharmacokinetic studies have suggested that DAP can be dosed three-times weekly following HD, but no studies have evaluated clinical outcomes of this regimen.

Methods. This was a multi-center, retrospective cohort study across 6 hospitals in the United States. Adult, nonpregnant patients who received HD and DAP between 2015 and 2020 were screened for inclusion. Electronic medical records were reviewed for relevant study data. The primary outcome was clinical and microbiological outcomes among patients who received DAP thrice weekly versus q48h dosing. Microbiological Failure was defined as positive cultures after 7 days and further study definitions are included under Table 3.

Results. Baseline characteristics are summarized in Table 1. Length of stay was similar between both groups at a median of 25 days and patients had a median QPitt score of 0 on admission. The average DAP dose used was 7 mg/kg and 7mg-7mg-9mg on HD days in the q48h dosing and thrice weekly dosing regimens, respectively. The majority of patients had bacteremia and the most commonly isolated bacteria was methicillin-resistant *Staphylococcus aureus*. No differences in clinical outcomes were observed (p=0.87). Microbiological failure was higher among patients who received DAP thrice weekly compared to q48h dosing (69.2% vs 34.8%, p=0.047).

Table 1: Baseline Characteristics

	Every 48 Hour Dosing (n=78)	3-Times Weekly Dosing (n=38)
Age, mean (SD)	60 (13.8)	59 (18.0)
Biological Gender		
Male, n (%)	31 (39.5)	20 (52.6)
Female, n (%)	47 (60.3)	18 (47.4)
Allergies		
Penicillin, n (%)	13 (16.7)	9 (23.7)
Vancomycin, n (%)	8 (10.3)	7 (18.4)
Sulfa Drugs, n (%)	10 (12.8)	2 (5.3)
Fluoroquinolones, n (%)	9 (11.5)	2 (5.3)
No Known Drug Allergies, n (%)	28 (35.9)	14 (36.8)
Comorbidities		
Atrial Fibrillation, n (%)	21 (26.9)	5 (13.2)
Benign Prostatic Hypertension, n (%)	3 (3.8)	2 (5.3)
Cancer, n (%)	5 (6.4)	0 (0)
Coronary Artery Disease, n (%)	18 (23.1)	11 (28.9)
Chronic Obstructive Pulmonary Disease, n (%)	8 (10.3)	0 (0)
Diabetes, n (%)	47 (60.3)	21 (55.3)
Hyperlipidemia, n (%)	18 (23.1)	16 (42.1)
Hypertension, n (%)	59 (75.6)	31 (81.6)
Obesity, n (%)	20 (25.6)	3 (7.9)
None, n (%)	5 (6.4)	0 (0)
Charleson Comorbidity Score, mean (SD)	6 (2.8)	6 (2.0)
Indication for Hemodialysis		
Progressive End Stage Renal Disease, n (%)	57 (73.1)	34 (89.5)
Renal Transplant, n (%)	2 (2.6)	0 (0)
Other, n (%)	19 (24.4)	4 (10.5)

Table 2: Hospitalization Characteristics

	Every 48 Hour Dosing (n=78)	3-Times Weekly Dosing (n=38)
Length of Hospital Stay, median (IQR)	25 (12.3-35.5)	22 (10.75-30.5)
QPitt Criteria on Admission, median (IQR)	0 (0-1)	0 (0-0)
Daptomycin Dosing (mg/kg)		
48-hour intervals, mean (SD)	7 (1.6)	7.2 (1.9)
72-hour intervals, mean (SD)	7 (1.6)	8.9 (2.2)
Total Duration of Antibiotic Therapy (days), median (IQR)	10 (5-20)	16.5 (10-41)
Antibiotic Indication		
Bacteremia, n (%)	25 (32.1)	18 (47.4)
Osteomyelitis, n (%)	11 (14.1)	10 (26.3)
Urinary Tract Infection, n (%)	9 (11.5)	0 (0)
Endocarditis, n (%)	10 (12.8)	3 (7.9)
Cellulitis, n (%)	6 (7.7)	0 (0)
Abscess, n (%)	5 (6.4)	2 (5.3)
Intra-Abdominal Infection, n (%)	2 (2.6)	0 (0)
Other, n (%)	9 (11.5)	5 (13.2)
Appropriate Source Control		
Yes, n (%)	23 (29.5)	16 (42.1)
No, n (%)	11 (14.1)	5 (13.2)
Unknown, n (%)	44 (56.4)	17 (44.7)
Culture Results		
MRSA, n (%)	12 (15.4)	13 (34.2)
MSSA, n (%)	4 (5.1)	1 (2.6)
Vancomycin-Resistant Enterococci, n (%)	11 (14.1)	4 (10.5)
Enterococcus faecium, n (%)	9 (11.5)	4 (10.5)
Enterococcus faecalis, n (%)	5 (6.4)	6 (15.8)
Not Specified, n (%)	11 (14.1)	5 (13.2)