Background. Ceftolozane/tazobactam (TOL-TAZ) is a novel cephalosporin antibiotic combined with a known β-lactamase inhibitor. It has activity against some extended-spectrum β-lactamase (ESBL)-producing Enterobacteriaceae and multidrug-resistant *Pseudomonas aeruginosa* (MDRPA). To date, little experience has been published on outcomes with TOL-TAZ for MDRPA infections in immunocompromised patients.

Methods. This was a retrospective study of adult patients (≥18 years) with an immunocompromising condition (solid-organ transplant; hematologic malignancy; solid tumors; metastatic cancer) at 20 academic medical centers who had microbiologically confirmed MDRPA isolated in culture and received TOL-TAZ for at least 24 hours. 30-day survival, in-hospital mortality, and the rates of microbiologic and clinical cure were assessed.

Results.

Characteristic	Result (*N* = 65)
Immunocompromising condition:	*n*(%)
Solid-organ transplant	35 (53.8)
Solid tumor	20 (30.7)
Leukemia	4 (6.1)
Lymphoma/multiple myeloma	3 (4.6)
Metastatic cancer	3 (4.6)
Male, n(%)	38 (58.4)
Age (median, IQR)	64 (20–87)
Charlson Comorbidity Index (median, IQR)	6 (1–12)
APACHE II score (median, IQR)	20 (4–41)
ICU, n(%)	37(56.9)
Hospital day index infection diagnosed (median, IQR)	17 (0–265)
Hospital day TOL-TAZ started (median, IQR)	19 (0–284)
3grs q8hrs, *n*(%)	23 (35.3)
1.5grs q8hrs, *n*(%)	23 (35.3)
Concomitant IV antibiotics, *n*(%)	15 (23.0)
Aminoglycoside, *n/N*(%)	7/15 (46.7)
Fluoroquinolone, *n/N*(%)	4/15 (26.7)
Polymyxin, *n/N*(%)	3/15 (20)
B-lactam, *n/N*(%)	1/15 (6.6)
TOL-TAZ susceptible isolates, *n/N* (%)	35/37 (94.6)

Outcomes by primary infection

Primary infection	n (%)	30-day survival n/N(%)	Microbiologic cure n/N(%)	Clinical cure n/N(%)
Pneumonia	33 (50.7)	30/33 (90.9)	24/33 (72.7)	28/33 (84.8)
Wound/Bone/Joint	12 (18.4)	8/12 (66.6)	7/12 (58.3)	7/12 (58.3)
UTI	9 (13.8)	7/9 (77.7)	7/9 (77.7)	8/9 (88.8)
Intra-abdominal	7 (10.7)	7/7 (100)	7/7 (100)	4/7 (57.1)
Bloodstream	4 (6.1)	4/4 (100)	4/4 (100)	4/4 (100)

Overall outcomes, n(%)

30-day survival	56 (86.1)
In-hospital mortality	17 (26.1)
Microbiologic cure	49 (75.3)
Clinical cure	51(78.4)

Conclusion. In this study of 65 critically-ill immunocompromised patients, the 30-day survival was 86.1%; clinical cure was78.4% and microbiologic cure 75.3%. TOL-TAZ is a viable option for immunocompromised patients with MDRPA infections.

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2383. *In Vitro* Activity of Ceftolozane–Tazobactam in Comparison With Ceftazidime–Avibactam vs. Antimicrobial Non-Susceptible *Pseudomonas aeruginosa* Clinical Isolates, Including Multidrug-Resistant and Extensively Drug-Resistant Subsets: CANWARD, 2007–2017

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Background. *Pseudomonas aeruginosa* (PA) is an important nosocomial pathogen. Treatment options for infections caused by multidrug-resistant (MDR) and extensively drug-resistant (XDR) isolates remain limited. Ceftolozane-tazobactam (C/T) and ceftazidime–avibactam (CZA) are two newer antimicrobials with antipseudomonal activity. The purpose of this study was to directly compare the *in vitro* activity of C/T and CZA vs. antimicrobial non-susceptible (NS) PA clinical isolates obtained as part of the CANWARD study.

Methods. Annually from 2007 to 2017, sentinel hospitals across Canada submitted blood, respiratory, urine, and wound isolates (consecutive, one per patient/infection site) from patients attending ERs, medical and surgical wards, hospital clinics, and ICUs (CANWARD). Susceptibility testing was performed using broth microdilution (and breakpoints) as described by CLSI. MDR PA were defined as isolates that tested NS to at least one antimicrobial from ≥3 classes. XDR PA were defined as isolates that tested NS to at least one antimicrobial from ≥5 classes.

Results. 4224 PA isolates were obtained as a part of CANWARD. 628 (14.9%) were MDR, and 129 (3.1%) were XDR. The *in vitro* activity of C/T and CZA (plus relevant comparators) is presented below.

	C/T		CZA		Meropenem		Piperacillin–tazobactam	
	MIC_{50}/MIC_{90}	%S	MIC_{50}/MIC_{90}	%S	MIC_{50}/MIC_{90}	%S	MIC_{50}/MIC_{90}	%S
All Isolates (*n* = 4,224)	0.5/2	98.2	2/8	94.1	0.5/8	81.2	4/64	83.3
Amikacin NS (*n* = 330)	1/8	86.4	4/16	84.8	1/32	61.5	8/256	63.9
Ceftazidime NS (*n* = 755)	1/4	90.5	8/16	68.9	4/32	48.2	64/512	21.6
CZA NS (*n* = 248)	2/16	77.8	16/>16	0.0	8/>32	29.4	64/512	17.3
C/T NS (*n* = 78)	16/>64	0.0	16/>16	29.5	8/>32	38.5	256/>512	23.1
Ciprofloxacin NS (*n* = 1,010)	1/4	94.8	4/16	85.3	2/32	56.9	16/256	64.8
Gentamicin NS (n = 823)	1/4	94.3	4/16	88.7	1/16	62.1	8/128	70.5
Meropenem NS (n = 793)	1/4	93.9	4/16	77.9	8/16	0.0	16/256	52.6
Piperacillin–tazobactam NS (*n* = 686)	1/4	91.3	8/16	70.1	4/32	45.2	64/512	0.0
Tobramycin NS (*n* = 283)	1/8	88.0	4/16	83.7	4/32	38.9	16/256	58.0
MDR (*n* = 628)	1/8	89.8	8/>16	69.4	8/32	22.6	64/512	22.0
XDR (*n* = 129)	2/16	78.3	8/>16	55.0	16/>32	0.0	128/512	0.0

Conclusion. The *in vitro* activity of C/T was superior to CZA vs. antimicrobial NS PA clinical isolates (including MDR and XDR isolates) recovered from patients across Canada.

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2384. Multidrug-Resistant Gram-Negative Infections Treated With Ceftolozane–Tazobactam: Impact of Delayed Initiation

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Background. Delayed appropriate antibiotic therapy for multidrug-resistant (MDR) Gram-negative bacterial (GNB) infections has been associated with increased mortality. Ceftolozane-tazobactam (C/T) is a novel antipseudomonal cephalosporin and β-lactamase inhibitor combination with excellent *in vitro* activity against MDR

GNB, however its ability to improve patient outcomes may be attenuated if initiation is delayed or it is reserved for salvage therapy. We sought to determine the impact of delayed C/T initiation on 30-day mortality in patients with MDR GNB infections.

Methods. This was a multicenter, retrospective cohort study including adult patients treated with C/T (≥72 hours) for suspected or confirmed MDR GNB (resistant to ≥1 drug from ≥3 classes) infections between January 2015 and February 2018. Classification and regression tree (CART) analysis was used to determine the time point of C/T initiation from index culture or diagnosis most predictive of 30-day mortality. Clinical characteristics and outcomes were compared between patients receiving early or delayed C/T, defined by the CART time point. Multivariable logistic regression was conducted to determine the independent association between early C/T initiation and 30-day mortality.

Results. A total of 144 patients were included. The median (IQR) age was 61 (49, 71) years with a male (65%) and African American (53%) predominance. The most common source of infection was respiratory (64%) and MDR *Pseudomonas aeruginosa* was isolated from 92% of cultures. A breakpoint in time was identified of 119 hours where 30-day mortality was significantly increased (11.8% vs. 26.2%; $P = 0.032$). Absence of prior infection or colonization with MDR GNB was the only variable independently associated with delayed C/T (*a*OR 3.28, 95% CI 1.53, 7.01). After adjustment for confounding variables, delayed C/T was associated with a > 3-fold increase in 30-day mortality (*a*OR 3.22, 95% CI 1.11, 9.40).

Conclusion. These data suggest that delaying C/T initiation by approximately 5 days substantially increases the risk of mortality in patients with MDR GNB infections, underscoring the importance of early appropriate therapy and the need for incorporation of C/T into automated susceptibility testing panels to support earlier initiation.

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2385. Ceftazidime–Avibactam in Combination With Fosfomycin: A Novel Therapeutic Strategy Against Multidrug-Resistant *Pseudomonas aeruginosa*

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Background. By targeting penicillin binding protein-3, the AmpC β-lactamase, and MurA, another enzyme involved in cell wall synthesis, with the ceftazidime–avibactam–fosfomycin combination, we previously overcame multidrug resistance (MDR) *in vitro* in an archived collection of *Pseudomonas aeruginosa* clinical isolates. Here, we further validate the ceftazidime–avibactam–fosfomycin combination using the MDR *P. aeruginosa* clinical isolate, CL232.

Methods. Whole genome and transcriptome sequencing, checkerboard analysis, and determination of mutation frequency as well as mutation prevention concentration were conducted. In addition, the ceftazidime–avibactam–fosfomycin combination was tested in a neutropenic thigh murine infection model with a high bacterial burden (2×10^7 colony forming units (CFUs)) of MDR *P. aeruginosa* clinical isolate CL232.

Results. Checkerboard analysis revealed slight synergy with fractional inhibitory concentration index of 0.53 for 25–6.25 μg/mL of ceftazidime–avibactam combined with 12.5 μg/mL of fosfomycin. Accordingly, the resistance elements in *P. aeruginosa* CL232 were analyzed via whole-genome sequencing (WGS) and transcriptome sequencing (RNAseq). WGS of CL232 revealed mutations in genes (e.g., *oprD*, *ampR*) that contribute to β-lactam resistance. Moreover, expression of the AmpC β-lactamase and the MexAB-OprM efflux pump were upregulated (~2–6-fold). The potential for the development of ceftazidime–avibactam-fosfomycin resistance was assessed *in vitro*. Fosfomycin alone was found to have a high mutation frequency 1.9×10^{-5}; however, the addition of ceftazidime–avibactam reduced this frequency by 3-logs. In addition, the ceftazidime–avibactam–fosfomycin combination possessed the lowest mutation prevention concentration at 64 mg/L–4 mg/L–64 mg/L. In a neutropenic thigh murine infection model, the ceftazidime–avibactam–fosfomycin combination was found to reduce CFUs by 5–6 logs compared with vehicle-treated mice, while ceftazidime–avibactam and fosfomycin dosed separately decreased CFUs by ~1 log and 2–3 logs, respectively.

Conclusion. The combination of ceftazidime–avibactam–fosfomycin is highly likely to offer patients who suffer from infections with a high bacteria burdens (i.e., pneumonia) a therapeutic hope against MDR *P. aeruginosa*.

Disclosures. **K. M. Papp-Wallace**, F. Hoffmann-La Roche Ltd: Grant Investigator, Research grant. **E. J. Ellis-Grosse**, Zavante Therapeutics, Inc.,: Employee and Shareholder, Salary.

2386. Efficacy of Lefamulin (LEF) vs. Moxifloxacin (MOX) Against Common Pathogens in Adults With Community-Acquired Bacterial Pneumonia (CABP): Results From the Phase 3 Lefamulin Evaluation Against Pneumonia (LEAP 1) Study

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Background. New CABP treatments with targeted activity and improved tolerability are needed. LEF, a novel pleuromutilin antibiotic that binds to a conserved region of the bacterial ribosome, is in development for IV or oral CABP treatment. This Phase 3 clinical study evaluated the efficacy of LEF vs. MOX in adults with CABP.

Methods. In this multicenter, randomized, double-blind study, 551 adult patients with CABP (Patient Outcomes Research Team Risk Class ≥III) were randomized to LEF 150 mg IV Q12 hours ($n = 276$) or MOX 400 mg IV Q24 hours ($n = 275$). After 6 IV doses, qualifying patients could be switched to oral therapy. Adjunctive linezolid was given with MOX for suspected methicillin-resistant *S. aureus*.

Primary outcomes were early clinical response (ECR) in the intent-to-treat (ITT) population (FDA endpoint), and investigator assessment of clinical response (IACR) at test of cure in the modified ITT (mITT) and clinically evaluable (CE-TOC) populations (co-primary EMA endpoints). The microITT population included all patients with a baseline CABP pathogen detected by respiratory tract or blood culture, urinary antigen test, serology, and real-time PCR from sputum, oropharyngeal and nasopharyngeal swabs. The microITT2 population included patients with a CABP pathogen detected by methods excluding PCR. Confirmatory identification and susceptibility testing of isolates, serology, and PCR were performed by a central laboratory.

Results. LEF was noninferior to MOX for ECR and IACR (LEF 87.3% [ITT], 81.7% [mITT], 86.9% [CE-TOC]; MOX 90.2% [ITT], 84.2% [mITT], 89.4% [CE-TOC]). The most common pathogen identified was *S. pneumoniae*. In the microITT population ($n = 159$ per arm), LEF and MOX demonstrated similar ECR and IACR rates (figure). LEF was efficacious against *S. pneumoniae* (including resistant phenotypes), *H. influenzae, M. catarrhalis, S. aureus*, and atypical pathogens. In the microITT2 population, response rates remained similar across baseline pathogens but showed more variation likely due to smaller sample sizes.

Conclusion. In this first Phase 3 clinical trial, LEF showed similar efficacy to MOX against the most commonly identified CABP pathogens. LEF demonstrates promise as a targeted monotherapy for the treatment of CABP in adults.

Efficiency of Lefamulin and Moxifloxacin Against Community-Acquired Bacterial Pneumonia Pathogens

	ECR				IACR			
	Lefamulin		Moxifloxacin		Lefamulin		Moxifloxacin	
Baseline pathogen, rate* (n/N)	microITT	microITT2	microITT	microITT2	microITT	microITT2	microITT	microITT2
Streptococcus pneumoniae (SP)	**88.2%** (82/93)	**85.7%** (36/42)	**93.8%** (91/97)	**88.6%** (39/44)	**84.9%** (79/93)	**81.0%** (34/42)	**87.6%** (85/97)	**86.4%** (38/44)
Multidrug-Resistant SP (MDRSP)	– (6/6)	– (6/6)	– (5/6)	– (5/6)	– (6/6)	– (6/6)	– (4/6)	– (4/6)
Staphylococcus aureus (SA)	– (10/10)	– (7/7)	– (4/4)	– (3/3)	– (8/10)	– (6/7)	– (4/4)	– (3/3)
Methicillin-Susceptible SA (MSSA)	– (7/7)	– (7/7)	– (3/3)	– (3/3)	– (6/7)	– (6/7)	– (3/3)	– **(3/3)**
Haemophilus influenzae	**92.2%** (47/51)	– (6/6)	**94.7%** (54/57)	– (5/6)	**84.3%** (43/51)	– **(5/6)**	**84.2%** (48/57)	– (6/6)
Moraxella catarrhalis	**92.0%** (23/25)	– (0/1)	**100%** (11/11)	– (1/1)	**80.0%** (20/25)	– (0/1)	**100%** (11/11)	– (1/1)
Mycoplasma pneumoniae	**84.2%** (16/19)	**92.3%** (12/13)	**90.0%** (18/20)	**91.7%** (11/12)	**84.2%** (16/19)	**84.6%** (11/13)	**95.0%** (19/20)	**91.7%** (11/12)
Chlamydophila pneumoniae	**90.9%** (10/11)	– (8/9)	**94.7%** (18/19)	**93.3%** (14/15)	**72.7%** **(8/11)**	– (7/9)	**68.4%** (13/19)	**73.3%** (11/15)
Legionella pneumophila	**88.9%** (16/18)	**88.2%** (15/17)	**85.7%** (12/14)	**85.7%** (12/14)	**77.8%** (14/18)	**82.4%** (14/17)	**78.6%** (11/14)	**78.6%** (11/14)

*Number of patients in each microITT treatment group = 159 for lefamulin and moxifloxacin ± linezolid; Number of patients in each microITT2 treatment group = 92 for lefamulin and 85 for moxifloxacin ± linezolid; n/N = patients with a response of success / patients with a specific baseline pathogen. ECR=early clinical response; IACR=investigator assessment of clinical response; microITT=patients in ITT population with ≥1 baseline CABP pathogen; microITT2=patients in ITT population with ≥1 baseline CABP pathogen confirmed by methods excluding PCR.

Disclosures. **T. File**, BioMerieux: Scientific Advisor, Consulting fee. Curetis: Scientific Advisor, Consulting fee. Melinta: Scientific Advisor, Consulting fee. Merck: Scientific Advisor, Consulting fee. MotifBio: Scientific Advisor, Consulting fee. Nabriva: Investigator and Scientific Advisor, Consulting fee and Research grant. Pfizer: Scientific Advisor, Consulting fee. Paratek: Scientific Advisor, Consulting fee. **L. Goldberg**, Nabriva: Employee, Employee Stock Options and Salary. **S. Paukner**, Nabriva: Employee and Shareholder, Salary. **A. Das**, Achaogen: Consultant, Consulting fee. Cempra: Consultant, Consulting fee. Contrafect: Consultant, Consulting fee. Paratek: Consultant, Consulting fee. Tetraphase: Consultant, Consulting fee. Wockhardt: Consultant, Consulting fee. Theravance: Consultant, Consulting fee. Zavante: Consultant, Consulting fee. UTILITY: Consultant, Consulting fee. **S. P. Gelone**, Nabriva Therapeutics: Employee, Equity, Shareholder and Salary. Achaogen: Shareholder, Equity, Shareholder. **J. Saviski**, Nabrica Therapeutics, plc: Employee, Salary. **C. Sweeney**, Nabriva: Employee, employee stock options and Salary. **E.**