Nuovi inibitori delle betalattamasi

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Conflicts of interest

- Investigator-initiated grants from Pfizer, Shionogi, Gilead Italia, bioMérieux, Tillotts Pharma, Menarini

- Fees for speaker/advisor from Pfizer, Tillotts Pharma, bioMérieux, Menarini, Advanz Pharma

Cefepime-enmetazobactam (AAI101)

- Enmetazobactam = penicillanic acid sulfone BLI (no intrinsic activity against GNB)

- *In vitro* activity against ESBL, AmpC, and some OXA producers
- Limited activity against KPC and MBL producers

Papp-Wallace KM, et al. Antimicrob Agents Chemother 2019; 63:e00105-19.
Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20.

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Cefepime-enmetazobactam (AAI101)

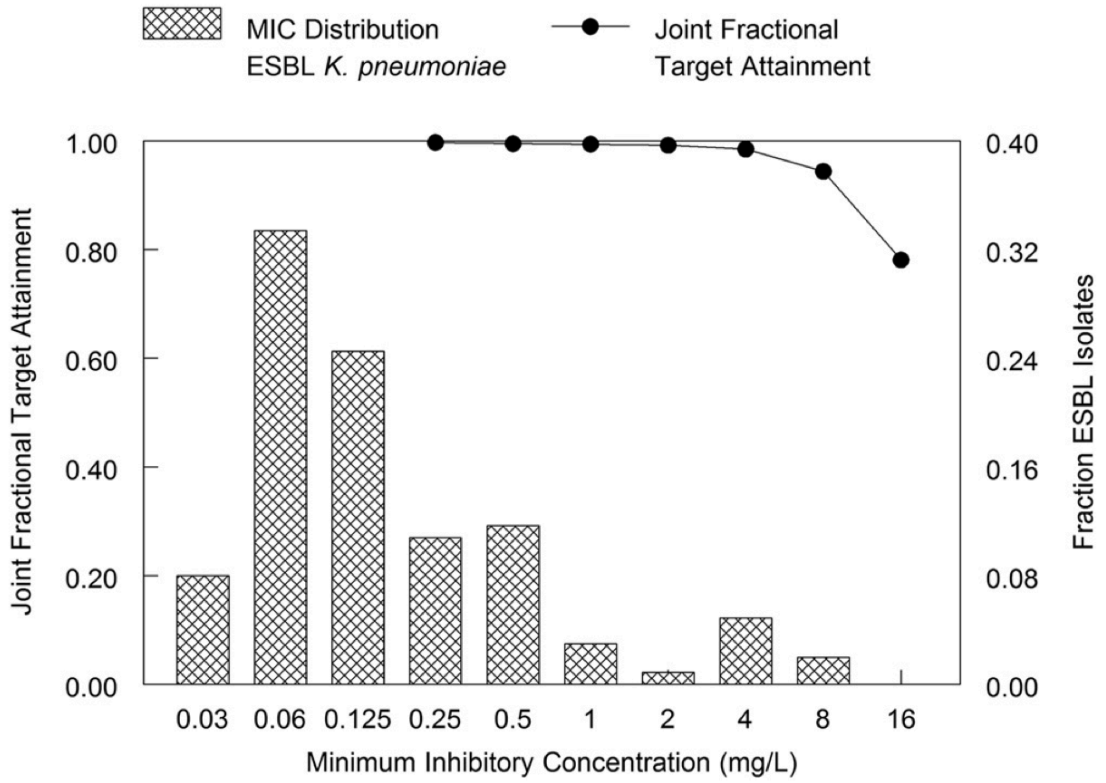


FIG 5 Probability of target attainment in ELF (solid circles) plotted with the distribution of MIC values for cefepime-enmetazobactam against 102 ESBL-producing *Klebsiella pneumoniae* isolates, represented by solid squares. The pharmacodynamic targets used to define success were determined from a preclinical murine model of pneumonia using a variety of *Klebsiella pneumoniae* strains as the challenge organisms.

DAS S, et al. Antimicrob Agents Chemother 2020 Dec 16;65(1):e01468-20.

Cefepime-enmetazobactam (AAI101)

- Phase 2 study in patients with UTI
- 45 patients
- Cefepime/AAI101: MR 83.3% (20/24) and CR 95.8% (23/24)
- Cefepime: MR 73.3% (11/15) and CR 93.3% (14/15)

Carmeli Y, et al. Open Forum Infect Dis. 2019 Oct; 6(Suppl 2): S539.

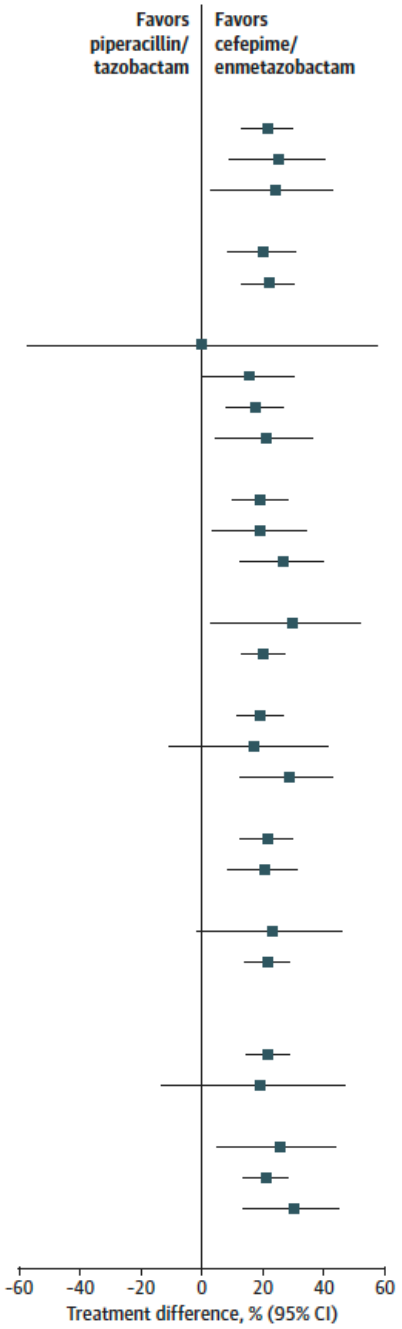
Cefepime-enmetazobactam (AAI101)

- Phase 3 study in patients with cUTI/AP (ALLIUM)
- 1034 patients (The primary analysis set included 678 patients who received at least 1 dose of treatment and had a gram-negative bacterium that was not resistant to either treatment)
- Cefepime/AAI101: success 79.1%
- Piperacillin/tazobactam: success 58.9%
- Adjusted difference, 21.2% (95% CI 14.3-27.9)

Kaye KS et al. JAMA 2022;328(13):1304-1314

Figure 2. Subgroup Analyses in the Primary Analysis Set

Subgroup	No./total (%) Cefepime/ enmetazobactam (n = 345)	Piperacillin/ tazobactam (n = 333)	Treatment difference, % (95% CI)
Age, y			
<65	172/209 (82.3)	137/220 (62.3)	21.5 (12.9 to 29.6)
65 to <75	65/85 (76.5)	36/70 (51.4)	25.3 (9.2 to 40.2)
≥75	36/51 (70.6)	23/43 (53.5)	24.0 (2.8 to 43.0)
Sex			
Male	114/144 (79.2)	74/127 (58.3)	20.1 (8.7 to 30.8)
Female	159/201 (79.1)	122/206 (59.2)	21.9 (12.9 to 30.4)
Baseline eGFR group, mL/min/1.73 m^2			
<30	1/2 (50.0)	1/5 (20.0)	0.0 (-57.3 to 57.3)
30-59	59/79 (74.7)	43/75 (57.3)	15.6 (0.1 to 30.2)
60-89	151/187 (80.7)	107/166 (64.5)	17.5 (8.0 to 26.8)
≥90	50/63 (79.4)	39/66 (59.1)	21.1 (4.4 to 36.2)
Infection type			
Acute pyelonephritis	144/171 (84.2)	115/178 (64.6)	19.3 (10.1 to 28.0)
Complicated UTI with removable source of infection	53/75 (70.7)	39/73 (53.4)	19.3 (3.4 to 34.1)
Complicated UTI without removable source of infection	76/99 (76.8)	42/82 (51.2)	26.7 (12.6 to 39.6)
Prior antibiotic therapy			
Short-acting antibiotic up to 24 h	23/25 (92.0)	14/23 (60.9)	29.8 (3.0 to 52.1)
None	250/320 (78.1)	182/310 (58.7)	20.3 (13.1 to 27.3)
Region			
Eastern Europe	197/238 (82.8)	153/240 (63.8)	19.3 (11.4 to 26.9)
Americas	17/22 (77.3)	13/22 (59.1)	16.9 (-10.7 to 41.3)
Other countries	59/85 (69.4)	30/71 (42.3)	28.7 (12.7 to 42.8)
Baseline Charlson Comorbidity Index score			
<3	163/198 (82.3)	126/205 (61.5)	21.5 (12.6 to 29.8)
>3	109/145 (75.2)	69/125 (55.2)	20.4 (8.7 to 31.4)
Presence of concurrent bacteremia at baseline			
Yes	27/38 (71.1)	14/28 (50.0)	23.3 (-1.5 to 45.9)
No	246/307 (80.1)	182/305 (59.7)	21.5 (14.2 to 28.5)
Race			
Black or African American	0/1	0	Not determined
White	260/327 (79.5)	186/316 (58.9)	21.6 (14.5 to 28.5)
Other (not including African descent)[a]	13/17 (76.5)	10/17 (58.8)	19.2 (-13.4 to 46.9)
Diabetes at baseline			
Yes	41/55 (74.5)	19/41 (46.3)	25.6 (4.8 to 44.1)
No	232/290 (80.0)	177/292 (60.6)	20.9 (13.4 to 28.1)
Enterobacterales baseline pathogen, ESBL-producing	56/76 (73.7)	34/66 (51.5)	30.2 (13.4 to 45.1)



Kaye KS et al. JAMA 2022;328(13):1304-1314

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Cefepime-enmetazobactam (AAI101)

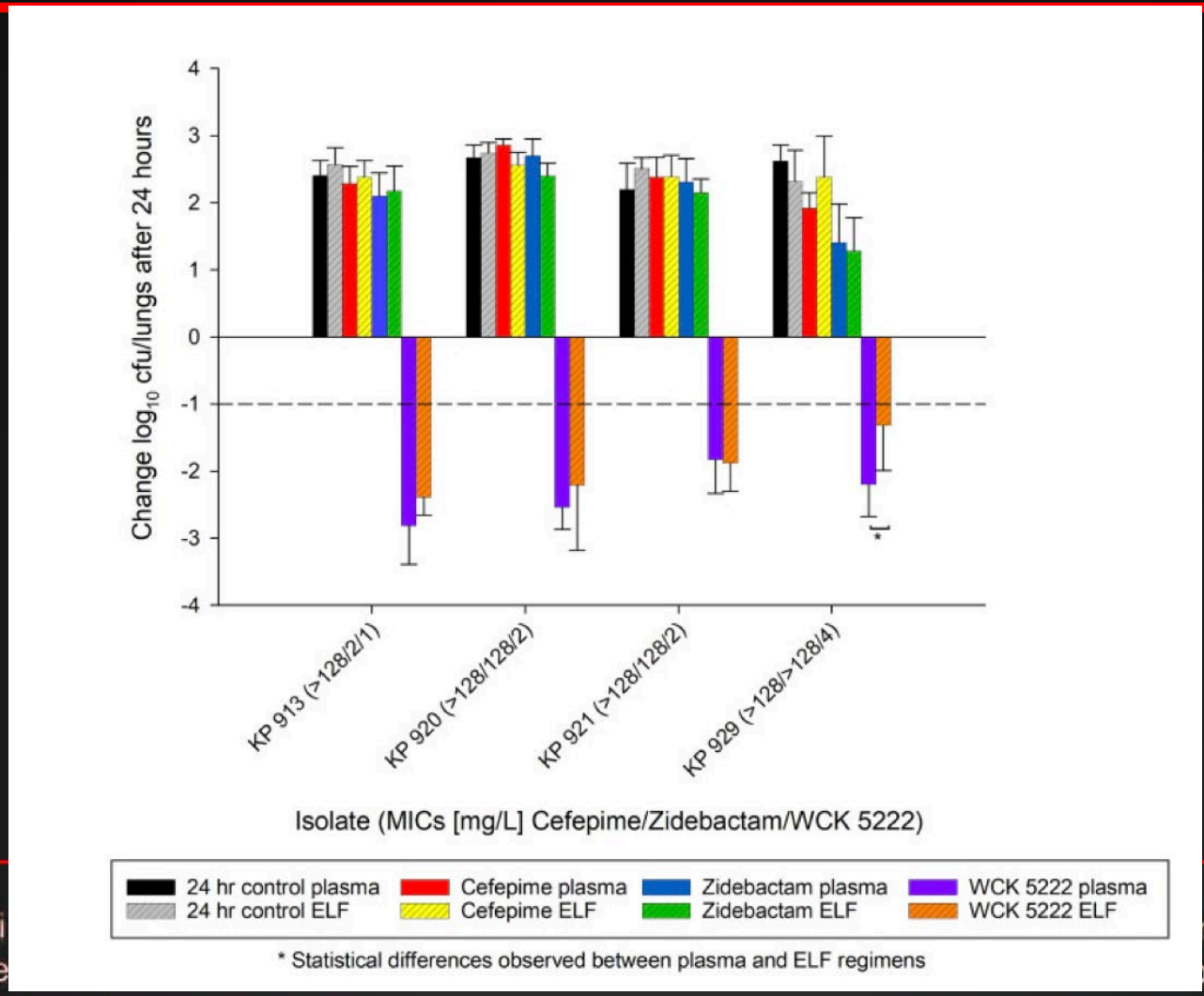
- Approved by FDA for cUTI and AP by designated susceptible organisms (*E. coli, K. pneumoniae, P. aeruginosa, P. mirabilis*, and *Enterobacter cloacae* complex)
- Approved by EMA for cUTI, AP, HAP, and VAP in adults (and of bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above)
- EMA justified the approval of cefepime/enmetazobactam for the treatment of HAP and VAP on the basis of the experience with cefepime alone and pharmacokinetic/pharmacodynamic (PK/PD) analyses for enmetazobactam (e.g., lung penetration similar to cefepime according to data in healthy volunteers)

Cefepime-zidebactam (WCK 5107)

- Zidebactam = non-beta-lactam BLI (and BL enhancer) that inhibits class A carbapenemases, MBL, and OXA-48
- Acitivity against Kp with defective OmpK35/36 porins
- Also active against activity against *P. aeruginosa* with AmpC overexpression and MBL
- Moderate activity against *A. baumannii* OXA-23/24/58

Avery LM, et al. Int J Antimicrob Agents 2020; 55:105863; Joshi P, et al. Diagn Microbiol Infect Dis 2021 Oct;101(2):115481
Thomson KS, et al. Antibiotics (Basel) 2019; 8:32; Khan Z, et al. J Antimicrob Chemother 2020; 74:2938 –2942.
Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20.

Cefepime-zidebactam (WCK 5107)



Lasko MJ, et al. J Antimicrob Chemother 2021 Aug 12;76(9):2310-2316

Cefepime-zidebactam (WCK 5107)

- Phase 3 ongoing (NCT04979806)
- Cefepime/zidebactam vs. meropenem for cUTI/AP
- Estimated enrollment: 504 patients
- Primary outcome: success at TOC

ClinicalTrials.gov Identifier: NCT04979806

Dubey *et al. Annals of Clinical Microbiology and Antimicrobials* (2023) 22:55
https://doi.org/10.1186/s12941-023-00606-x

Annals of Clinical Microbiology and Antimicrobials

BRIEF REPORT **Open Access**

Compassionate use of a novel β-lactam enhancer-based investigational antibiotic cefepime/zidebactam (WCK 5222) for the treatment of extensively-drug-resistant NDM-expressing *Pseudomonas aeruginosa* infection in an intra-abdominal infection-induced sepsis patient: a case report

European Journal of Clinical Microbiology & Infectious Diseases
https://doi.org/10.1007/s10096-024-04791-1

BRIEF REPORT

Successful treatment of sino-pulmonary infection & skull base osteomyelitis caused by New Delhi metallo-β-lactamase-producing *Pseudomonas aeruginosa* in a renal transplant recipient by using an investigational antibiotic cefepime/zidebactam (WCK 5222)

Rajeev Soman[1,2] · Rasika Sirsat[3] · Ayesha Sunavala[4] · Neha Punatar[3] · Jugal Mehta[3] · Camilla Rodrigues[5] · Balaji Veeraraghavan[6]

Successful Use of Cefepime-Zidebactam (WCK 5222) as a Salvage Therapy for the Treatment of Disseminated Extensively Drug-Resistant New Delhi Metallo-β-Lactamase-Producing *Pseudomonas aeruginosa* Infection in an Adult Patient with Acute T-Cell Leukemia

Praveen Kumar Tirlangi,[a] Bala Saheb Wanve,[b] Ramakanth Reddy Dubbudu,[c] Boorgula Sushma Yadav,[d] L. Siva Kumar,[e] Anand Gupta,[e] Racha Amarthya Sree,[f] Hari Priya Reddy Challa,[g] P. Naveen Reddy[h]

AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy®
August 2023 Volume 67 Issue 8
10.1128/aac.00500-23

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Cefepime-taniborbactam (VNRX-5133)

- Taniborbactam = boronic-acid-containing BLI

- *In vitro* activity against producers of class A, B (not IMP) and D carbapenemases
- Active against some CRPA and some KPC-3-producing CAZ-AVI resistant *Enterobacterales*

Hamrick JC et al. Antimicrob Agents Chemother 2019; 64:e01963-19. Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20. Daigle D, et al. Open Forum Infect Dis 2018; 5:S419 –S420

Cefepime-taniborbactam (VNRX-5133)

- Phase 3 (CERTAIN-1)
- Cefepime-taniborbactam vs. meropenem for cUTI/AP
- Primary outcome: composite microbiological eradication and clinical success in the microITT population (436 patients)
- Composite success achieved in 70.6% (FTB) and 58.0% (MEM)
- Treatment difference 12.6%; 95% CI, 3.1 to 22.2

Wagenlehner FM, et al. N Engl J Med 2024;390:611-22.

Cefepime-taniborbactam (VNRX-5133)

Table 2. Primary and Secondary Efficacy Outcomes.*

Outcome, Population, and Time of Assessment	Cefepime–Taniborbactam	Meropenem	Treatment Difference (95% CI)
	no./total no. of patients (%)		*percentage points*
Microbiologic intention-to-treat population			
Primary outcome†			
Composite success at test of cure	207/293 (70.6)	83/143 (58.0)	12.6 (3.1 to 22.2)‡
Microbiologic§	229/293 (78.2)	95/143 (66.4)	11.7 (2.9 to 21.0)
Clinical¶	251/293 (85.7)	116/143 (81.1)	4.5 (–2.6 to 12.6)
Secondary outcome‖			
Composite success at end of treatment	261/293 (89.1)	123/143 (86.0)	3.1 (–3.2 to 10.4)
Microbiologic§	284/293 (96.9)	139/143 (97.2)	–0.3 (–3.5 to 4.1)
Clinical¶	265/293 (90.4)	127/143 (88.8)	1.6 (–4.1 to 8.5)
Composite success at late follow-up	187/293 (63.8)	74/143 (51.7)	12.1 (2.2 to 21.9)
Microbiologic§	207/293 (70.6)	90/143 (62.9)	7.7 (–1.6 to 17.3)
Clinical¶	238/293 (81.2)	102/143 (71.3)	9.9 (1.5 to 18.8)
Extended microbiologic intention-to-treat population			
Secondary outcome			
Composite success at test of cure	216/305 (70.8)	86/147 (58.5)	12.3 (3.0 to 21.8)
Microbiologic§	238/305 (78.0)	98/147 (66.7)	11.4 (2.7 to 20.5)
Clinical¶	262/305 (85.9)	119/147 (81.0)	4.9 (–2.1 to 12.9)

Nacubactam

- Nacubactam = non-BL BLI (and BL enhancer)
- First proposed in combination with meropenem
- Active against class A, C, and some B and D beta-lactamases
- *In vitro* activity against ESBL, KPC, NDM, and OXA producing isolates
- Active against some CRPA and against some KPC-3-producing CAZ-AVI resistant *Enterobacterales*

Mushtaq S. J Antimicrob Chemother 2019; 74:953–960. Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20.
Asempa TE, et al. Int J Antimicrob Agents 2020; 55:105838. Monogue ML, et al. Antimicrob Agents Chemother 2018; 62:e02596-17.

Cefepime-nacubactam e aztreonam-nacubactam

- Efficacy and Safety of Cefepime/Nacubactam or Aztreonam/Nacubactam Compared to Imipenem/Cilastatin in Subjects With Complicated Urinary Tract Infections or Acute Uncomplicated Pyelonephritis (INTEGRAL-1) - NCT05887908
- Efficacy and Safety of Cefepime/Nacubactam and Aztreonam/Nacubactam Versus Best Available Therapy for Adults With Infection Due to Carbapenem Resistant Enterobacterales (INTEGRAL-2) - NCT05905055

Sulbactam-durlobactam (ETX2514)

- Durlobactam = non-BL BLI (and BL enhancer)

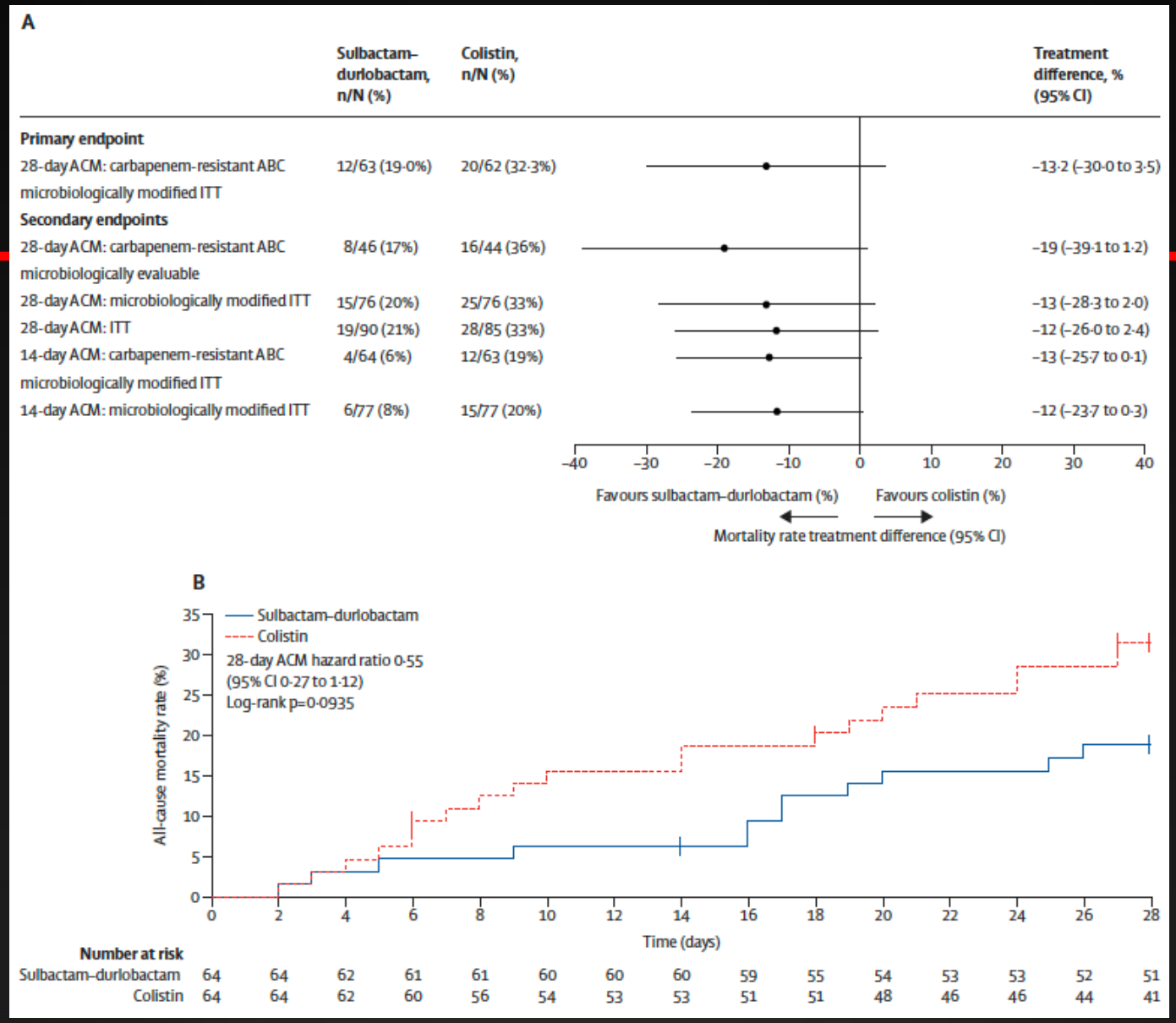
- Active against class A, C, and D beta-lactamases
- *In vitro* activity against CRAB

Durand-Reville TF, et al. Nat Microbiol 2017; 2:17104 Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20.
McLeod SM, et al. 2020; Antimicrob Agents Chemother 64:e02534-19.

Sulbactam-durlobactam (ETX2514)

- Phase 3 study in patients with *Acinetobacter* infections (ATTACK)
- 125 patients with infection due to CRAB included in primary analysis
- Primary endpoint: 28-day all-cause mortality
- Imipenem/cilastatin in both arms
- Sulbactam/durlobactam: 19.0% (12/63)
- Colistin: 32.3% (20/62)
- Treatment difference -13.2% (95% CI -3.0 to 3.5)

Kaye KS et al. Lancet Infect Dis 2023 May 11;S1473-3099(23)00184-6



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Kaye KS et al. Lancet Infect Dis 2023 May 11;S1473-3099(23)00184-6

JAC Antimicrob Resist
https://doi.org/10.1093/jacamr/dlad078

JAC-Antimicrobial Resistance

Salvage therapy with sulbactam/durlobactam against cefiderocol-resistant *Acinetobacter baumannii* in a critically ill burn patient: clinical challenges and molecular characterization

Giusy Tiseo [1], Cesira Giordano[2], Alessandro Leonildi[2], Niccolò Riccardi[1], Valentina Galfo[1], Federica Limongi[3], Manuela Nicastro[3], Simona Barnini[2] and Marco Falcone [1]*

[1]*Infectious Diseases Unit, Department of Clinical and Experimental Medicine, Azienda Ospedaliero Universitaria Pisana, University of Pisa, Pisa, Italy;* [2]*Microbiology Unit, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy;* [3]*Department of Anaesthesia and Critical Care Medicine, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy*

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Open Forum Infectious Diseases

NOVEL ID CASES

Novel Combination Therapy for Extensively Drug-Resistant *Acinetobacter baumannii* Necrotizing Pneumonia Complicated by Empyema: A Case Report

Dana J. Holger,[1] Ashlan J. Kunz Coyne,[1] Jing J. Zhao,[2] Avnish Sandhu,[3,4] Hossein Salimnia,[5] and Michael J. Rybak[1,4]

[1]Anti-Infective Research Laboratory, Department of Pharmacy Practice, Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, Michigan, USA, [2]Department of Pharmacy, Harper University Hospital, Detroit Medical Center, Detroit, Michigan, USA, [3]Detroit Receiving Hospital, Detroit Medical Center, Detroit, Michigan, USA, [4]Division of Infectious Diseases, Department of Medicine, Wayne State University, Detroit, Michigan, USA, and [5]Detroit Medical Center University Laboratories, Detroit, Michigan, USA

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https://doi.org/10.1093/ofid/ofac092

Imipenem/funobactam

- Funobactam = diazabicyclooctane BLI active against class A, C, and D β-lactamases, including KPC-type and OXA-48 carbapenemases in Enterobacterales, and OXA-23 and OXA-24 carbapenemases in *A. baumannii*

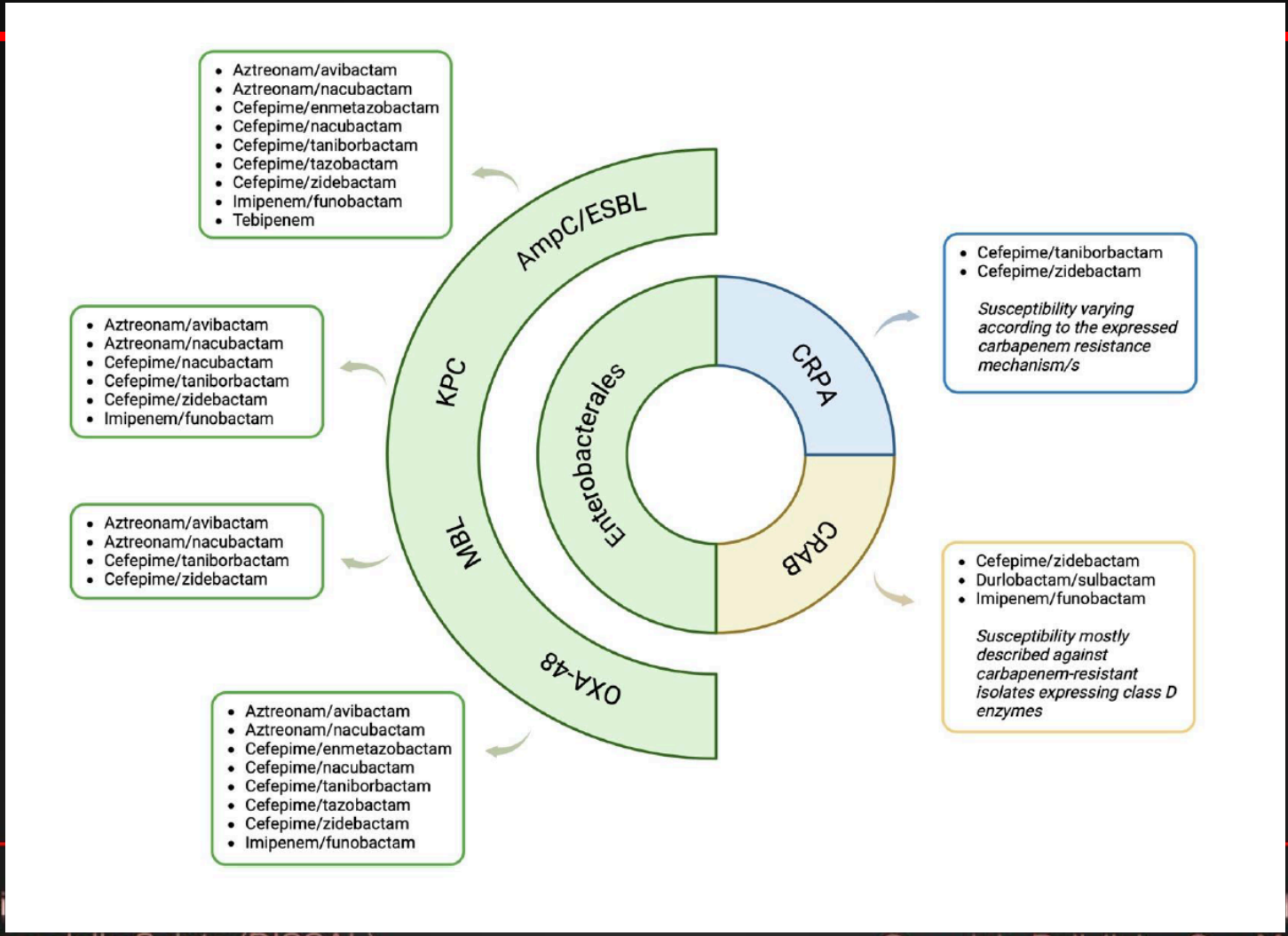
Li Y, et al. Journal of global antimicrobial resistance. 2022 Dec;31:1-9
Fratoni AJ, et al. J Antimicrob Chemother. 2023 Sep 5;78(9):2343-2353.

Imipenem/funobactam

- Phase-3 RCT vs. meropenem for cUTI/AP in adults estimated to be completed around December 2025

- Phase-3 RCT vs. imipenem for HAP/VAP in adults estimated to be completed around December 2025

Activity according to *in vitro* studies



Bassetti M, et al. Expert Rev Anti Infect Ther 2024. doi: 10.1080/14787210.2024.2407068

Cefpodoxime proxetil-ETX0282

- ETX0282 = prodrug of the BLI ETX1317

- *In vitro* activity against ESBL and KPC producers
- Active against KPC-3 producers resistant to CAZ-AVI

Shapiro AB, et al. ACS Infect Dis. 2021 Jan 8;7(1):79-87
Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20.

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Ceftibuten-Ledaborbactam (VNRX 7145)

- VNRX 7145 = boronic-acid-containing BLI
- Active against ESBL, AmpC, KPC, and OXA-48 producing *Enterobacterales*

Karlowsky JA, et al. Antimicrob Agents Chemother 2021. doi: 10.1128/AAC.01304-21
Karaiskos I, et al. Expert Rev Anti Infect Ther 2021. doi: 10.1080/14787210.2021.1935237
Karlowsky JA, et al. Antimicrob Agents Chemother 2022 Nov 15;66(11):e0093422

Xeruborbactam (QPX7728)

- Xeruborbactam = boronic-acid-containing BLI
- Evaluated in vitro in combinations with various BL
- Active against class A, B, C, and D beta-lactamases
- *In vitro* activity against CRPA and CRAB
- In phase I with cefiderocol and ceftibuten

Giacobbe DR, Bassetti M. Future Microbiol 2022 Apr;17:393-396.
Lomovskaya O, et al. Open Forum Infect Dis 2019; 6 Suppl 2):S310 –S311. Yahav D, et al. Clin Microbiol Rev 2021; 34:e00115-20.
Castanheira M, et al. 2019; Open Forum Infect Dis 6 (Suppl 2):S309 –S309.

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Activity according to *in vitro* studies

	ESBL	KPC	MBL	OXA-48	CRPA	CRAB
Cefepime-enmetazobactam	+	-	-	+	-	-
Cefepime-zidebactam	+	+	+	+	+/-	+/-
Cefepime-taniborbactam	+	+	+/-	+	+/-	-
Cefpodoxime proxetil-ETX0282	+	+	-	+	-	-
Ceftibuten-Ledaborbactam	+	+	-	+	-	-
Nacubactam combinations	+	+	+	+	+/-	-
Durlobactam/sulbactam	-	-	-	-	-	+
Aztreonam/avibactam	+	+	+	+	+/-	-
Cefiderocol/Xeruborbactam Ceftibuten/Xeruborbactam	+	+	+	+	+	+

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J Antimicrob Chemother 2023; **78**: 2505–2514
https://doi.org/10.1093/jac/dkad262 Advance Access publication 22 August 2023

Journal of Antimicrobial Chemotherapy

Mortality in KPC-producing *Klebsiella pneumoniae* bloodstream infections: a changing landscape

Daniele Roberto Giacobbe[1,2*], Cristina Marelli[2], Greta Cattardico[1,2], Chiara Fanelli[2,3], Alessio Signori[4], Gabriele Di Meco[2], Vincenzo Di Pilato[5], Malgorzata Mikulska[1,2], Maria Mazzitelli[6], Anna Maria Cattelan[6,7], Carlo Pallotto[8], Daniela Francisci[8], Alessandra Calabresi[9], Andrea Lombardi[10,11], Andrea Gori[11,12], Valerio Del Bono[13], Chiara Aldieri[13], Angela Raffaella Losito[14], Francesca Raffaelli[14], Andrea Cortegiani[15,16], Marta Milazzo[15], Filippo Del Puente[17], Emanuele Pontali[17], Francesco Giuseppe De Rosa[18,19], Silvia Corcione[18], Alessandra Mularoni[20], Giovanna Russelli[20], Mauro Giacomini[21], Flavia Badalucco Ciotta[22], Chiara Oltolini[22], Francesco Saverio Serino[23], Elena Momesso[24], Michele Spinicci[25,26], Lucia Graziani[25], Carlo Torti[27,28], Enrico Maria Trecarichi[27,28], Marco Merli[29], Federico D'Amico[29], Anna Marchese[5,30], Antonio Vena[1,2] and Matteo Bassetti[1,2]†; on behalf of the CARBANEW study group

Infect Dis Ther (2024) 13:1929–1948
https://doi.org/10.1007/s40121-024-01016-y

Check for updates

ORIGINAL RESEARCH

Use of Cefiderocol in Adult Patients: Descriptive Analysis from a Prospective, Multicenter, Cohort Study

Daniele Roberto Giacobbe · Laura Labate · Chiara Russo Artimagnella · Cristina Marelli · Alessio Signori · Vincenzo Di Pilato · Chiara Aldieri · Alessandra Bandera · Federica Briano · Bruno Cacopardo · Alessandra Calabresi · Federico Capra Marzani · Anna Carretta · Annamaria Cattelan · Luca Ceccarelli · Giovanni Cenderello · Silvia Corcione · Andrea Cortegiani · Rosario Cultrera · Francesco Giuseppe De Rosa · Valerio Del Bono · Filippo Del Puente · Chiara Fanelli · Fiorenza Fava · Daniela Francisci · Nicholas Geremia · Lucia Graziani · Andrea Lombardi · Angela Raffaella Losito · Ivana Maida · Andrea Marino · Maria Mazzitelli · Marco Merli · Roberta Monardo · Alessandra Mularoni · Chiara Oltolini · Carlo Pallotto · Emanuele Pontali · Francesca Raffaelli · Matteo Rinaldi · Marco Ripa · Teresa Antonia Santantonio · Francesco Saverio Serino · Michele Spinicci · Carlo Torti · Enrico Maria Trecarichi · Mario Tumbarello · Malgorzata Mikulska · Mauro Giacomini · Anna Marchese · Antonio Vena · Matteo Bassetti · CEFI-SITA investigators

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Thank you

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