Fetroja® – PERSEUS (Real-World Evidence) Study

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Summary

- PERSEUS was a retrospective, multicenter, medical chart review study in hospitalized patients (N=261) with Gram-negative bacterial infections in Spain[1]
- Adult patients were included if they had a documented Gram-negative bacterial infection (except for *Acinetobacter* spp.) and received cefiderocol continuously for ≥72 h for the first time through the EAP (2018–2022)[1]
  - Patients with infections caused by *Acinetobacter* spp. were enrolled into the ARES study[1]
- The most common Gram-negative pathogen was *Pseudomonas aeruginosa*, isolated in 174 (66.7%) patients. Additional pathogens included *Pseudomonas* spp. (n=15), *Klebsiella pneumoniae* (n=26), and other Enterobacterales (n=12)[1]
- The most common infection sites were respiratory (47.9%), urinary (14.6%), intra-abdominal (14.6%), and skin/soft tissue (10%)[1]
- Overall, 210 (80.5%) patients achieved clinical cure at the end of treatment, and ACM at Day 28 occurred in 56 (21.5%) patients[1]
  - In the *P. aeruginosa* subset (n=174), clinical cure was achieved in 147 (84.5%) patients and Day 28 ACM occurred in 30 (17.2%) patients[1]
- Univariate and multivariate logistic regression analyses demonstrated that the duration of prior antibiotic therapy before cefiderocol initiation (>7 days versus 0 day) was significantly associated with decreased probability of attaining clinical cure (OR, 0.19; 95% CI, 0.05–0.56)[1]
- Unadjusted Kaplan-Meier survival analysis demonstrated that the probability of survival was significantly reduced when patients received previous antibiotic therapy >7 days compared to patients with no previous antibiotic therapy (*P*=0.047)[1]
- Overall, clinical cure was achieved in approximately 80% of infections that were resistant to ceftazidime–avibactam, ceftolozane–tazobactam, or both[1]
- Overall, Day 28 ACM was approximately 20% in infections that were resistant to ceftazidime–avibactam, ceftolozane–tazobactam, or both[1]
- In the screened population (N=314), 7 (2.2%) patients experienced an ADR[1]
  - 3 (1%) patients discontinued cefiderocol treatment due to an ADR and a serious ADR

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PERSEUS Clinical Study

PERSEUS was a retrospective, multicenter, medical chart review study in hospitalized patients (N=261) with Gram-negative bacterial infections, excluding *Acinetobacter* spp., in Spain.[1]

Methods

Study Design[1]

- Adult patients were included if they had a documented Gram-negative bacterial infection (except for *Acinetobacter* spp.) and received cefiderocol continuously for ≥72 h for the first time through the EAP (2018–2022)
  - Patients with infections caused by *Acinetobacter* spp. were enrolled into the ARES study and were excluded from this study

Outcome Measures[1]

- The main outcomes were clinical cure and ACM at Day 28 from treatment initiation in patients treated with cefiderocol for ≥72 h and up to 28 days
  - Clinical cure was defined as the cessation treatment with cefiderocol due to the resolution of symptoms and clinical signs of infection
  - Clinical success was the composite outcome of clinical cure or survival at Day 28
- Another goal was to evaluate the association between the timing of cefiderocol therapy and outcomes
  - Unadjusted Kaplan-Meier survival analysis from the beginning of cefiderocol therapy through 28 days was performed for patients based on the duration of previous antibiotic treatment

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PERSEUS Clinical Study (Cont.)

Results

Patient characteristics[1]

- Baseline characteristics and demographics are presented in **Table 1**
  - The most common Gram-negative pathogen was *P. aeruginosa*, isolated in 174 (66.7%) patients. Additional pathogens included *Pseudomonas* spp. (n=15), *K. pneumoniae* (n=26), and other Enterobacterales (n=12)
- Information on the utilization of cefiderocol is shown in **Table 2**
  - Cefiderocol was used as first-line treatment in 42 (16.1%) patients
  - The median treatment duration of cefiderocol treatment was 10 days
  - Cefiderocol was used in combination with other antibiotics in 91 (34.9%) patients
    - Colistin was the mostly commonly administered antibiotic (19.5%) with cefiderocol

Table 1. Baseline Characteristics in the PERSEUS Study[1]

	Overall (N=261)	*P. aeruginosa* (n=174)
Age (years), median (IQR)	61 (49–68)	61 (52–68)
Male, n (%)	202 (77.4)	138 (79.3)
ICU, n (%)	165 (63.2)	109 (62.6)
Mechanical ventilation at baseline, n (%)	123 (47.1)	79 (45.4)
Septic shock, n (%)	73 (28)	47 (27)
Creatinine clearance <60 mL/min, n (%)[a]	177 (30.5)	37/119 (31.1)
Primary infection site, n (%)		
Respiratory	47.9)	81 (46.6)
Urinary	4.6)	28 (16.1)
Intra-abdominal	4.6)	23 (13.2)
Skin and soft tissue	0]	22 (12.6)
Bloodstream Catheter-related Unknown source	.2) .7) 3.4)	11 (6.3) 7 (4) 4 (2.3)
Bone and joint	9 (2.3)	6 (3.4)
Other[b]	4 (1.5)	3 (1.7)
Secondary bloodstream infection, n (%)	45 (17.2)	28 (16.1)
Polymicrobial Gram-negative infection, n (%)[c]	51 (19.5)	36 (20.7)
Meropenem-resistant, n/N (%)[d]	189/206 (91.7)	139/147 (94.6)
Ceftazidime–avibactam-resistant, n/N (%)	134/160 (83.8)	96/112 (85.7)
Ceftolozane–tazobactam-resistant, n/N (%)	99/130 (76.2)	75/105 (71.4)
Resistant to ceftazidime–avibactam and ceftolozane–tazobactam, n/N (%)[e]	99/129 (76.7)	74/103 (71.8)

Table 2. Cefiderocol Use in the Overall Population and in Patients with *P. aeruginosa* Infections[1]

	Overall (N=261)	*P. aeruginosa* (n=174)
Prior antibiotics, n (%)[a]	212 (81.2)	147 (84.5)
Number of prior courses of antibiotics, median (IQR) 1, n (%) 2, n (%) ≥3, n (%) None, n (%) Unknown, n	2 (1–3) 54 (25.5) 62 (29.2) 96 (45.3) 16.1)	2 (1–4) 37 (25.2) 43 (29.3) 67 (45.6) 25 (14.4) 2
Duration of prior antibiotic treatment (days) ≤3, n (%) 4–7, n (%) >7, n (%)		5.5 (3–9.5) 48/147 (31.3) 47/147 (32) 54/147 (36.7)
Rationale for administration of cefiderocol Resistant to all tested antibiotics Treatment failure of prior antibiotics AE with other susceptible antibiotics Other		116 (66.7) 75 (43.1) 14 (8) 16 (9.2)
Cefiderocol as first-line treatment, n (%)		25 (14.4)
Duration of cefiderocol treatment (days), median (IQR)	(7–14)	11 (7–15)
Combination therapy given with cefiderocol, n (%)[c]	91 (34.9)	56 (32.2)
Number of antibiotics used concomitantly with cefiderocol, n/N (%) 1 2 ≥3	N=91 41 (15.7) 25 (9.6) 25 (9.6)	N=56 25 (14.4) 16 (9.2) 15 (8.6)

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PERSEUS Clinical Study (Cont.)

Table 1. Baseline Characteristics in the PERSEUS Study[1]

	Overall (N=261)	*P. aeruginosa* (n=174)
Age (years), median (IQR)	61 (49–68)	61 (52–68)
Male, n (%)	202 (77.4)	138 (79.3)
ICU, n (%)	165 (63.2)	109 (62.6)
Mechanical ventilation at baseline, n (%)	123 (47.1)	79 (45.4)
Septic shock, n (%)	73 (28)	47 (27)
Creatinine clearance <60 mL/min, n (%)[a]	54/177 (30.5)	37/119 (31.1)
Primary infection site, n (%)		
Respiratory	125 (47.9)	81 (46.6)
Urinary	38 (14.6)	28 (16.1)
Intra-abdominal	38 (14.6)	23 (13.2)
Skin and soft tissue	26 (10)	22 (12.6)
Bloodstream Catheter-related Unknown source	24 (9.2) 15 (5.7) 9 (3.4)	11 (6.3) 7 (4) 4 (2.3)
Bone and joint	6 (2.3)	6 (3.4)
Other[b]	4 (1.5)	3 (1.7)
Secondary bloodstream infection, n (%)	45 (17.2)	28 (16.1)
Polymicrobial Gram-negative infection, n (%)[c]	51 (19.5)	36 (20.7)
Meropenem-resistant, n/N' (%)[d]	189/206 (91.7)	139/147 (94.6)
Ceftazidime–avibactam-resistant, n/N' (%)	134/160 (83.8)	96/112 (85.7)
Ceftolozane–tazobactam-resistant, n/N' (%)	99/130 (76.2)	75/105 (71.4)
Resistant to ceftazidime–avibactam and ceftolozane–tazobactam, n/N' (%)[e]	99/129 (76.7)	74/103 (71.8)

Abbreviations: CNS, central nervous system; ICU, intensive care unit; IQR, interquartile range; RRT, renal replacement therapy.
N'=number of patients with available information.
[a]Excluding patients on RRT; denominator excludes missing data.
[b]Includes CNS infection (n=2), mediastinitis (n=2) in overall.
[c]Primary pathogen in polymicrobial infections, for which cefiderocol was requested, was confirmed by the treating physician.
[d]Susceptibility test results were reported at local site.
[e]Includes patients with susceptibility test results for both ceftazidime–avibactam and ceftolozane–tazobactam.
Table adapted from Torre-Cisneros et al. *Eur J Clin Microbiol Infect Dis*. 2025.

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PERSEUS Clinical Study (Cont.)

Table 2. Cefiderocol Use in the Overall Population and in Patients with *P. aeruginosa* Infections[1]

	Overall (N=261)	*P. aeruginosa* (n=174)
Prior antibiotics, n (%)[a]	212 (81.2)	147 (84.5)
Number of prior courses of antibiotics, median (IQR) 1, n (%) 2, n (%) ≥3, n (%) None, n (%) Unknown, n	2 (1–3) 54 (25.5) 62 (29.2) 96 (45.3) 42 (16.1) 7	2 (1–4) 37 (25.2) 43 (29.3) 67 (45.6) 25 (14.4) 2
Duration of prior antibiotic treatment (days), median (IQR) ≤3, n (%) 4–7, n (%) >7, n (%)	6 (3–10.1) 55/212 (25.9) 70/212 (33) 87/212 (41)	5.5 (3–9.5) 46/147 (31.3) 47/147 (32) 54/147 (36.7)
Rationale for administration of cefiderocol, n (%)[b] Resistant to all tested antibiotics Treatment failure of prior antibiotics AE with other susceptible antibiotics Other	 169 (64.8) 116 (44.4) 21 (8) 26 (10)	 116 (66.7) 75 (43.1) 14 (8) 16 (9.2)
Cefiderocol as first-line treatment, n (%)	42 (16.1)	25 (14.4)
Duration of cefiderocol treatment (days), median (IQR)	10 (7–14)	11 (7–15)
Combination therapy given with cefiderocol, n (%)[c]	91 (34.9)	56 (32.2)
Number of antibiotics used concomitantly with cefiderocol, n/N' (%) 1 2 ≥3	N'=91 41 (15.7) 25 (9.6) 25 (9.6)	N'=56 25 (14.4) 16 (9.2) 15 (8.6)

Abbreviations: AE, adverse event; IQR, interquartile range.
N'=number of patients with available information.
[a]Prior antibiotics were administered to a total of 219 patients overall; data are shown for 212 patients with full data set; information was missing for 7 patients.
[b]Investigators could select more than 1 option.
[c]Includes antibiotics with Gram-negative coverage that have been started before, concomitantly or during the same treatment period.
Table adapted from Torre-Cisneros et al. *Eur J Clin Microbiol Infect Dis*. 2025.

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PERSEUS Clinical Study (Cont.)

Outcomes[1]

- Overall, 210 (80.5%) patients achieved clinical cure at the end of treatment and ACM at Day 28 occurred in 56 (21.5%) patients
- In the *P. aeruginosa* subset (n=174), clinical cure was achieved in 147 (84.5%) patients and Day 28 ACM occurred in 30 (17.2%) patients
- Clinical cure and Day 28 ACM by infection site in the overall population and in the *P. aeruginosa* subset can be seen in Table 3
- Cefiderocol, administered as first-line treatment, demonstrated clinical cure and ACM Day 28 rates of 90.5 and 14.3%, respectively (see Table 4)
- Cefiderocol, administered as monotherapy and in combination with other antibiotics demonstrated clinical cure rates of 84.1 and 73.6%, respectively
- The Day 28 ACM rate was 17.6 and 28.6% when cefiderocol was administered as monotherapy or as part of combination treatment, respectively (see Table 4)
- Cefiderocol was discontinued in 1 patient due to the development of resistance during treatment (*Klebsiella oxytoca*)

Table 3. Clinical Cure and Day 28 ACM by Infection Site[1]

Infection Site	Overall (N=261)		*P. aeruginosa* (n=174)	
	Clinical Cure n/N (%)	Day 28 ACM n/N (%)	Clinical Cure n/n (%)	Day 28 ACM n/n (%)
Respiratory	95/125 (76)	34/125 (27.2)	64/81 (79)	18/81 (22.2)
Urinary tract	36/38 (94.7)		27/28 (96.4)	4/28 (14.3)
Intra-abdominal	26/38 (68.4)		16/23 (69.6)	5/23 (21.7)
Skin/soft tissue	24/26 (92.3		0/22 (90.9)	2/22 (9.1)
Bloodstream[a]	19/24 (79.2)		11/11 (100)	1/11 (9.1)
Bone/joint	6/6 (100)		6/6 (100)	0/6 (0)
Other	4/4 (100)[b]	0/4 (0)[b]	3/3 (100)[c]	0/3 (0)[c]

Table 4. Clinical Outcomes by Previous Antibiotic Use and Resistance in the Overall Population[1,2]

Characteristic	Clinical Cure n (%)	Day 28 ACM n (%)	Composite Clinical Success n (%)
Meropenem-resistant (n=189)	152 (80.4)	39 (20.6)	160 (84.7)
Ceftolozane–tazobactam-resistant (n=99)	82 (82.8)	17 (17.2)	85 (85.9)
Ceftazidime–avibactam-resistant (n=134)	107 (79.9)	31 (23.1)	111 (82.8)
Cross-resistance to ceftolozane–tazobactam and ceftazidime–avibactam resistant (n=99)		17 (17.2)	85 (85.9)
Number of days with prior antibiotics (n=21			
≤3 (n=55)		9 (16.4)	49 (89.1)
4–7 (n=70)		13 (18.6)	62 (88.6)
>7 (n=87)		28.7)	67 (77)
Cefiderocol given as first-line treatmer		14.3)	38 (90.5)
Cefiderocol administered as monother		17.6)	150 (88.2)
Cefiderocol administered as combination		26 (28.6)	70 (76.9)
Prior antibiotic treatment			
Ceftazidime–avibactam (n=81)		23 (28.4)	62 (76.5)
Ceftolozane–tazobactam (n=12)	9 (75)	2 (16.7)	10 (83.3)
Colistin (n=95)	74 (77.9)	25 (26.3)	76 (62.1)
Meropenem (n=80)	58 (72.5)	23 (28.8)	63 (78.8)

- Univariate and multivariate logistic regression analyses demonstrated that the following factors were significantly associated with decreased the probability of attaining clinical cure:
  - Duration of prior antibiotic therapy before cefiderocol initiation (>7 days versus 0 day): OR 0.19; 95% CI, 0.05–0.56
  - Receipt of mechanical ventilation: OR 0.32; 95% CI, 0.15–0.67
- Unadjusted Kaplan-Meier survival analysis demonstrated that the probability of survival was significantly reduced when patients received previous antibiotic therapy >7 days compared to patients with no previous antibiotic therapy (*P*=0.047)

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PERSEUS Clinical Study (Cont.)

Table 3. Clinical Cure and Day 28 ACM by Infection Site[1]

Infection Site	Overall (N=261)		*P. aeruginosa* (n=174)	
	Clinical Cure n/N (%)	Day 28 ACM n/N (%)	Clinical Cure n/n (%)	Day 28 ACM n/n (%)
Respiratory	95/125 (76)	34/125 (27.2)	64/81 (79)	18/81 (22.2)
Urinary tract	36/38 (94.7)	6/38 (15.8)	27/28 (96.4)	4/28 (14.3)
Intra-abdominal	26/38 (68.4)	9/38 (23.7)	16/23 (69.6)	5/23 (21.7)
Skin/soft tissue	24/26 (92.3)	2/26 (7.7)	20/22 (90.9)	2/22 (9.1)
Bloodstream[a]	19/24 (79.2)	5/24 (20.8)	11/11 (100)	1/11 (9.1)
Bone/joint	6/6 (100)	0/6 (0)	6/6 (100)	0/6 (0)
Other	4/4 (100)[b]	0/4 (0)[b]	3/3 (100)[c]	0/3 (0)[c]

Abbreviations: ACM, all-cause mortality; CNS, central nervous system.
[a]Data are bloodstream infection of unknown origin/catheter-related bloodstream infection.
[b]Includes CNS infection (n=2) and mediastinitis (n=2).
[c]Includes CNS infection (n=2) and mediastinitis (n=1).
Table adapted from Torre-Cisneros et al. *Eur J Clin Microbiol Infect Dis*. 2025.

- Duration of prior antibiotic therapy before cefiderocol initiation (>7 days versus 0 day): OR 0.19; 95% CI, 0.05–0.56
- Receipt of mechanical ventilation: OR 0.32; 95% CI, 0.15–0.67
- Unadjusted Kaplan-Meier survival analysis demonstrated that the probability of survival was significantly reduced when patients received previous antibiotic therapy >7 days compared to patients with no previous antibiotic therapy (*P*=0.047)

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PERSEUS Clinical Study (Cont.)

Table 4. Clinical Outcomes by Previous Antibiotic Use and Resistance in the Overall Population[1,2]

Characteristic	Clinical Cure n (%)	Day 28 ACM n (%)	Composite Clinical Success n (%)
Meropenem-resistant (n=189)	152 (80.4)	39 (20.6)	160 (84.7)
Ceftolozane–tazobactam-resistant (n=99)	82 (82.8)	17 (17.2)	85 (85.9)
Ceftazidime–avibactam-resistant (n=134)	107 (79.9)	31 (23.1)	111 (82.8)
Cross-resistance to ceftolozane–tazobactam and ceftazidime–avibactam resistant (n=99)	82 (82.9)	17 (17.2)	85 (85.9)
Number of days with prior antibiotics (n=212) ≤3 (n=55) 4–7 (n=70) >7 (n=87)	 49 (89.1) 59 (84.3) 60 (69)	 9 (16.4) 13 (18.6) 25 (28.7)	 49 (89.1) 62 (88.6) 67 (77)
Cefiderocol given as first-line treatment (n=42)[a]	38 (90.5)	6 (14.3)	38 (90.5)
Cefiderocol administered as monotherapy (n=170)	143 (84.1)	30 (17.6)	150 (88.2)
Cefiderocol administered as combination (n=91)	67 (73.6)	26 (28.6)	70 (76.9)
Prior antibiotic treatment			
Ceftazidime–avibactam (n=81)	59 (72.8)	23 (28.4)	62 (76.5)
Ceftolozane–tazobactam (n=12)	9 (75)	2 (16.7)	10 (83.3)
Colistin (n=95)	74 (77.9)	25 (26.3)	78 (82.1)
Meropenem (n=80)	58 (72.5)	23 (28.8)	63 (78.8)

Abbreviation: ACM, all-cause mortality.
[a]Patients with first-line treatment received no prior antibiotic treatment for the current infection.
Table adapted from Torre-Cisneros et al. *Eur J Clin Microbiol Infect Dis*. 2025 (plus Supplementary Material).

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PERSEUS Clinical Study (Cont.)

Safety[1]

- In the screened population (N=314), 7 (2.2%) patients experienced an ADR
- 3 (1%) patients discontinued cefiderocol treatment due to an ADR and a serious ADR. The discontinuations were due to:
  - Mild leukopenia (n=1)
  - Fatal toxic epidermal necrolysis (n=1)
  - Septic rash (n=1, this patient was withdrawn from the efficacy analysis because of cefiderocol treatment <72 h)
- 1 death occurred due to a serious ADR of fatal toxic epidermal necrolysis

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[3]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms:
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Proteus mirabilis*
  - *Pseudomonas aeruginosa*
  - *Enterobacter cloacae* complex
- Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms:
  - *Acinetobacter baumannii* complex
  - *Escherichia coli*
  - *Enterobacter cloacae* complex
  - *Klebsiella pneumoniae*
  - *Pseudomonas aeruginosa*
  - *Serratia marcescens*

Fetroja is contraindicated in:[3]

- Patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of **Fetroja**

Please read the attached **Fetroja Full Prescribing Information**

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Literature Search

As of May 2026, a computerized search of the published medical literature using internal and external databases (ie, Medline® and Embase®) identified an additional relevant reference regarding the PERSEUS study. For your review, this reference is listed below:

- Torre-Cisneros J, Ferrer R, Martos CF, et al. Cefiderocol treatment for patients infected by *Stenotrophomonas maltophilia*, *Burkholderia cepacia* complex and *Achromobacter* spp.: subgroup analysis from the PERSEUS study. *Eur J Clin Microbiol Infect Dis*. 2025;44(6):1367-1374. [Web Link]

Please keep in mind that medical literature databases, while considered a major source of biomedical information, are selective in their sources, and the information derived from them should not be considered all-inclusive.

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Abbreviations

ACM	all-cause mortality	h	hours
ADR	adverse drug reaction	HABP	hospital-acquired bacterial pneumonia
AE	adverse event	ICU	intensive care unit
CNS	central nervous system	IQR	interquartile range
cUTI	complicated urinary tract infection	RRT	renal replacement therapy
EAP	expanded access program	US	United States
FDA	US Food and Drug Administration	VABP	ventilator-associated bacterial pneumonia

References

1. Torre-Cisneros J, Almirante B, Martos CF, et al. Effectiveness and safety of cefiderocol treatment in patients with Gram-negative bacterial infections in Spain in the early access programme: results of the PERSEUS study. *Eur J Clin Microbiol Infect Dis*. 2025;44(6):1375-1390. [Web Link]
2. Torre-Cisneros J, Almirante B, Martos CF, et al. Effectiveness and safety of cefiderocol treatment in patients with Gram-negative bacterial infections in Spain in the early access programme: results of the PERSEUS study. *Eur J Clin Microbiol Infect Dis*. 2025;44(6):1375-1390 (Supplementary Material). [Web Link]
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Enclosure

Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.