EMBLAVEO®
aztreonam/avibactam

EMBLAVEO mode of action (video)

EMBLAVEO dosing guide

Optimising EMBLAVEO - PK/PD principles

Patient profiles

REVISIT pivotal phase III study

ASSEMBLE study in MBL-positive infections

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

EMA, European Medicines Agency; MBL, metallo-β-lactamase; PD, pharmacodynamics; PK, pharmacokinetics; SmPC, summary of product characteristics.
Before prescribing Pfizer medicinal products, please refer to the current mandatory information, available at https://www.ema.europa.eu/de/documents/product-information/emblaveo-epar-product-information_de.pdf and https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo.
PP-A1E-GLB-0250; March 2026.

Pfizer

EMBLAVEO®
aztreonam/avibactam

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®: Optimised dosing to achieve a joint PTA of 90->99%*,1–3

EMBLAVEO®
aztreonam/avibactam

Formulation and strength#,4

EMBLAVEO® 1.5 g/0.5 g powder for concentrate for solution for infusion

Each vial contains 1.5 g of aztreonam and 0.5 g of avibactam in a fixed 3:1 ratio. After reconstitution, 1 mL of solution contains 131.2 mg of aztreonam and 43.7 mg of avibactam.

The EMBLAVEO® dosing schedule has been optimised based on PK modelling and PTA analyses1

The dosing regimen of EMBLAVEO® optimises the simultaneous achievement of both aztreonam and avibactam PK/PD targets, and achieved >90% joint PTA during first dosing interval and at steady state across most renal function groups (patients with end-stage renal disease achieved 89.1% joint PTA at steady state).1–3

- For the aztreonam and avibactam combination, a joint PK/PD target (defined as attainment of 60% *f*T > MIC of 8 mg/L for aztreonam and 50% *f*T > 2.5 mg/L for avibactam, achieved simultaneously), required for antibacterial efficacy, was considered[1]
- A loading dose improves probability of achieving both avibactam and aztreonam target exposures in the first dosing interval[1]
- A loading dose plus 3-hour maintenance infusions of aztreonam/avibactam in a 3:1 fixed ratio every 6 hours optimises joint PTA[1]

Recommended intravenous dose in adult patients aged ≥18 years with CrCL§ >50 mL/min, for all the approved therapeutic indications¶,4

First dose (loading dose)	Maintenance doses‖,**
2 g/0.67 g, 3-hour infusion	1.5 g/0.5 g, 3-hour infusion every 6 hours

Table 1. Duration of treatment by type of infection[4]

Type of infection	cIAI	HAP, including VAP	cUTI, including pyelonephritis	Infections due to aerobic Gram-negative organisms in patients with limited treatment options
Days	5–10 days	7–14 days	5–10 days	Duration in accordance with the site of infection and may continue for **up to 14 days**

Special populations[4]

No dose adjustment is required in:	Elderly patients based on age	Patients with hepatic impairment	Patients with mild renal impairment (estimated CrCL >50 to ≤80 mL/min)
		Close monitoring is recommended during treatment with EMBLAVEO®	In patients with renal impairment, close monitoring is recommended during treatment with EMBLAVEO®

Table 2. Recommended doses of EMBLAVEO® for patients with estimated CrCL ≤50 mL/min[4]

	Dose of EMBLAVEO® (aztreonam/avibactam)‡‡			
Estimated CrCL (mL/min)#	Loading	Maintenance	Infusion time	Dosing interval
>30 to ≤50	2 g/0.67 g	0.75 g/0.25 g	3 hours	Every 6 hours
>15 to ≤30	1.35 g/0.45 g	0.675 g/0.225 g	3 hours	Every 8 hours
≤15 mL/min, on intermittent haemodialysis§§	1 g/0.33 g	0.675 g/0.225 g	3 hours	Every 12 hours

There are insufficient data to make dosing adjustment recommendations for patients undergoing renal replacement therapy other than haemodialysis (e.g. continuous venovenous haemofiltration or peritoneal dialysis). Patients receiving CRRT need a higher dose than patients on haemodialysis. For patients receiving CRRT, the dose should be adjusted as guided by the CLCRRT.

EMBLAVEO® (aztreonam/avibactam) has the potential to address an important unmet medical need in MDR aerobic Gram-negative bacterial infections4,5

- High *in vitro* activity against MBL-producing isolates of carbapenem-resistant Enterobacterales and *Stenotrophomonas maltophilia*[4,6–12]
- Optimised dosing to achieve joint PTA above 90% across most renal function groups (patients with end-stage renal disease achieved 89.1% joint PTA at steady state)¶¶,1,2,4
- Data support the use of EMBLAVEO® against MDR Gram-negative pathogens, including MBL-producing carbapenem-resistant Enterobacterales and *S. maltophilia*[4, 11, 13–15]
- Favourable risk–benefit profile[4,5,13–15]
- The most common adverse drug reactions in patients treated with EMBLAVEO® (aztreonam/avibactam) were anaemia (6.9%), diarrhoea (6.2%), alanine aminotransferase increased (6.2%), and aspartate aminotransferase increased (5.2%)[4]

*Except in ESRD patients who achieved 89.1% at steady state; #EMBLAVEO® contains approximately 44.6 mg of sodium per vial[4]; §Calculated using the Cockcroft-Gault formula[4]; ¶For cIAI infection type: to be used in combination with metronidazole when anaerobic pathogens are known or suspected to be contributing to the infectious process[4]; ‖Beginning at the next dosing interval[4]; **A single loading dose is followed by maintenance doses beginning at the next dosing interval[4]; ##Dose recommendations are based on PK modelling and simulation[4]; §§Both aztreonam and avibactam are removed by haemodialysis; on haemodialysis days, EMBLAVEO® should be administered after the haemodialysis session. Aztreonam/avibactam should not be used in patients with CrCL ≤15 mL/min unless haemodialysis or another form of renal replacement therapy is initiated[4]; ¶¶Patients with end-stage renal disease, including those on haemodialysis (CrCL ≤15 mL/min)[2].

cIAI, complicated intra-abdominal infection; CLCRRT, continuous renal replacement therapy clearance; CrCL, creatinine clearance; CRRT, continuous renal replacement therapy; cUTI, complicated urinary tract infection; ERSD, end-stage renal disease; *f*T, time of unbound drug concentration; HAP, hospital-acquired pneumonia; MBL, metallo-β-lactamase; MDR, multidrug-resistant; MIC, minimum inhibitory concentration; PD, pharmacodynamics; PK, pharmacokinetics; PTA, probability of target attainment; VAP, ventilator-associated pneumonia.

1. Das S, et al. *Eur J Clin Pharmacol*. 2024;80:529–43; 2. Raber S, et al. *Open Forum Infect Dis*. 2025;12(Suppl 1):ofae631.1438; 3. Xie R, et al. *Antimicrob Agents Chemother*. 2025;69(8):e0195024; 4. EMBLAVEO® (aztreonam/avibactam). Summary of Product Characteristics. Pfizer. 2026; 5. European Medicines Agency. New antibiotic to fight infections caused by multidrug resistant bacteria. https://www.ema.europa.eu/en/news/new-antibiotic-fight-infections-caused-multidrug-resistant-bacteria (Accessed March 2026); 6. Sader HS, et al. *JAC Antimicrob Resist*. 2023;5:dlad032; 7. Sader HS, et al. Open Forum Infect Dis. 2025;12(Suppl 1):ofae631.1268; 8. Estabrook M, et al. Open Forum Infect Dis. 2025;12(Suppl 1):ofae631.1677; 9. Estabrook M, et al. *Open Forum Infect Dis*. 2025;12(Suppl 1):ofae631.1678; 10. Rossolini GM, et al. *J Glob Antimicrob Resist*. 2024;36:123–31; 11. Biagi M, et al. *Antimicrob Agents Chemother*. 2020;64:e00297-20; 12. Wise MG, et al. *Eur J Clin Microbiol Infect Dis*. 2023;42:1135–43; 13. Cornely OA, et al. *J Antimicrob Chemother*. 020;75:618–27; 14. Carmeli Y, et al. *Lancet Infect Dis*. 2025;25:218–30; 15. Daikos GL, et al. *JAC Antimicrob Resist*. 2025;7:dlaf131.

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

EMBLAVEO
IT'S IN THE NAME

Pfizer

Pfizer

ENGINEERED TO STAY OPTIMISED[1–3]

So patients get the right exposure, by design[1,2,4]

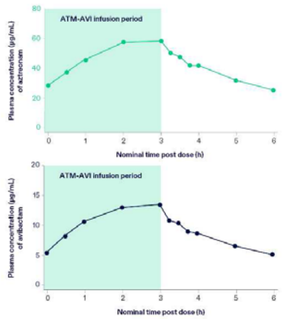
EMBLAVEO® aztreonam/avibactam

EMBLAVEO brings together ATM and AVI in a single, purpose-built system[1,5,6]

Precisely configured, to balance both components[2,7]

Steady-state plasma exposure for ATM and AVI are closely synchronised[2,7]

Steady-state mean plasma concentrations assessed via intensive PK sampling on Day 4[7]



Adapted from Corney *et al.* 2020.

EMBLAVEO delivers a high probability of joint target attainment[1,2]

Joint PTA with EMBLAVEO is 90–>99%, except in those with ESRD (joint PTA ~89%)[2]

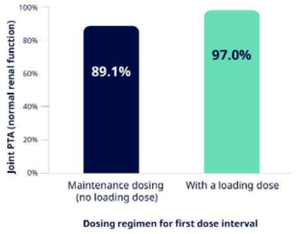
High joint PTA at steady state:

Joint PTA was defined as the PK/PD target of 60% fT >MIC of 8 mg/L for ATM and 50% fT>CT of 2.5 mg/L for AVI, achieved simultaneously. These values correlate with the restoration of ATM efficacy against MBL-positive CRE in preclinical models.[2]

Providing optimised exposure from the very first dose[2]

With a loading dose, ~97% of patients with normal renal function achieve joint PTA for ATM-AVI*

Joint PTA in the first dosing interval, with a loading dose or a maintenance dose of EMBLAVEO



Adapted from Xie *et al.* 2025.

The loading dose benefit:

+3% to +29.6%

incremental joint PTA achievement across varying renal function groups, in the first dosing interval[2]

Renal impairment is common in patients with serious Gram-negative infections[2,8–10]

Without a loading dose, joint PTA in the first dose interval was <80% for subgroups with ARC or moderate or severe renal impairment[2]

*Calculated using the Cockcroft-Gault formula.

Designed with MBL-positive CRE in mind[1,5,6]

Reasons to choose EMBLAVEO:

- **Fixed-dose combination**, administered via a single line[1]
- **Regulator-approved** with label including dosing for patients with renal impairment[1]
- **PK/PD-optimised** for >90% joint PTA[2,3†]
- Optimised exposure **from the very first dose**[2,3]
- **Efficacy and safety profile established** via two Phase 3 trials[11,12]
- **Susceptibility testing breakpoints** established by EUCAST[13,14]
- **Reduces antibiotic overuse**[15–17]

†With a loading dose, joint PTA with EMBLAVEO is 90–>99% both in the first dosing interval and at steady state, except for patients with ESRD (joint PTA at steady state 89.1%).[2]

IMPORTANT: use of CAZ-AVI with ATM is not recommended by Pfizer, due to the risk of suboptimal exposure[2]
The joint PTA target for ATM-AVI is more stringent than that for CAZ-AVI, requiring 2.5x greater magnitude of CT and a 1.2x longer %fT >MIC. In addition, CAZ-AVI+ATM, having a different BL:BLI ratio as compared to ATM-AVI, results in lower AVI AUC at steady state vs the fixed-dose combination of EMBLAVEO, compromising joint PTA.[2]

As dose regimens and PK/PD considerations are key components of breakpoint determinations, the EUCAST MIC breakpoints for ATM-AVI are not applicable to CAZ-AVI + ATM dose regimens such as those proposed by IDSA; therefore this combination cannot be considered equivalent to EMBLAVEO.

See Summary of Product Characteristics for full dosing information.

References: 1. EMBLAVEO Summary of Product Characteristics. 2. Xie R, *et al. Antimicrob Agents Chemother* 2025;69(8):e0195024. 3. Das S, *et al. Eur J Clin Pharmacol* 2024;80(4):529–543. 4. EMA. Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antimicrobial medicinal products. EMA/CHMP/594085/2015. July 2016. 5. Biedenbach DJ, *et al. Antimicrob Agents Chemother* 2015;59(7):4239–4248. 6. EMA. EMBLAVEO Public assessment report (EPAR). EMA/147600/2024. May 2024. 7. Cornely OA, *et al. J Antimicrob Chemother* 2020;75(3):618–627. 8. Ahn JY, *et al. Microorganisms* 2023;11(5):1121. 9. Oweis AO, *et al. J Multidiscip Healthc* 2022;15:2759–2766. 10. Su G, *et al. Sci Rep* 2018;8:13372. 11. Carmeli Y, *et al. Lancet Infect Dis* 2025;25(2):218–230. 12. Daikos GL, *et al. JAC Antimicrob Resist* 2025;7(4):dlaf131. 13. EMA. MIC breakpoints; EMA/916812/2022. April 2025. Available at: https://www.ema.europa.eu/en/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx. Last accessed January 2026. 14. Chan L M-W, *et al. Antibiotics (Basel)* 2025;14(7):675. 15. Carmeli Y et al. Clin Infect Dis 2025;81(4):e243. 16. Song J-H, *et al. Am J Infect Control* 2008;36(4 Suppl):S83–S92. 17. Veeraraghavan B, *et al. Lancet Reg Health Southeast Asia* 2023;15:100225.

ATM, aztreonam; AVI, avibactam; CAZ, ceftazidime; CRE, carbapenem-resistant Enterobacterales; CT, concentration duration; EMA, European Medicines Agency; ESRD, end-stage renal disease; EUCAST, European Committee on Antimicrobial Susceptibility Testing; fT, free time; MBL, metallo-β-lactamase; MIC, minimum inhibitory concentration; PD, pharmacodynamic; PK, pharmacokinetic; PTA, probability of target attainment; SBL, serine-β-lactamase.

PP-A1E-GLB-0265 April 2026

Pfizer

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

Explore these hypothetical patient cases* to understand the risk factors associated with MBL-positive bacterial infections

EMBLAVEO®
aztreonam/avibactam

cIAI, recent travel to MBL-endemic country

Go to case study

Nosocomial pneumonia, MBL outbreak

Go to case study

*Hypothetical patients for illustrative purposes only.

Before prescribing Pfizer medicinal products, please refer to the current mandatory information, available at https://www.ema.europa.eu/de/documents/product-information/emblaveo-epar-product-information_de.pdf and https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo.

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

Explore these hypothetical patient cases* to understand the risk factors associated with MBL-positive bacterial infections

EMBLAVEO®
aztreonam/avibactam

cIAI, recent travel to MBL-endemic country

Go to case study

Nosocomial pneumonia, MBL outbreak

Go to case study

*Hypothetical patients for illustrative purposes only.

Before prescribing Pfizer medicinal products, please refer to the current mandatory information, available at https://www.ema.europa.eu/de/documents/product-information/emblaveo-epar-product-information_de.pdf and https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo.

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

Chris – Patient History and Clinical Profile

Patient history and background

- **Male, 44 years of age**
- History of travel to an MBL-endemic country in the prior 2 weeks: **hospitalisation for cUTI and administration of third-generation cephalosporin empirically**
- Discharged after improvement in clinical condition

Clinical developments

- 3 months later, admitted to the emergency department of his country of origin for severe abdominal pain and nausea
- Complained of right lower-quadrant abdominal pain that radiated to the left lower quadrant, which was associated with fever, vomiting, and abdominal distention
- Admitted to ICU for hypotension, tachycardia and tachypnoea
- CT revealed signs of acute perforated appendicitis and peritonitis
- Underwent laparoscopic appendectomy
- Peri-operatively, treated with a carbapenem for the infection
- Continued to worsen and hence a combination of two antibiotics was started

Clinical profile at admission

Symptoms

- Lower-right abdominal pain that was radiating to the left lower quadrant
- High fever
- Nausea
- Constipation

Medical history

- Smoker
- Obese BMI
- Diabetic

Observations

- Temperature: 38.4°C
- Blood pressure: 100/60 mmHg
- CRP: 70 mg/L
- WBC: 20 cells/µL

BMI, body mass index; CRP, C-reactive protein; CT, computed tomography; cUTI, complicated urinary tract infection; ICU, intensive care unit; MBL, metallo-β-lactamase; WBC, white blood cell.

Back to case selection

What would your diagnosis be?

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

Chris – Diagnosis

A patient with cIAI: 44-year-old male, history of travel to an MBL-endemic country, presented with abdominal pain following recent laparoscopic appendectomy

Diagnosis at admission
Complicated appendicitis

Suspected pathogen(s):
E. coli or ***K. pneumoniae***, most likely carbapenem resistant

Microbiological diagnosis

- Post surgery – Gram stain revealed Gram-negative rods from pus samples
- 24 hours after surgery – Characterization of carbapenemase in ***K. pneumoniae*** from positive culture pellets through rapid test (lateral flow immunoassay): **NDM+KPC**
- 48 hours post surgery – Pus samples revealed **CR *K. pneumoniae***

cIAI, complicated intra-abdominal infection; CR, carbapenem resistant; E. coli, *Escherichia coli*; KPC, *Klebsiella pneumoniae* carbapenemase; *K. pneumoniae*, *Klebsiella pneumoniae*; MBL, metallo-β-lactamase; NDM, New Delhi metallo-β-lactamase.

Back to case selection

What are the risk factors for MBL infections?

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

Patient Risk Factors for MBL Infections

Risk factors for MBL infections include:

- Prior colonisation[1]
- ICU admission[1]
- Prior antimicrobial use*[1,2]
- Mechanical ventilation[1]
- Healthcare exposure[1,2]
- Dialysis and the presence of indwelling catheters[1,2]
- Comorbidities[1,2]
- Travel to endemic areas[3]

Inappropriate antimicrobial use compounds the mortality and cost burden associated with β-lactamase production and MDR in Enterobacterales[4]

*e.g. carbapenem in the past 30 days.

ICU, intensive care unit; MBL, metallo-β-lactamase; MDR, multi-drug resistant.

1. Timsit JF, et al. *Antibiotics (Basel)*. 2022;11:144; 2. Tan X, et al. *Infect Drug Resist*. 2021;14:125-142; 3. Van Duin D, Doi Y. *Virulence*. 2017;8:460-469; 4. Castanheira M, et al. *Open Forum Infect Dis*. 2019;6(Suppl 1):S23-S33.

Back to case selection

What clinical challenge do MBL producers pose?

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

MBLs: A Significant Clinical Problem[1]

- Gram-negative bacteria possess multiple modes of antibiotic resistance, including β-lactamases (SBLs and MBLs)[2]
- MBLs are among the 'Big Five' carbapenemases, which are the most common types of β-lactamases reported in Enterobacterales globally[3,4]
- MBL-positive bacteria often co-harbour multiple resistance mechanisms including serine-β-lactamases like class A (e.g. ESBLs and KPC), C (e.g. AmpC) and D (e.g. OXA-48-like) enzymes[5–7]
- Enterobacterales are a family of Gram-negative bacteria that commonly causes infections in healthcare settings[2,8]
- MBL-producing Enterobacterales have become more prevalent in clinical settings worldwide[9]

Clinically relevant β-lactamases[#11]

The 'Big Five' carbapenemases[3,4]

[#]Summary of Ambler classification. Non-exhaustive enzyme list.

ESBL, extended spectrum β-lactamase; IMP, imipenemase; KPC, *Klebsiella pneumoniae* carbapenemase; MBL, metallo-β-lactamase; NDM, New Delhi metallo-β-lactamase; SBL, serine-β-lactamase; VIM, Verona integron-encoded MBL.

1. Rossolini GM, et al. *J Glob Antimicrob Resist*. 2022;30:214-221; 2. Peleg AY, Hooper DC. *N Engl J Med*. 2010;362:1804-1813; 3. UK Health Security Agency. ESPAUR report 2024 to 2025. Available at https://assets.publishing.service.gov.uk/media/6936ac34b612700b2cb73607/ESPAUR-report-2024-to-2025.pdf. London: UK. Accessed on February 2026; 4. Exner M, et al. *GMS Hyg Infect Control*. 2017;12:Doc05; 5. Karlowsky JA, et al. *Antimicrob Agents Chemother*. 2017;61:e00472-17; 6. Biedenbach DJ, et al. *Antimicrob Agents Chemother*. 2015;59:4239-4248; 7. Kazmierczak KM, et al. *Antimicrob Agents Chemother*. 2015;60:1067-1078; 8. Mehrad B, et al. *Chest*. 2015;147:1413-1421; 9. Wu W, et al. *Clin Microbiol Rev*. 2019;32:e00115-18;
10. Bush K. *Antimicrob Agents Chemother*. 2018;62:e01076-18; 11. Bush K. *Ann N Y Acad Sci*. 2013;1277:84-90.

Back to case selection

What are the considerations for treatment of MBL infections?

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

The Rise of Infections Caused by MBL Producers Has Resulted in a Lack of Effective Treatment Options and a High Level of Unmet Need[1,2]

Significant unmet need[3–5]

Despite advancements in medicine, efficacious treatment options for CRE infections, particularly those producing MBL, are limited especially for severely and critically ill patients

Addressing treatment gaps[6,7]

Treatment options against infections caused by MBL producers remain limited despite recent approval of novel antibiotics

Complexity in treatment[8,9]

Suboptimal dosing of current treatment options may reduce efficacy and can result in poor treatment outcomes

Challenges with existing treatments[10–12]

Current treatment options face multiple challenges, including antimicrobial susceptibility testing, poor treatment outcomes, resistance development and safety concerns

CRE, carbapenem-resistant Enterobacterales; MBL, metallo-β-lactamase.

1. Mojica MF, et al. *Lancet Infect Dis*. 2022;22:e28–e34; 2. Deshmukh DG, et al. *J Lab Physicians*. 2011;3:93–97; 3. Timsit JF, et al. *Antibiotics*. 2022;11:144; 4. Karaiskos I, et al. *Front Public Health*. 2019;7:151; 5. World Health Organization. Lack of innovation set to undermine antibiotic performance and health gains. https://www.who.int/news/item/22-06-2022-22-06-2022-lack-of-innovation-set-to-undermine-antibiotic-performance-and-health-gains. (Accessed March 2026); 6. Tamma PD, et al. *Clin Infect Dis*. 2021;72:e169–e183; 7. Zeng M, et al. *J Microbiol Immunol Infect*. 2023;56:653–671; 8. Bassetti S, et al. *Eur J Intern Med*. 2022;99:7–12; 9. Appaneal H, et al. *BMC Geriatrics*. 2021;21:436; 10. Martin A, et al. *Open Forum Infect Dis*. 2018;5:ofy150; 11. Oliveira J, Reygaert WC. Gram-negative bacteria. In: *StatPearls*. Treasure Island, FL: StatPearls Publishing, 2024. https://ncbi.nlm.nih.gov/books/NBK538213/ (Accessed March 2026); 12. Bianco G, et al. *Eur J Clin Microbiol Infect Dis*. 2022;41:63–70.

Back to case selection

Select a new case

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

Explore these hypothetical patient cases* to understand the risk factors associated with MBL-positive bacterial infections

EMBLAVEO®
aztreonam/avibactam

cIAI, recent travel to MBL-endemic country

Go to case study

Nosocomial pneumonia, MBL outbreak

Go to case study

*Hypothetical patients for illustrative purposes only.

Before prescribing Pfizer medicinal products, please refer to the current mandatory information, available at https://www.ema.europa.eu/de/documents/product-information/emblaveo-epar-product-information_de.pdf and https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo.

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

Simon – Patient History and Clinical Profile

Patient history and background

- **Male, 77 years of age**
- Known c/o **COPD with 3 admissions in the last year** including 2 episodes of mechanical ventilation
- **Hospitalisation in ICU and mechanically ventilated** due to medical complications
- **ICU Day 5, MBL-plasmid mediated outbreak** in hospital unit confirmed: IPC measures implemented

Medical history

- Smoker
- Cardiovascular disorders, including heart failure
- Chronic pulmonary disease

Initial empiric treatment

- Carbapenem plus oxazolidinone therapy

Clinical progression - Day 5

- Temperature: 38.3°C
- Leukocytosis with neutrophil left shift
- Elevation of serum inflammatory markers (CRP, IL-6)
- New lung infiltrate on chest X-ray
- Worsening hypoxia, hypotension requiring vasopressors
- Purulent bronchopulmonary secretions

COPD, chronic obstructive pulmonary disease; CRP, C-reactive protein; ICU, intensive care unit; IL, interleukin; IPC, infections, prevention and control; MBL, metallo-β-lactamase.

Back to case selection

What would your diagnosis be?

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

Simon – Diagnosis

A patient with nocosomial pneumonia: 77-year-old male, history of hospitalisation due to COPD including ICU stay with MBL outbreak

Diagnosis - Day 5
Suspected VAP

Suspected pathogen(s): CR MBL-producing *K. pneumoniae*

Microbiological diagnosis - Day 7

- Rapid molecular diagnosis on Day 5 from the BAL sample showed presence of ***K. pneumoniae*** **with ESBL plus OXA plus VIM**
- Day 7 cultures confirmed *K. pneumoniae* resistant to first-line antibiotics
- Susceptibility to higher antibiotics awaited

BAL, bronchoalveolar lavage; COPD, chronic obstructive pulmonary disease; CR, carbapenem resistant; ESBL, extended-spectrum β-lactamase; ICU, intensive care unit; *K. pneumoniae, Klebsiella pneumoniae;* MBL, metallo-β-lactamase; OXA, oxacillinase; VAP, ventilator-associated pneumonia; VIM, Verona integron-encoded metallo-β-lactamase.

Back to case selection

What are the risk factors for MBL infections?

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

Patient Risk Factors for MBL Infections

Risk factors for MBL infections include:

- Prior colonisation[1]
- ICU admission[1]
- Prior antimicrobial use*[1,2]
- Mechanical ventilation[1]
- Healthcare exposure[1,2]
- Dialysis and the presence of indwelling catheters[1,2]
- Comorbidities[1,2]
- Travel to endemic areas[3]

Inappropriate antimicrobial use compounds the mortality and cost burden associated with β-lactamase production and MDR in Enterobacterales[4]

*e.g. carbapenem in the past 30 days

ICU, intensive care unit; MBL, metallo-β-lactamase; MDR, multi-drug resistant

1. Timsit JF, et al. *Antibiotics (Basel)*. 2022;11:144; 2. Tan X, et al. *Infect Drug Resist*. 2021;14:125-142; 3. Van Duin D, Doi Y. *Virulence*. 2017;8:460-469; 4. Castanheira M, et al. *Open Forum Infect Dis*. 2019;6(Suppl 1):S23-S33.

Back to case selection

Are MBL producers a spreading public health concern?

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

MBL-producing Enterobacterales: A Spreading Public Health Concern[1–3]

High mobility

MBL genes are highly mobile, accelerating their spread all over the world[3]

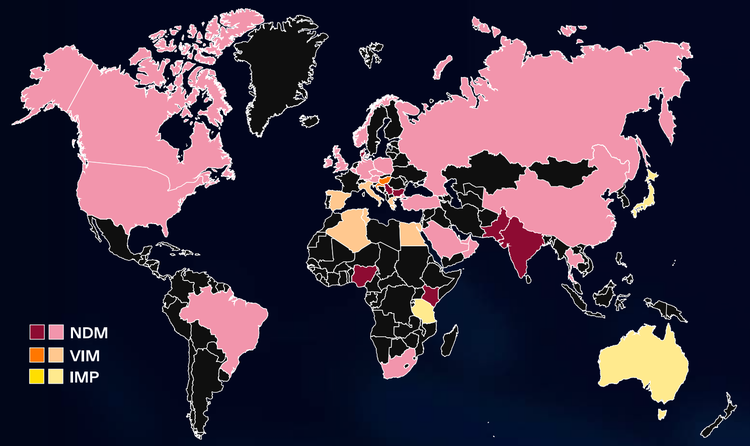
Rising prevalence

MBL-producing Gram-negative bacteria are on the rise globally[1]

Global spread

MBL subtypes NDM, VIM and IMP have been identified in community, hospital, and environmental settings throughout the world[1]

Global distribution of acquired MBL-positive Enterobacterales (reported 2020)*[1]



Full-tone colour: the specific MBL is the most prevalent carbapenemase in the country
Light-tone colour: the most prevalent MBL group in countries where serine carbapenemases (KPC or OXA-48-like) are more prevalent

*Adapted from Boyd SE, et al. *Antimicrob Agents Chemother.* 2020.[1]

IMP, imipenemase; *KPC, Klebsiella pneumoniae* carbapenemase; MBL, metallo-β-lactamase; NDM, New Delhi metallo-β-lactamase; VIM, Verona integron-encoded MBL.

1. Boyd SE, et al. *Antimicrob Agents Chemother*. 2020;64:e00397-20; 2. Rodriguez-Baño J, et al. *Clin Microbiol Rev*. 2018;31:e00079-17; 3. Deshmukh DG, et al. *J Lab Physicians*. 2011;3:93-97.

Back to case selection

What are the considerations for treatment of MBL infections?

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

EMBLAVEO®
aztreonam/avibactam

The Rise of Infections Caused by MBL Producers Has Resulted in a Lack of Effective Treatment Options and a High Level of Unmet Need[1,2]

Significant unmet need[3–5]

Despite advancements in medicine, efficacious treatment options for CRE infections, particularly those producing MBL, are limited especially for severely and critically ill patients

Addressing treatment gaps[6,7]

Treatment options against infections caused by MBL producers remain limited despite recent approval of novel antibiotics

Complexity in treatment[8,9]

Suboptimal dosing of current treatment options may reduce efficacy and can result in poor treatment outcomes

Challenges with existing treatments[10–12]

Current treatment options face multiple challenges, including antimicrobial susceptibility testing, poor treatment outcomes, resistance development and safety concerns

CRE, carbapenem-resistant Enterobacterales; MBL, metallo-β-lactamase.

1. Mojica MF, et al. *Lancet Infect Dis*. 2022;22:e28–e34; 2. Deshmukh DG, et al. *J Lab Physicians*. 2011;3:93–97; 3. Timsit JF, et al. *Antibiotics*. 2022;11:144; 4. Karaiskos I, et al. *Front Public Health*. 2019;7:151; 5. World Health Organization. Lack of innovation set to undermine antibiotic performance and health gains. https://www.who.int/news/item/22-06-2022-22-06-2022-lack-of-innovation-set-to-undermine-antibiotic-performance-and-health-gains. (Accessed March 2026); 6. Tamma PD, et al. *Clin infect Dis*. 2021;72:e169–e183; 7. Zeng M, et al. *J Microbiol Immunol Infect*. 2023;56:653–671; 8. Bassetti S, et al. *Eur J Intern Med*. 2022;99:7–12; 9. Appaneal H, et al. *BMC Geriatrics*. 2021;21:436; 10. Martin A, et al. *Open Forum Infect Dis*. 2018;5:ofy150; 11. Oliveira J, Reygaert WC. Gram-negative bacteria. In: FL:*StatPearls*. Treasure Island, StatPearls Publishing, 2024. https://ncbi.nlm.nih.gov/books/NBK538213/ (Accessed March 2026); 12. Bianco G, et al. *Eur J Clin Microbiol Infect Dis*. 2022;41:63–70.

Back to case selection

Select a new case

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

REVISIT data supporting the efficacy and safety of EMBLAVEO® (± MTZ) in adult patients with cIAI and HAP/VAP caused by Gram-negative bacteria, including MDR pathogens and critically ill patients*

EMBLAVEO® aztreonam/avibactam

Objectives[1]

To investigate efficacy and safety of EMBLAVEO® in the treatment of cIAI and HAP/VAP due to Gram-negative bacteria, including MBL-producing MDR pathogens

Methods[1]

- Phase III, prospective, descriptive, randomised, parallel-group, comparative study in countries with emerging or high incidence of carbapenem resistance and where MBL-producing MDR pathogens are prevalent
- Patients randomised 2:1 to EMBLAVEO® ± MTZ or MER ± COL for 5–14 days (cIAI) or 7–14 days (HAP/VAP)

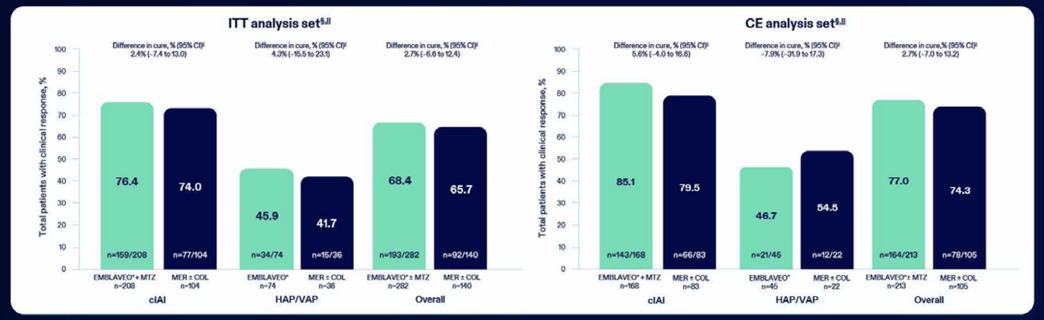
Baseline patient characteristics[1]

	EMBLAVEO ± MTZ (n=282)	MER ± COL (n=140)
Age, years, mean (SD)	55.2 (17.8)	54.0 (16.3)
Male, n (%)	186 (66)	101 (72)
CrCL, mL/min, mean (range)	104.2 (19.0–337.0)	103.0 (29.0–404.0)
APACHE II score, mean (SD)	9.8 (6.5)	10.1 (6.7)
Previous antibiotic treatment failure, n (%)	75 (27)	30 (21)

- Majority of patients (74%) in both groups had a diagnosis of cIAI
- HAP–VAP subgroup showed greater illness severity, with higher 28-day mortality (11% vs 4% overall for EMBLAVEO®; 19% vs 7% for meropenem)
- The most commonly identified baseline pathogens were *E. coli* (n=177), *K. pneumoniae* (n=59), *P. aeruginosa* (n=26) and anaerobic pathogens (n=44)
- MBL-positive pathogens were identified in 10 patients overall
- The MIC at which 90% of isolates were inhibited (MIC90) was 0.25 mg/L

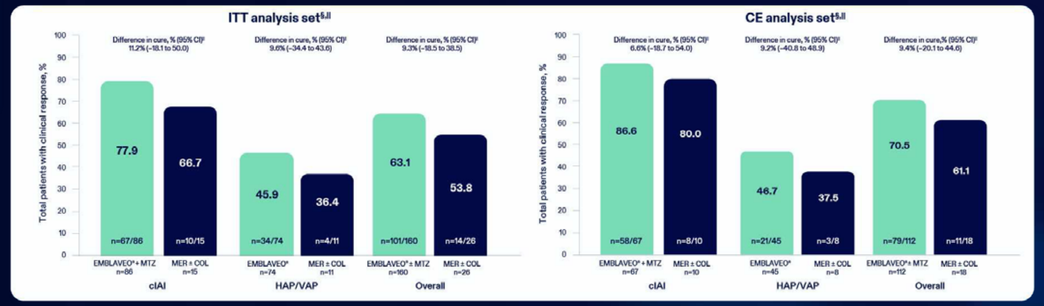
Primary endpoint outcomes[#,¶,1]

Adjudicated clinical response at TOC visit



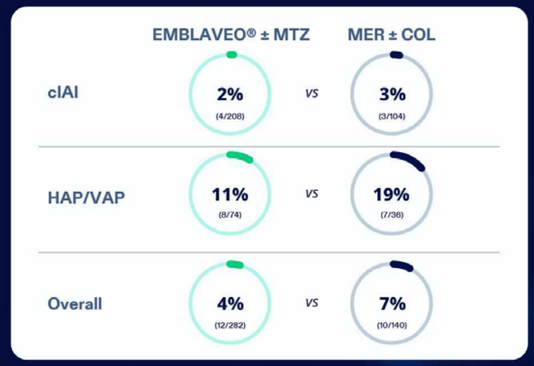
Subgroup analysis[2]

Adjudicated clinical cure rates at the TOC visit for EMBLAVEO® ± MTZ (only patients with APACHE II score ≥8) and adjunctive COL with MER subgroups



Secondary endpoint outcomes[1]

28-day all-cause mortality rates (ITT analysis set)



Overview of AEs[1] (safety analysis set[§])

n (%)	EMBLAVEO ± MTZ (n=275)	MER ± COL (n=137)
AEs	177 (64)	87 (64)
SAEs	53 (19)	25 (18)

- EMBLAVEO® was well tolerated, with no new safety findings[1]
- Most frequent TEAEs with EMBLAVEO® ± MTZ were increased AST and ALT, diarrhoea and abnormal hepatic function
- In the subgroup analysis, TEAEs were more frequent in patients treated with MER + COL vs EMBLAVEO® ± MTZ[2]

*According to an *ad hoc* subgroup analysis of REVISIT in critically ill patients, 186 patients (160 in the EMBLAVEO® ± MTZ group and 26 in the MER ± COL group) had an APACHE II score ≥8 at baseline; #Primary endpoint is descriptive only with no formal hypothesis testing; ¶The CI for the difference is calculated using the unstratified Miettinen and Nurminen method; §The ITT analysis set included all randomised patients regardless of receipt of study drug. The CE analysis set included patients in the ITT analysis set who received ≥48 hours of study treatment; met other protocol-specified disease, pathogen and prior/concomitant treatment criteria; and did not have an indeterminate clinical response at TOC. The safety analysis set included all patients in the ITT set who received any amount of study drug; ‖Treatment duration was 5–14 days for cIAI and 7–14 days for HAP/VAP. Clinical cure at TOC visit (Day 28±3), evaluated in ITT and CE analysis sets, was the primary efficacy endpoint. Single-arm CIs were computed using Jeffreys method. NOTE: 99.75% CI data of the treatment difference in cure rates for each analysis set (by infection type and overall) were erroneously included in the abstract. This chart has been corrected with 95% CI data[3]. AE, adverse event; ALT, alanine aminotransferase; APACHE II, Acute Physiology and Chronic Health Evaluation; AST, aspartate aminotransferase; CE, clinically evaluable; CI, confidence interval; cIAI, complicated intra-abdominal infection; COL, colistin; CrCL, creatinine clearance; *E. coli*, *Escherichia coli*; HAP, hospital-acquired pneumonia; ITT, intention-to-treat; *K. pneumoniae*, *Klebsiella pneumoniae*; MBL, metallo-β-lactamase; MDR, multidrug-resistant; MER, meropenem; MIC, minimum inhibitory concentration; MTZ, metronidazole; *P. aeruginosa*, *Pseudomonas aeruginosa*; SAE, serious adverse event; SD, standard deviation; TEAE, treatment-emergent adverse event; TOC, test of cure; VAP, ventilator-associated pneumonia. 1. Carmeli Y, et al. *Lancet Infect Dis*. 2025;25:218–30; 2. Leister-Tebbe H, et al. *Open Forum Infect Dis*. 2025;12(Suppl 1):ofae631.312; 3. Yuan J, et al. P-105. Presented at: IDWeek 2024, Los Angeles, CA, USA, 16–19 October 2024.

EMBLAVEO® IT'S IN THE NAME

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich

Before prescribing Pfizer medicinal products, please refer to the current mandatory information, available at https://www.ema.europa.eu/de/documents/product-information/emblaveo-epar-product-information_de.pdf and https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo

Pfizer

EMBLAVEO mode of action (video) | EMBLAVEO dosing guide | Optimising EMBLAVEO - PK/PD principles | Patient profiles | REVISIT pivotal phase III study | ASSEMBLE phase III study in MBLs

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here

Pfizer

MBL-positive Gram-negative bacteria are an increasingly serious threat to patients[1,2]

MBL-positive infections are associated with increased risk of death[3–5]

Up to 55% mortality with **MBL-positive CRE infections (n=38)** vs 14.7% for controls (n=68)[3–5,*]

Up to 77% mortality reported for ***S. maltophilia*** pneumonia[6,#]

The WHO considers carbapenem-resistant (including MBL-positive) Enterobacterales to be critical priority pathogens[¶] because they can hydrolyse almost all current β-lactam antibiotics[7,8]

EMBLAVEO® is the first[§] approved β-lactam/β-lactamase inhibitor combination antibiotic designed with MBLs in mind[9–12,‖]

ASSEMBLE investigated EMBLAVEO® specifically in MBL-positive infections[13]

EMBLAVEO® aztreonam/avibactam

Design

Prospective, randomised, descriptive, multicentre, open-label, parallel-group comparative study conducted with 15 adult patients. An independent adjudication committee was involved in the study[13,14,**]

Outcomes

Primary outcome:
Clinical cure at TOC (micro-ITT analysis set; TOC visit carried out on Day 28±3)[13]

Secondary outcomes:
Clinical response at TOC, per-patient and per-pathogen microbiological response at TOC, 28-day mortality; and safety[13]

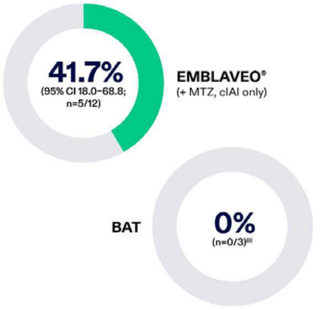
Patient characteristics
(Micro-ITT analysis set; not exhaustive – refer to the publication for full list)

	EMBLAVEO® ± MTZ (cIAI only; n=12)	BAT (n=3)
Monomicrobial infection, n (%)	6 (50)	3 (100)
Pathogen(s), n (%)		
Enterobacterales	10 (83.3)	3 (100.0)
P. aeruginosa	2 (16.7)	0
S. maltophilia	3 (25.0)	0
Resistance subtypes, n (%)		
MBL-positive[##]	12 (100)	3 (100)
NDM-1	6 (50)	2 (66.7)
NDM-5	3 (25)	1 (33.3)
VIM-2	2 (16.7)	0
L1	3 (25)	0
ESBL-positive	9 (75)	3 (100)
Serine carbapenemase-positive	3 (25)	0

Most patients' pathogens carried additional resistance mechanisms as well as MBLs[13]

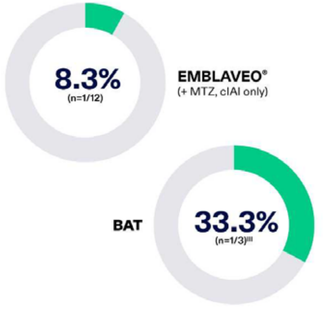
Primary outcome

Clinical cure at TOC: (micro-ITT[¶¶] analysis set)[13]

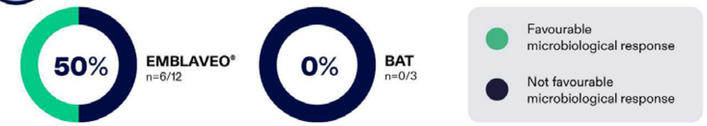


Secondary outcome

All-cause 28-day mortality (ITT[¶¶] analysis set)[13]

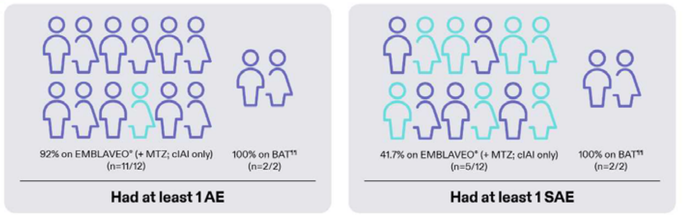


TOC microbiological response[13]



Microbiological responses mirrored clinical outcomes: 50% (6/12) favourable in the EMBLAVEO® ± MTZ group vs 0% (0/3) in the BAT group at TOC[13]

Safety[13]



- One SAE (acute kidney injury) in the BAT group was related to the treatment[13]
- No treatment-related SAEs occurred with EMBLAVEO® ± MTZ[13]

These study findings suggest a potential role for EMBLAVEO® for treating serious infections caused by MBL-producing MDR Gram-negative bacteria, for which there are few treatment options[13]

Given the small number of study participants and the descriptive, open-label design, the findings should be interpreted accordingly[13]

*In-hospital mortality in cases with NDM-1 Enterobacterales vs controls (adjusted for co-morbid disease). *K. pneumoniae* was the most common NDM-1 producer. Specimens collected 48 hours after admission[5]; #Reported mortality rates in patients with *S. maltophilia* pneumonia vary between 23% and 77%, with highest rates observed among patients with cancer and concomitant bacteraemia[6]; ¶The 2024 critical priority group comprises carbapenem-resistant Enterobacterales, third-generation cephalosporin-resistant Enterobacterales, carbapenem-resistant *Acinetobacter baumannii*, and rifampicin-resistant *Mycobacterium tuberculosis*[7]; §First approved in the European Union; ‖Including MBL-producing, carbapenem-resistant Enterobacterales and *S. maltophilia*, with additional activity against ESBLs that produce AmpC and the carbapenemase enzymes KPC and OXA-48-like[9]; **Patients were enrolled at sites in China, Greece, India, Malaysia, Mexico, the Philippines, Romania, Thailand and the Russian Federation. No formal hypothesis testing was planned[13]; ##Three patients (all in the aztreonam–avibactam group) had two MBL-producing pathogens, including one patient with two NDM-1 MBL pathogens[13]; ¶¶One patient in the BAT arm (n=3) withdrew consent and was subsequently excluded from both the microbiologically evaluable and safety analysis sets; Micro-ITT population consisted of patients with at least one MBL-positive, Gram-negative pathogen[14]; ‖‖One patient in the BAT arm (n=3) withdrew consent and was subsequently excluded from the safety analysis set.[13]

AE, adverse event; AmpC, ampicillin class C; BAT, best available therapy; CI, confidence interval; cIAI, complicated intra-abdominal infection; CRE, carbapenem-resistant Enterobacterales; ESBL, extended-spectrum β-lactamase; ITT, intention-to-treat; KPC, *Klebsiella pneumoniae* carbapenemase; MBL, metallo-β-lactamase; MDR, multidrug-resistant; micro-ITT, microbiological intention-to-treat; MTZ, metronidazole; NDM, New Delhi metallo-β-lactamase; OXA, oxacillinase; SAE, serious adverse event; SmPC, summary of product characteristics; TOC, test of cure; VIM, Verona integron-encoded metallo-β-lactamase; WHO, World Health Organization.

1. Boyd SE, et al. *Antimicrob Agents Chemother*. 2020;64:e00397–20; 2. Antimicrobial Resistance Collaborators. *Lancet*. 2022;399:629–55; 3. Daikos GL, et al. *Antimicrob Agents Chemother*. 2009;53:1868–73; 4. Hayakawa K, et al. *J Antimicrob Chemother*. 2020;75:697–708; 5. de Jager P, et al. *PLoS One*. 2015;10:e0123337; 6. Looney WJ, et al. *Lancet Infect Dis*. 2009;9:312–23; 7. World Health Organization. WHO bacterial priority pathogens list, 2024: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance. https://www.who.int/publications/i/item/9789240093461 (Accessed March 2026); 8. Mojica MF, et al. *Lancet Infect Dis*. 2022;22:e28–34; 9. EMBLAVEO® (aztreonam–avibactam) Summary of Product Characteristics. Pfizer, 2026. https://www.ema.europa.eu/en/documents/product-information/emblaveo-epar-product-information_en.pdf (Accessed March 2026); 10. European Medicines Agency. EMBLAVEO. 2026. https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo (Accessed March 2026); 11. Biedenbach DJ, et al. *Antimicrob Agents Chemother*. 2015;59:4239–48; 12. Pfizer (press release). European Commission Approves Pfizer's EMBLAVEO® for Patients with Multidrug-Resistant Infections and Limited Treatment Options. April 2024. https://www.pfizer.com/news/press-release/press-release-detail/european-commission-approves-pfizers-emblaveor-patients. (Accessed March 2026); 13. Daikos GL, et al. *JAC Antimicrob Resist*. 2025;7:dlaf131; 14. ClinicalTrials.gov. NCT03580044: Efficacy, safety, and tolerability of ATM-AVI in the treatment of serious infection due to MBL-producing Gram-negative bacteria. https://clinicaltrials.gov/study/NCT03580044 (Accessed March 2026).

The EMBLAVEO® SmPC is available at the Pfizer booth / Die aktuelle Fachinformation ist am Stand erhältlich.

Before prescribing Pfizer medicinal products, please refer to the current mandatory information, available at https://www.ema.europa.eu/de/documents/product-information/emblaveo-epar-product-information_de.pdf and https://www.ema.europa.eu/en/medicines/human/EPAR/emblaveo.

Hier geht es zu den aktuellen Pflichtangaben

EMA SmPC available here