Efficacy, Pharmacokinetics (PK), and Safety Profile of MEDI3902, an Anti-*Pseudomonas aeruginosa* Bispecific Human Monoclonal Antibody in Mechanically Ventilated Intensive Care Unit Patients; Results of the Phase 2 EVADE Study Conducted by the Public–Private COMBACTE–MAGNET Consortium in the Innovative Medicines Initiative (IMI) Program

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Abstract

Background: *Pseudomonas aeruginosa* (PA) pneumonia is associated with morbidity and mortality in mechanically ventilated, intensive care unit (MV ICU) patients despite best clinical care. We assessed efficacy, PK, and safety of MEDI3902 in MV ICU subjects in the placebo-controlled, randomized Phase 2 EVADE study (NCT02696902; EudraCT 2015-001706-34).

Methods: Subjects with PCR-confirmed PA colonization of the lower respiratory tract were randomized to either a single IV infusion of 1500 mg MEDI3902 (n = 85) or placebo (n = 83). Primary efficacy endpoint was Endpoint Adjudication Committee-determined relative risk reduction (RRR) of PA pneumonia incidence in MEDI3902 vs. placebo recipients within 21 days post-dose (2-sided α = 0.2). Serum MEDI3902 PK levels were measured through 49 days post-dose. Treatment-emergent adverse events (TEAEs) and serious AEs (SAEs) were assessed through 49 days post-dose.

Results: Baseline characteristics were similar between groups. MEDI3902 did not meet the primary endpoint of PA pneumonia vs. placebo (22.4% vs. 18.1%; RRR –23.7%, P=0.491). Mean serum MEDI3902 level was 9.46 μg/mL (target 1.7μg/mL) at 21 days post dose, with a $t_{½}$ 5.6 days. Proportion of subjects with TEAEs was similar between groups: ≥1 TEAE (98.8% MEDI3902; 97.6% placebo); ≥1 serious; and/or ≥grade 3 severity SAE (70.6% MEDI3902; 66.3% placebo). Deaths were numerically higher, although not statistically significant (24 (28.2%) MEDI3902 vs 19 (22.9%) Placebo; RRR –23.3%, P=0.429). Post-hoc analyses suggested RRR 47% among ~70% of the study population who had baseline procalcitonin levels <0.55 μg/L (12.5% MEDI3902 vs. 23.7% placebo; 80%CI 6.1%-69.9%; P=0.135). Similarly, RRR 83% was observed among 50% of study subjects with baseline absolute neutrophil count (ANC) of <8170 /μL (2.8% MEDI3902 vs. 17.0% placebo; 80%CI 39.5%–95.5%; P=0.038). Subjects with procalcitonin <0.55 μg/L and ANC <8170/μL also had higher serum PK exposure.

Conclusions: A single IV dose of MEDI3902 provided PK exposure above the target level but did not achieve primary efficacy endpoint of reduction in PA pneumonia. Efficacy trends were observed in subjects with lower levels of baseline inflammatory biomarkers. MEDI3902 may have a path forward in certain patient populations such as ICU patients with lower baseline inflammation.

Background

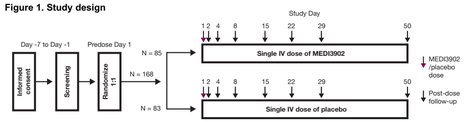
- *Pseudomonas aeruginosa* causes 26.6% of ventilator-associated pneumonia cases across the USA, Europe, and Latin America.[1]
- Pneumonia due to *P. aeruginosa* is associated with significant mortality and morbidity, increased length of stay in hospital and intensive care units (ICU), increased rates of mechanical ventilation, and substantial healthcare costs, despite antibiotic use.[2]
- No systemic agents are currently approved for the prevention or pre-emption of *P. aeruginosa* pneumonia development.[3,4]
- MEDI3902 (gremubamab) is a first-in-class, bivalent, bispecific human immunoglobulin G1 kappa monoclonal antibody that selectively binds to the *P. aeruginosa* PcrV protein and Psl exopolysaccharide, involved in host cell cytotoxicity and *P. aeruginosa* colonization and tissue adherence, respectively.[5]
- Here we report the efficacy, pharmacokinetics (PK), and safety results of the Phase 2 EVADE study (NCT02696902; EudraCT 2015-001706-34) in mechanically ventilated subjects in the ICU.

Methods

Study design

- EVADE was a Phase 2, randomized, double-blind, placebo-controlled, single-dose, proof-of-concept study conducted across 48 sites in Europe, the USA, and Israel.
- Subjects were randomly assigned (1:1:1) to receive a single intravenous (IV) dose of MEDI3902 500 mg or 1500 mg or placebo.
  - Based on the results of other studies, a single dose of MEDI3902 500 mg was not expected to maintain the target level of 1.7 μg/mL for 21 days, and enrolment in this arm was discontinued after 16 subjects were treated. Subsequently, enrolled subjects were randomized (1:1) to MEDI3902 1500 mg or placebo (Figure 1).
- Subjects were followed until the end of the study period (Day 50).

Figure 1. Study design



Patients were randomized following positive PCR to identify *P. aeruginosa* colonization in the lower respiratory tract.
IV, intravenous; PCR, polymerase chain reaction.

Subjects

- Main inclusion criteria:
  - Adults (≥18 years of age) were intubated and on mechanical ventilation in the ICU and expected to remain so for ≥72 hours.
  - Lower respiratory tract *P. aeruginosa* colonization confirmed by polymerase chain reaction ≤36 hours prior to randomization.
  - No diagnosis of new-onset pneumonia ≤72 hours prior to randomization.
  - Expected to survive for >2 weeks based on investigator judgment, and to participate in the study through 49 days post-dose.
- Main exclusion criteria
  - Acute confirmed or suspected pseudomonal disease at study enrolment and treatment.
  - Clinical Pulmonary Infection Score ≥6 based on contributing parameters measured ≤24 hours prior to treatment.
  - Acute Physiology and Chronic Health Evaluation-II score ≥25 or Sequential Organ Failure Assessment score ≥12 at randomization.
  - Active pulmonary disease that would impair the ability to diagnose pneumonia.
  - Receipt of anti-*P. aeruginosa* antibiotics (systemic/aerosolized colistin) for >72 hours within 96 hours of randomization.

Efficacy

- Primary endpoint: Endpoint Adjudication Committee (EAC)-determined relative risk reduction (RRR) of nosocomial *P. aeruginosa* pneumonia incidence through 21 days post-dose in MEDI3902 1500 mg recipients versus placebo.

PK and safety

- Secondary endpoints: MEDI3902 serum concentration, PK and anti-drug antibody (ADA) response measured through 49 days post-dose.
- Primary endpoint: The incidence of treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), and adverse events of special interest (AESI) were assessed through 49 days post-dose.

Post-hoc analysis

- The impact of key baseline covariates on RRR of *P. aeruginosa* pneumonia was assessed in MEDI3902 1500 mg recipients versus placebo.

Statistical analysis

- Efficacy and PK were assessed in the modified intent-to-treat population defined as all subjects who were randomized and treated, analyzed by randomized treatment group. The primary efficacy analysis compared MEDI3902 1500 mg and placebo.
- Safety was assessed in the as-treated population, including all subjects who were randomized and treated, analyzed by the treatment received.
- The RRR, defined as 1 – relative risk and its corresponding 2-sided 80% confidence interval (CI), were estimated from a Poisson regression model with treatment group as a covariate (2-sided alpha = 0.2).
- Data were analyzed descriptively, and no multiplicity adjustments were made.

Results

Subjects

- A total of 184 subjects were randomized and received MEDI3902 500 mg (n=16), 1500 mg (n=85), or placebo (n=83) (Figure 1).
  - In total 134/184 (72.8%) subjects completed the study; 12 (75.0%) MEDI3902 500 mg, 59 (69.4%) MEDI3902 1500 mg, and 63 (75.9%) placebo recipients.
  - The most frequent reason for discontinuation was death in 3 (18.8%), 24 (28.2%), and 19 (22.9%) subjects, respectively.
- Baseline characteristics were generally similar between groups (Table 1); however, subjects in the MEDI3902 arms appeared to have higher baseline inflammation compared with placebo, as measured by higher white blood cell and neutrophil counts, and procalcitonin levels (Table 1).

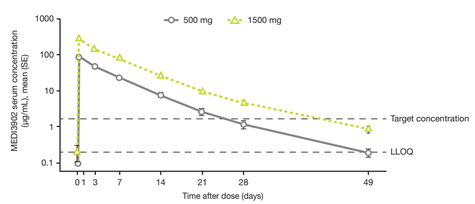
Efficacy

- The EAC-determined *P. aeruginosa* pneumonia incidence was 19/85 (22.4%) and 15/83 (18.1%) in MEDI3902 1500 mg and placebo recipients, respectively.
- The primary endpoint of EAC-determined RRR in *P. aeruginosa* pneumonia incidence was not met.
  - A single dose of MEDI3902 1500 mg resulted in a RRR of –23.7% (80% CI: –83.8%, 16.8%; P=0.491) resulting in a risk increase versus placebo 21 days post-dose.

PK

- The mean serum concentration–time profile following a single IV infusion of MEDI3902 is shown in Figure 2.
- MEDI3902 PK parameters are summarized in Table 2.

Figure 2. Serum concentration–time profile following a single IV dose of MEDI3902 500 or 1500 mg



IV, intravenous; SE, standard error.

Table 1. Demographics and baseline characteristics (mITT)

	MEDI3902 500 mg (n=16)	MEDI3902 1500 mg (n=85)	Placebo (n=83)	Total (N=184)
Age, years; mean (SD)	62.7 (9.3)	60.3 (15.2)	64.1 (12.9)	62.2 (13.8)
Age <65 years; n (%)	7 (43.8)	42 (49.4)	39 (47.0)	88 (47.8)
Sex, male; n (%)	10 (62.5)	54 (63.5)	62 (74.7)	126 (68.5)
Race, n (%)				
Asian	0 (0.0)	0 (0.0)	1 (1.2)	1 (0.5)
Black or African American	0 (0.0)	2 (2.4)	4 (4.8)	6 (3.3)
Native Hawaiian or Other Pacific Islander	0 (0.0)	0 (0.0)	1 (1.2)	1 (0.5)
White	16 (100.0)	81 (95.3)	75 (90.4)	172 (93.5)
Other	0 (0.0)	2 (2.4)	2 (2.4)	4 (2.2)
Weight, kg; mean (SD)	82.5 (25.2)	78.8 (19.5)	84.4 (21.0)	81.6 (20.7)
Height, cm; mean (SD)	167.9 (10.0)	169.1 (9.6)	171.1 (10.0)	169.9 (9.8)
BMI, kg/m^2; mean (SD)	29.5 (9.4)	27.5 (6.4)	29.0 (7.7)	28.4 (7.3)
BMI ≤30 kg/m^2; n (%)	11 (68.8)	60 (70.6)	54 (65.1)	125 (67.9)
Clinical severity scores at baseline; mean (SD)				
APACHE-II	16.9 (2.9)	15.3 (5.4)	15.5 (5.2)	15.5 (5.1)
SOFA	4.5 (2.4)	4.4 (2.7)	4.0 (2.1)	4.2 (2.4)
CPIS	3.5 (1.5)	3.0 (1.5)	3.2 (1.5)	3.1 (1.5)
CLSI susceptibility at baseline; n (%)				
Any culture result, n	16	83	82	181
P. aeruginosa positive	15 (93.8)	72 (86.7)	67 (81.7)	154 (85.1)
Non-MDR	6 (37.5)	37 (44.6)	25 (30.5)	68 (37.6)
MDR	4 (25.0)	12 (14.5)	16 (19.5)	32 (17.7)
XDR	4 (25.0)	14 (16.9)	21 (25.6)	39 (21.5)
PDR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Unknown[a]	1 (6.3)	9 (10.8)	5 (6.1)	15 (8.3)
P. aeruginosa negative[b]	1 (6.3)	11 (13.3)	15 (18.3)	27 (14.9)
White blood cell count, 10^3/μL; mean (SD)	11.6 (4.4)	13.2 (6.3)	11.4 (6.1)	–
Neutrophil count, 10^3/μL; mean (SD)	9.1 (4.1)	10.6 (6.0)	8.4 (4.3)	–
Procalcitonin, μg/L; mean (SD)	4.8 (15.5)	1.01 (2.4)	0.61 (1.34)	–

[a]Subjects with *P. aeruginosa* positive culture results but missing minimum inhibitory concentration records.
[b]All randomized subjects were positive for *P. aeruginosa* by PCR within 36 hours of randomization, but not all had *P. aeruginosa* positive cultures.
APACHE-II, Acute Physiology and Chronic Health Evaluation II; BMI, body mass index; CLSI, Clinical and Laboratory Standards Institute; CPIS, Clinical Pulmonary Infection Score; MDR, multidrug-resistant; mITT, modified intent-to-treat population; PDR, pan drug-resistant; SD, standard deviation; SOFA, Sequential Organ Failure Assessment; XDR, extensively drug-resistant

Table 2. Summary of MEDI3902 PK parameters

	MEDI3902 500 mg (N=16)		MEDI3902 1500 mg (N=85)	
PK Parameter	**n**	**Mean (SD)**	**n**	**Mean (SD)**
C_{max}, μg/mL	16	87.6 (23.9)	84	299 (94.1)
C_{21}, μg/mL	14	2.56 (2.23)	72	9.46 (7.91)
$AUC_{0\text{-}21}$, day*μg/mL	16	418 (126)	81	1410 (599)
AUC_{∞}, day*μg/mL	16	440 (135)	81	1510 (675)
CL, L/day	16	1.31 (0.64)	81	1.27 (0.86)
$t_{½}$, day	16	6.56 (4.03)	81	5.65 (2.69)
	n/N	**%**	**n/N**	**%**
Subjects with serum MEDI3902 levels >target level of 1.7 μg/mL on Day 22	8/16	50.0%	58/72	80.6%

$AUC_{0\text{-}21}$, area under the concentration–time curve from time zero to 21 days post-dose; AUC_{∞}, area under the concentration–time curve from zero to infinity; CL, clearance; C_{max}, maximum observed concentration; C_{21}, concentration 21 days post-dose; IV, intravenous; SD, standard deviation; $t_{½}$, half-life.

- Following a single 1500 mg IV infusion:
  - At 21 days post-dose, mean serum MEDI3902 concentration was 9.46 μg/mL, with 80.6% of subjects above the target level of 1.7 μg/mL.
  - MEDI3902 clearance was 1270 mL/day, and the half-life was 5.65 days.
- ADA were detected at baseline in 2/16 and 2/85 subjects in the MEDI3902 500 mg and 1500 mg groups, respectively, and 3/83 in the placebo group. Persistent ADA (positive at ≥2 or last post-baseline assessments) were detected in 2/16 and 4/85 subjects in the MEDI3902 500 mg and 1500 mg groups and 4/83 in the placebo group.

Safety

- The incidence of TEAEs, and at least 1 SAE and/or TEAE of ≥grade 3 severity through 49 days post-dose was broadly similar between groups (Table 3).

Table 3. Overall summary of TEAEs through 49 days post-dose

Subjects[a], n (%) with ≥1	MEDI3902 500 mg N=16	MEDI3902 1500 mg N=85	Placebo N=83
TEAE	15 (93.8)	84 (98.8)	81 (97.6)
Treatment-related TEAE	0 (0.0)	3 (3.5)	1 (1.2)
TEAE of ≥ grade 3 severity[b]	12 (75.0)	60 (70.6)	54 (65.1)
Death (grade 5 severity[b])	3 (18.8)	24 (28.2)	19 (22.9)
Serious[c] TEAE	4 (25.0)	38 (44.7)	35 (42.2)
Serious[c] and/or ≥ grade 3 severity[b] TEAE	12 (75.0)	60 (70.6)	55 (66.3)
Treatment-related serious[c] TEAE	0 (0.0)	0 (0.0)	1 (1.2)
TEAE leading to discontinuation of treatment	0 (0.0)	0 (0.0)	0 (0.0)
AESI	0 (0.0)	2 (2.4)	1 (1.2)
Treatment-related AESI	0 (0.0)	2 (2.4)	0 (0.0)
AESI of ≥ grade 3 severity[b]	0 (0.0)	1 (1.2)	1 (1.2)

[a]Subjects are counted once for each category regardless of the number of events.
[b]Grade 3, Severe; Grade 4, Life-threatening; Grade 5, Fatal based on CTCAE criteria.
[c]Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/congenital disability (in the offspring of the subject).
AESI, adverse event of special interest; CTCAE, Common Terminology Criteria for Adverse Events; TEAE, treatment-emergent adverse event.

- The most common TEAEs in the MEDI3902 and placebo groups, respectively, were hypotension (23.8% and 18.1%), diarrhea (15.8% and 13.3%), hypokalemia (14.9% and 9.6%), pseudomonal pneumonia (14.9% and 14.5%), pyrexia (14.9% and 16.9%) and constipation (12.9% and 13.3%).
- There were 46 deaths overall through 49 days post-dose.
  - The number of deaths was numerically higher in the MEDI3902 1500 mg group (24/85, 28.2%) versus placebo (19/83, 22.9%), although the RRR was not statistically significant (RRR MEDI3902 vs placebo –23.3%, 80% CI: –73.3%, 12.2%).

Post-hoc analysis

- Among the baseline covariates tested, procalcitonin and absolute neutrophil count (ANC) had the greatest effect on the RRR of *P. aeruginosa* pneumonia (Table 4).

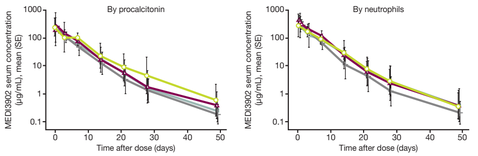
Table 4. Impact of baseline covariates on *P. aeruginosa* pneumonia efficacy in the overall study

Covariate	RRR	80% CI	P-value
Overall study population	–23.7%	(–83.8, 16.8)	0.491
Prior MV duration	–15.5%	(–71.3, 22.0)	0.6382
SOFA score	–15.4%	(–70.7, 21.9)	0.6374
APACHE-II	–36.6%	(–104.5, 8.6)	0.3201
P. aeruginosa PCR cycle threshold value	–19.7%	(–76.7, 18.8)	0.5534
Procalcitonin	–4.6%	(–58.9, 31.0)	0.8882
Neutrophil/lymphocyte ratio	–15.5%	(–75.9, 24.1)	0.6596
ANC	10.6%	(–33.9, 40.4)	0.7216
White blood cells	–14.5%	(–68.2, 22.0)	0.6506

RRR (MEDI3902 1500 mg versus placebo), 80% CI, and p-value based on unconditional CI on the ratio of proportions.
ANC, absolute neutrophil count; APACHE-II, Acute Physiology and Chronic Health Evaluation-II; CI, confidence interval; MV, mechanical ventilation; PCR, polymerase chain reaction; RRR, relative risk reduction; SOFA, Sequential Organ Failure Assessment.

- At baseline, 68.5% of the study population had procalcitonin levels ≤0.55 μg/L (n=56 and n=59 in MEDI3902 1500 mg and placebo groups, respectively, across the first 3 quartiles).
  - Post-hoc analyses suggested a RRR in *P. aeruginosa* pneumonia incidence of 47.3% for MEDI3902 versus placebo among these subjects (12.5% MEDI3902 1500 mg vs 23.7% placebo; 80% CI: 6.1%, 69.9%; P=0.135).
- A baseline ANC of ≤8170/μL was observed in 49.4% of subjects (n=36 and n=47 in MEDI3902 1500 mg and placebo groups, respectively, across the first 2 quartiles).
  - Post-hoc analyses suggested a RRR in *P. aeruginosa* pneumonia incidence of 83.6% for MEDI3902 versus placebo among these subjects (2.8% MEDI3902 vs 17.0% placebo; 80% CI: 39.5%, 95.5%; P=0.038).
  - The RRR in all-cause mortality was 56.5% for MEDI3902 versus placebo among these subjects (11.1% MEDI3902 vs 25.5% placebo; 80% CI: 11.9%, 79.4%; P=0.110).
- Subjects with procalcitonin <0.1 μg/L and ANC <12,600/μL also had slightly higher serum PK exposure (Figure 3).

Figure 3. Serum concentration–time profiles following a single IV dose of MEDI3902 1500 mg according to baseline procalcitonin (μg/L) and neutrophil count (10^3/μL) quartiles



IV, intravenous; SE, standard error.

Conclusions

- A single IV dose of MEDI3902 1500 mg provided PK exposure above the target level but did not achieve the primary efficacy endpoint of reduction of *P. aeruginosa* pneumonia incidence.
- The safety profile with MEDI3902 was acceptable, with a broadly similar incidence of TEAEs and SAEs between MEDI3902 and placebo groups.
- Post-hoc analyses suggested that subjects with lower baseline procalcitonin and neutrophil counts may experience greater MEDI3902 efficacy in reducing the incidence of *P. aeruginosa* pneumonia (RRR 47.3–83.6%), all-cause mortality (RRR 56.5% with ANC <8170/μL) compared with placebo, and corresponding higher mean MEDI3902 serum levels.
- MEDI3902 may be useful for preventing *P. aeruginosa* pneumonia in specific populations, such as ICU patients with lower baseline inflammation.

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Disclosures

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