



Clinical trial results:

A partially-blinded, active-controlled, multicenter, randomized study evaluating efficacy, safety, tolerability, pharmacokinetic (PK) and pharmacodynamic (PD) of an anti-CD40 monoclonal antibody, CFZ533, in de novo and maintenance kidney transplant recipients (CIRRUS I)

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.

Summary

EudraCT number	2017-003607-22
Trial protocol	SE NL NO FR GB DE ES CZ BE HU SK LV LT IT HR
Global end of trial date	29 October 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	CCFZ533A2201
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03663335
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No	No

1901/2006 apply to this trial?

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 October 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 October 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Primary objectives:

Cohort 1:

To demonstrate that CFZ533 600 mg and/or 300 mg bi-weekly (Q2W) subcutaneous (SC) are non-inferior to a Tacrolimus (TAC)-based regimen with respect to the proportion of patients who experience composite efficacy failure event (biopsy proven acute rejection (BPAR), graft loss, or death) over 12 months post-transplantation.

Cohort 2:

To demonstrate that CFZ533 450 mg bi-weekly (Q2W) subcutaneous (SC) is non-inferior to a TAC-based regimen with respect to the proportion of patients who experience composite efficacy failure event (biopsy proven acute rejection (BPAR), graft loss, or death) over 12 months post-conversion.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 November 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 19
Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	Belgium: 19
Country: Number of subjects enrolled	Brazil: 53
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Czechia: 14
Country: Number of subjects enrolled	France: 56
Country: Number of subjects enrolled	Germany: 20
Country: Number of subjects enrolled	Hungary: 7

Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Japan: 33
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Latvia: 3
Country: Number of subjects enrolled	Netherlands: 37
Country: Number of subjects enrolled	Norway: 9
Country: Number of subjects enrolled	Spain: 36
Country: Number of subjects enrolled	Sweden: 7
Country: Number of subjects enrolled	Switzerland: 2
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	United States: 61
Worldwide total number of subjects	403
EEA total number of subjects	214

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	357
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were enrolled at 74 sites. 403 patients were randomized.

Pre-assignment

Screening details:

This study comprised of a screening period.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS

Arm description:

Eligible patients were randomized to CFZ533 600 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 600 mg sc (2 injections of 2 mL CFZ533 at 150 mg/mL) Q2W, up to a planned Month 59.5 visit.

Arm type	Experimental
Investigational medicinal product name	Mycophenolate Mofetil (MMF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Capsule, Solution for injection/infusion
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Per local practice, 250 mg or 500 mg taken orally or 500 mg taken intravenously.

Investigational medicinal product name	Iscalimab
Investigational medicinal product code	CFZ533
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use, Intravenous use

Dosage and administration details:

CFZ533 600 mg was first administered intravenously and subcutaneously thereafter.

Investigational medicinal product name	Basiliximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Lyophilized solution taken intravenously

Investigational medicinal product name	Rabbit anti-thymocyte globulin (rATG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion

Routes of administration	Intravenous use
Dosage and administration details:	
Lyophilized vial taken intravenously	
Investigational medicinal product name	Corticosteroids
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Intravenous use, Oral use
Dosage and administration details:	
Taken either orally or intravenously.	
Arm title	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS
Arm description:	
Eligible patients were randomized to CFZ533 300 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 300 mg sc (1 injection of 2 mL CFZ533 at 150 mg/mL, and 1 injection of 2 mL of the generic placebo) sc, Q2W, up to a planned Month 59.5 visit.	
Arm type	Experimental
Investigational medicinal product name	Iscalimab
Investigational medicinal product code	CFZ533
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use, Subcutaneous use
Dosage and administration details:	
CFZ533 300 mg was first administered intravenously and subcutaneously thereafter.	
Investigational medicinal product name	Mycophenolate Mofetil (MMF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Capsule, Solution for injection/infusion
Routes of administration	Oral use, Intravenous use
Dosage and administration details:	
Per local practice, 250 mg or 500 mg taken orally or 500 mg taken intravenously.	
Investigational medicinal product name	Corticosteroids
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Intravenous use, Oral use
Dosage and administration details:	
Taken either orally or intravenously.	
Investigational medicinal product name	Basiliximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Lyophilized solution taken intravenously	
Investigational medicinal product name	Rabbit anti-thymocyte globulin (rATG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion

Routes of administration	Intravenous use
Dosage and administration details: Lyophilized vial taken intravenously	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Solution taken subcutaneously and was used for blinding of the CFZ533 doses	
Arm title	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
Arm description: Patients randomized to the TAC control arm were initiated on a TAC-based regimen with MMF and corticosteroids.	
Arm type	Active comparator
Investigational medicinal product name	Tacrolimus (TAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Standard of care immunosuppressive regimen	
Investigational medicinal product name	Corticosteroids
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Intravenous use, Oral use
Dosage and administration details: Taken either orally or intravenously.	
Investigational medicinal product name	Basiliximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: Lyophilized solution taken intravenously	
Investigational medicinal product name	Rabbit anti-thymocyte globulin (rATG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: Lyophilized vial taken intravenously	
Investigational medicinal product name	Mycophenolate Mofetil (MMF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Capsule, Solution for injection/infusion
Routes of administration	Oral use, Intravenous use
Dosage and administration details: Per local practice, 250 mg or 500 mg taken orally or 500 mg taken intravenously.	
Arm title	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF

± CS

Arm description:

Eligible patients who were 6 to 24 months post renal transplantation and were on a stable regimen containing TAC+MMF/Enteric-coated mycophenolate sodium (EC-MPS)±CS were randomized to CFZ533 450 mg sc Q2W. On Day 1, patients randomized to Arm 1 were administered the 1st dose of CFZ533 at 30 mg/kg IV, concomitantly with MMF/EC-MPS and 50% of the current TAC dose. At Day 15, CFZ533 was administered sc 450 mg (1 injection of 2 mL & 1 injection of 1 mL CFZ533 at 150 mg/mL) concomitantly with MMF/EC-MPS, and TAC reduced by a further 50%. By Day 29, patients were fully tapered off their TAC. Subsequent doses of 450 mg sc Q2W, were administered in combination with MMF/EC-MPS with or without corticosteroids, up to Month 59.5 visit.

Arm type	Experimental
Investigational medicinal product name	Iscalimab
Investigational medicinal product code	CFZ533
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

CFZ533 450 mg was first administered intravenously and subcutaneously thereafter.

Investigational medicinal product name	Mycophenolate Mofetil (MMF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Capsule, Solution for injection/infusion
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Per local practice, 250 mg or 500 mg taken orally or 500 mg taken intravenously.

Investigational medicinal product name	Corticosteroids
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Taken either orally or intravenously.

Investigational medicinal product name	Enteric-coated mycophenolate sodium (EC-MPS)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet that was taken orally

Arm title	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
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Arm description:

Patients received TAC-based regimen throughout the study.

Arm type	Active comparator
Investigational medicinal product name	Corticosteroids
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Dose was administered based on Investigator determination.

Investigational medicinal product name	Enteric-coated mycophenolate sodium (EC-MPS)
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Tablet that was taken orally	
Investigational medicinal product name	Mycophenolate Mofetil (MMF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet, Capsule, Solution for injection/infusion
Routes of administration	Intravenous use, Oral use
Dosage and administration details:	
Per local practice, 250 mg or 500 mg taken orally or 500 mg taken intravenously.	
Investigational medicinal product name	Tacrolimus (TAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Standard of care immunosuppressive regimen	

Number of subjects in period 1	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
Started	108	109	74
Completed	0	0	0
Not completed	108	109	74
Adverse event, serious fatal	9	1	2
Physician decision	-	-	-
Study terminated by Sponsor	71	73	53
Adverse event, non-fatal	8	19	3
Subject decision	3	5	3
Unsatisfactory therapeutic effect	5	2	1
Patient not continuing after Month12	12	9	11
Lost to follow-up	-	-	1

Number of subjects in period 1	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
Started	70	42
Completed	0	0
Not completed	70	42
Adverse event, serious fatal	1	2
Physician decision	-	1
Study terminated by Sponsor	60	33
Adverse event, non-fatal	6	-

Subject decision	-	4
Unsatisfactory therapeutic effect	-	-
Patient not continuing after Month12	3	2
Lost to follow-up	-	-

Baseline characteristics

Reporting groups

Reporting group title	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS
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Reporting group description:

Eligible patients were randomized to CFZ533 600 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 600 mg sc (2 injections of 2 mL CFZ533 at 150 mg/mL) Q2W, up to a planned Month 59.5 visit.

Reporting group title	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS
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Reporting group description:

Eligible patients were randomized to CFZ533 300 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 300 mg sc (1 injection of 2 mL CFZ533 at 150 mg/mL, and 1 injection of 2 mL of the generic placebo) sc, Q2W, up to a planned Month 59.5 visit.

Reporting group title	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
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Reporting group description:

Patients randomized to the TAC control arm were initiated on a TAC-based regimen with MMF and corticosteroids.

Reporting group title	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS
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Reporting group description:

Eligible patients who were 6 to 24 months post renal transplantation and were on a stable regimen containing TAC+MMF/Enteric-coated mycophenolate sodium (EC-MPS)±CS were randomized to CFZ533 450 mg sc Q2W. On Day 1, patients randomized to Arm 1 were administered the 1st dose of CFZ533 at 30 mg/kg IV, concomitantly with MMF/EC-MPS and 50% of the current TAC dose. At Day 15, CFZ533 was administered sc 450 mg (1 injection of 2 mL & 1 injection of 1 mL CFZ533 at 150 mg/mL) concomitantly with MMF/EC-MPS, and TAC reduced by a further 50%. By Day 29, patients were fully tapered off their TAC. Subsequent doses of 450 mg sc Q2W, were administered in combination with MMF/EC-MPS with or without corticosteroids, up to Month 59.5 visit.

Reporting group title	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
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Reporting group description:

Patients received TAC-based regimen throughout the study.

Reporting group values	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
Number of subjects	108	109	74
Age Categorical Units: Participants			
< 60 years	86	79	54
>= 60 6years	22	30	20
Sex: Female, Male Units: Participants			
Female	34	32	14
Male	74	77	60

Race/Ethnicity, Customized Units: Subjects			
White	84	86	59
Black or African American	14	6	6
Asian: Indian	2	0	0
Asian: Japanese	4	12	3
Asian: Korean	1	0	0
Multiple	3	4	3
American Indian or Alaskan Native	0	0	1
Asian - Other	0	1	2
Other - Unknown	0	0	0

Reporting group values	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS	Total
Number of subjects	70	42	403
Age Categorical Units: Participants			
< 60 years	53	32	304
>= 60 6years	17	10	99
Sex: Female, Male Units: Participants			
Female	18	14	112
Male	52	28	291
Race/Ethnicity, Customized Units: Subjects			
White	47	32	308
Black or African American	3	4	33
Asian: Indian	1	0	3
Asian: Japanese	12	4	35
Asian: Korean	3	0	4
Multiple	2	1	13
American Indian or Alaskan Native	0	0	1
Asian - Other	1	1	5
Other - Unknown	1	0	1

End points

End points reporting groups

Reporting group title	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS
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Reporting group description:

Eligible patients were randomized to CFZ533 600 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 600 mg sc (2 injections of 2 mL CFZ533 at 150 mg/mL) Q2W, up to a planned Month 59.5 visit.

Reporting group title	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS
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Reporting group description:

Eligible patients were randomized to CFZ533 300 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 300 mg sc (1 injection of 2 mL CFZ533 at 150 mg/mL, and 1 injection of 2 mL of the generic placebo) sc, Q2W, up to a planned Month 59.5 visit.

Reporting group title	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
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Reporting group description:

Patients randomized to the TAC control arm were initiated on a TAC-based regimen with MMF and corticosteroids.

Reporting group title	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS
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Reporting group description:

Eligible patients who were 6 to 24 months post renal transplantation and were on a stable regimen containing TAC+MMF/Enteric-coated mycophenolate sodium (EC-MPS)±CS were randomized to CFZ533 450 mg sc Q2W. On Day 1, patients randomized to Arm 1 were administered the 1st dose of CFZ533 at 30 mg/kg IV, concomitantly with MMF/EC-MPS and 50% of the current TAC dose. At Day 15, CFZ533 was administered sc 450 mg (1 injection of 2 mL & 1 injection of 1 mL CFZ533 at 150 mg/mL) concomitantly with MMF/EC-MPS, and TAC reduced by a further 50%. By Day 29, patients were fully tapered off their TAC. Subsequent doses of 450 mg sc Q2W, were administered in combination with MMF/EC-MPS with or without corticosteroids, up to Month 59.5 visit.

Reporting group title	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
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Reporting group description:

Patients received TAC-based regimen throughout the study.

Subject analysis set title	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Eligible patients were randomized to CFZ533 600 mg sc bi-weekly (Q2W) + Mycophenolate Mofetil (MMF) + Corticosteroids. Patients randomized to CFZ533 arms were administered the first dose of CFZ533 at 30 mg/kg IV pre- or intra-operatively (Day 1) with completion of the infusion within one hour of unclamping and prior graft revascularization, in combination with MMF and corticosteroids. MMF and corticosteroids might be initiated prior to surgery according to local practice. A second IV dose of CFZ533 at 15 mg/kg was infused at Day 5 post-transplant. Subsequent doses starting at Day 15: 600 mg sc (2 injections of 2 mL CFZ533 at 150 mg/mL) Q2W, up to a planned Month 59.5 visit.

Subject analysis set title	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Patients randomized to the TAC control arm were initiated on a TAC-based regimen with MMF and corticosteroids.

Subject analysis set title	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS
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Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Eligible patients who were 6 to 24 months post renal transplantation and were on a stable regimen containing TAC+MMF/Enteric-coated mycophenolate sodium (EC-MPS)±CS were randomized to CFZ533 450 mg sc Q2W.	
On Day 1, patients randomized to Arm 1 were administered the 1st dose of CFZ533 at 30 mg/kg IV, concomitantly with MMF/EC-MPS and 50% of the current TAC dose.	
At Day 15, CFZ533 was administered sc 450 mg (1 injection of 2 mL & 1 injection of 1 mL CFZ533 at 150 mg/mL) concomitantly with MMF/EC-MPS, and TAC reduced by a further 50%. By Day 29, patients were fully tapered off their TAC. Subsequent doses of 450 mg sc Q2W, were administered in combination with MMF/EC-MPS with or without corticosteroids, up to Month 59.5 visit.	
Subject analysis set title	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Patients received TAC-based regimen throughout the study.	

Primary: Percentage of participants with composite efficacy failure event (Biopsy Proven Acute Rejection (BPAR), Graft Loss or Death) over 12 months post-transplantation (Cohort 1)

End point title	Percentage of participants with composite efficacy failure event (Biopsy Proven Acute Rejection (BPAR), Graft Loss or Death) over 12 months post-transplantation (Cohort 1) ^[1]
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End point description:

The composite efficacy failure event is defined as any of the following:

(1) biopsy-proven acute rejection (BPAR) or (2) graft loss or (3) death. BPAR (BANFF ≥ 1A) is based on the central and adjudicated assessments. Graft loss is defined as when the allograft was presumed lost on the day the participant started dialysis and was not able to subsequently be removed from dialysis or re-transplanted. If the participant underwent allograft nephrectomy prior to start of permanent dialysis, the day of the nephrectomy was day of graft loss.

End point type	Primary
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End point timeframe:

12 Months

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The statistical analysis is only being presented here for arms in this cohort (Cohort 1) and not for all arms in the baseline period.

End point values	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	41	
Units: Percentage of participants				
number (not applicable)	60.6	38.6	22.0	

Statistical analyses

Statistical analysis title	CFZ533 300 mg vs. TAC
Comparison groups	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS v Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS

Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
Parameter estimate	Rate Difference
Point estimate	5.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.67
upper limit	16.9

Notes:

[2] - less than a non-inferiority (NI) margin of 20% in the de novo cohort (Cohort 1)

Statistical analysis title	CFZ533 600 mg vs. TAC
Comparison groups	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS v Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
Parameter estimate	Rate Difference
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.86
upper limit	27.74

Notes:

[3] - less than a non-inferiority (NI) margin of 20% in the de novo cohort (Cohort 1)

Primary: Percentage of participants with composite efficacy failure event (BPAR, Graft Loss or Death) over 12 months post-conversion (Cohort 2)

End point title	Percentage of participants with composite efficacy failure event (BPAR, Graft Loss or Death) over 12 months post-conversion (Cohort 2) ^[4]
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End point description:

The composite efficacy failure event is defined as any of the following:

(1) biopsy-proven acute rejection (BPAR) or (2) graft loss or (3) death. BPAR (BANFF $\geq$ 1A) is based on the central and adjudicated assessments. Graft loss is defined as when the allograft was presumed lost on the day the participant started dialysis and was not able to subsequently be removed from dialysis or re-transplanted. If the participant underwent allograft nephrectomy prior to start of permanent dialysis, the day of the nephrectomy was day of graft loss.

End point type	Primary
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End point timeframe:

12 Months

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The statistical analysis is only being presented here for arms in this cohort (Cohort 2) and not for all arms in the baseline period.

End point values	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	18		
Units: Percentage of participants				
number (not applicable)	14.7	11.1		

Statistical analyses

Statistical analysis title	CFZ533 450 mg vs TAC
Comparison groups	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS v Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
Parameter estimate	Rate Difference
Point estimate	-1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.24
upper limit	11.39

Notes:

[5] - less than a non-inferiority (NI) margin of 20% in the de novo cohort (Cohort 1)

Secondary: Cohort 1: Mean estimated Glomerular Filtration Rate (eGFR) ((MDR4) at 12 months post-transplantation

End point title	Cohort 1: Mean estimated Glomerular Filtration Rate (eGFR) ((MDR4) at 12 months post-transplantation ^[6]
End point description:	In the de novo population (Cohort 1), the mean eGFR at Month 12 post-transplantation was the endpoint of interest. Estimated GFR using central laboratory serum creatinine values was calculated using the MDRD-4 formula.
End point type	Secondary
End point timeframe:	12 months

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The statistical analysis is only being presented here for arms in this cohort (Cohort 1) and not for all arms in the baseline period.

End point values	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	58	51	
Units: mL/min/1.73m**2				
arithmetic mean (standard error)	58.83 (± 1.971)	60.63 (± 1.976)	54.12 (± 2.101)	

Statistical analyses

Statistical analysis title	CFZ533 600 mg vs TAC (mean eGFR)
Comparison groups	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS v Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.103
Method	ANOVA
Parameter estimate	mean difference
Point estimate	4.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	10.38
Variability estimate	Standard deviation
Dispersion value	2.873

Statistical analysis title	CFZ533 300 mg vs TAC (mean eGFR)
Comparison groups	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS v Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025
Method	ANOVA
Parameter estimate	mean difference
Point estimate	6.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	12.18
Variability estimate	Standard error of the mean
Dispersion value	2.875

Secondary: Cohort 2: Mean change in estimated Glomerular Filtration Rate (eGFR) ((MDR4) at 12 months post-conversion

End point title	Cohort 2: Mean change in estimated Glomerular Filtration Rate (eGFR) ((MDR4) at 12 months post-conversion ^[7]
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End point description:

In the maintenance population (Cohort 2), a baseline kidney function and the mean change from baseline at Month 12 post-conversion of eGFR was the endpoint of interest. Estimated GFR using central laboratory serum creatinine values was calculated using the MDRD-4 formula.

End point type	Secondary
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End point timeframe:

12 months

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The statistical analysis is only being presented here for arms in this cohort (Cohort 2) and not for all arms in the baseline period.

End point values	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	27		
Units: mL/min/1.73m ²				
arithmetic mean (standard error)	4.30 (± 1.722)	1.42 (± 1.866)		

Statistical analyses

Statistical analysis title	CFZ533 450 mg vs TAC (mean change in eGFR)
Comparison groups	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS v Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.153
Method	ANOVA
Parameter estimate	mean change difference
Point estimate	2.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	6.85
Variability estimate	Standard error of the mean
Dispersion value	1.987

Secondary: Free CFZ533 plasma concentrations over time (Cohort 1)

End point title	Free CFZ533 plasma concentrations over time (Cohort 1) ^[8]
End point description:	Pharmacokinetics were determined for free CFZ533 plasma concentrations during the treatment period.
End point type	Secondary
End point timeframe:	60 Months

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis was planned for this endpoint.

End point values	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	109	110	70	
Units: µg/mL				
arithmetic mean (standard deviation)				
Day 1 Pre-dose (n = 96, 94, 0)	0.00 (± 0.000)	0.00 (± 0.000)	999 (± 999)	
Day 1 post-dose (n = 106, 106, 0)	441.67 (± 246.474)	471.20 (± 222.169)	999 (± 999)	
Day 5 pre-dose (n = 95, 97, 0)	205.16 (± 77.632)	231.93 (± 102.947)	999 (± 999)	
Day 5 post-dose (n = 98, 99, 0)	502.32 (± 186.159)	502.48 (± 211.592)	999 (± 999)	
Day 15 pre-dose (n = 104, 98, 0)	242.99 (± 83.780)	251.17 (± 92.466)	999 (± 999)	
Day 29 pre-dose (n = 98, 95, 0)	187.38 (± 79.884)	197.47 (± 74.937)	999 (± 999)	
Month 1.5 pre-dose (n = 93, 93, 0)	122.80 (± 38.604)	172.84 (± 67.444)	999 (± 999)	
Month 2 pre-dose (n = 89, 90, 0)	102.52 (± 33.798)	155.68 (± 64.661)	999 (± 999)	
Month 2.5 pre-dose (n = 86, 88, 0)	85.21 (± 34.835)	151.81 (± 58.367)	999 (± 999)	
Month 3 pre-dose (n = 84, 83, 0)	86.16 (± 35.463)	147.62 (± 51.971)	999 (± 999)	
Month 4 pre-dose (n = 81, 72, 0)	68.72 (± 27.269)	159.58 (± 70.382)	999 (± 999)	
Month 6 pre-dose (n = 69, 77, 0)	73.27 (± 35.126)	161.21 (± 63.195)	999 (± 999)	
Month 8 pre-dose (n = 60, 64, 0)	71.92 (± 33.683)	151.34 (± 52.778)	999 (± 999)	
Month 10 pre-dose (n = 56, 58, 0)	62.55 (± 31.199)	141.18 (± 46.999)	999 (± 999)	
Month 12 pre-dose (n = 51, 55, 0)	56.81 (± 30.717)	148.71 (± 62.106)	999 (± 999)	
Month 15 pre-dose (n = 36, 40, 0)	48.37 (± 20.604)	149.86 (± 58.888)	999 (± 999)	
Month 18 pre-dose (n = 43, 37, 0)	49.68 (± 31.768)	122.24 (± 54.056)	999 (± 999)	

Month 21 pre-dose (n = 40, 32, 0)	59.96 (± 36.583)	132.51 (± 65.146)	999 (± 999)	
Month 24 pre-dose (n = 36, 33, 0)	60.96 (± 31.988)	139.55 (± 53.177)	999 (± 999)	
Month 30 pre-dose (n = 11, 12, 0)	56.63 (± 23.195)	140.80 (± 47.339)	999 (± 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Free CFZ533 plasma concentrations over time (Cohort 2)

End point title	Free CFZ533 plasma concentrations over time (Cohort 2) ^[9]
End point description:	Pharmacokinetics were determined for free CFZ533 plasma concentrations during the treatment period.
End point type	Secondary
End point timeframe:	60 Months

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint.

End point values	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	70	40		
Units: µg/mL				
arithmetic mean (standard deviation)				
Day 1 Pre-dose (n = 67, 0)	0.00 (± 0.000)	999 (± 999)		
Day 1 post-dose (n = 68, 0)	681.59 (± 698.086)	999 (± 999)		
Day 15 pre-dose (n = 67, 0)	181.81 (± 72.297)	999 (± 999)		
Day 29 pre-dose (n = 65, 0)	147.56 (± 43.749)	999 (± 999)		
Month 1.5 pre-dose (n = 65, 0)	127.55 (± 39.794)	999 (± 999)		
Month 2 pre-dose (n = 61, 0)	121.81 (± 44.801)	999 (± 999)		
Month 2.5 pre-dose (n = 66, 0)	114.53 (± 44.759)	999 (± 999)		
Month 3 pre-dose (n = 63, 0)	104.40 (± 42.563)	999 (± 999)		
Month 4 pre-dose (n = 62, 0)	108.61 (± 51.790)	999 (± 999)		
Month 6 pre-dose (n = 56, 0)	112.14 (± 46.932)	999 (± 999)		
Month 8 pre-dose (n = 51, 0)	118.08 (± 42.868)	999 (± 999)		

Month 10 pre-dose (n = 41, 0)	106.98 (± 53.798)	999 (± 999)		
Month 12 pre-dose (n = 37, 0)	111.05 (± 54.629)	999 (± 999)		
Month 15 pre-dose (n = 25, 0)	104.11 (± 67.744)	999 (± 999)		
Month 18 pre-dose (n = 24, 0)	115.59 (± 66.227)	999 (± 999)		
Month 21 pre-dose (n = 24, 0)	116.89 (± 53.953)	999 (± 999)		
Month 24 pre-dose (n = 18, 0)	111.03 (± 39.901)	999 (± 999)		
Month 30 pre-dose (n = 3, 0)	132.97 (± 65.132)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Semi-quantitative analysis of anti-CFZ533 antibodies in plasma (CFZ533 treated patients only) (Cohort 1)

End point title	Semi-quantitative analysis of anti-CFZ533 antibodies in plasma (CFZ533 treated patients only) (Cohort 1) ^[10]
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End point description:

The presence of anti-CFZ533 antibodies was assessed using screening and confirmatory assays.

End point type	Secondary
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End point timeframe:

60 Months

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis was planned for this endpoint.

End point values	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	109	110		
Units: Participants				
Subject with an on-study result	108	109		
Binding antibody positive at any time	0	2		
Subject with a result at baseline	101	104		
Binding antibody positive at or before baseline	0	0		
Subject with a post-baseline result	103	102		
ADA positive post-dose with positive result at BL	0	0		
ADA positive post-dose with negative result at BL	0	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Semi-quantitative analysis of anti-CFZ533 antibodies in plasma (CFZ533 treated patients only) (Cohort 2)

End point title	Semi-quantitative analysis of anti-CFZ533 antibodies in plasma (CFZ533 treated patients only) (Cohort 2) ^[11]
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End point description:

The presence of anti-CFZ533 antibodies was assessed using screening and confirmatory assays.

End point type	Secondary
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End point timeframe:

60 Months

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis was planned for this endpoint.

End point values	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Participants				
Subject with an on-study result	70			
Binding antibody positive at any time	0			
Subject with a result at baseline	68			
Binding antibody positive at or before baseline	0			
Subject with a post-baseline result	69			
ADA positive post-dose with positive result at BL	0			
ADA positive post-dose with -ve or no result at BL	0			

Statistical analyses

No statistical analyses for this end point

Post-hoc: All Collected Deaths

End point title	All Collected Deaths ^[12]
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End point description:

On-treatment deaths were collected from start of First Patient First Treatment (FPFT) up to last dose of assigned treatment, for a maximum duration of approx. 2.9 years.

Randomized but not treated deaths were collected after randomization but before treatment with study drug.

Deaths post-treatment survival follow-up were collected after last dose of assigned treatment until end of study participation.

Deaths Post-study participation were collected after patients completed trial participation but before LPLV of the study.

End point type	Post-hoc
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End point timeframe:

from FPFT to last on-treatment death (76 weeks), from FPFT to LPLV (2.9 years)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis was planned for this endpoint.

End point values	Arm 1/Cohort 1 (De Novo Cohort): CFZ533 600 mg + MMF + CS	Arm 2/Cohort 1 (De Novo Cohort): CFZ533 300 mg + MMF + CS	Arm 3/Cohort 1 (De Novo Cohort): TAC + MMF + CS	Arm 1/Cohort 2 Maintenance Cohort): CFZ533 450 mg + MMF ± CS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	108	109	74	70
Units: Participants				
Total Deaths	9	2	2	2
Deaths On-treatment	2	0	1	0
Deaths Post-treatment	7	1	0	1
Deaths - Randomized, not treated	0	0	1	0
Deaths Post-study participation	0	1	0	1

End point values	Arm 2/Cohort 2 (Maintenance Cohort): TAC+ MMF ± CS			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: Participants				
Total Deaths	2			
Deaths On-treatment	0			
Deaths Post-treatment	2			
Deaths - Randomized, not treated	0			
Deaths Post-study participation	0			

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were reported from first dose of study treatment until LPLV, up to approx. 2.9 years.

Adverse event reporting additional description:

Adverse Events (AE): Any sign or symptom that occurs during treatment up to end of study, approx. 2.9 years, for a median duration of exposure to CFZ533 600 mg of 365.5 days, to CFZ533 300 mg of 365 days and to TAC of 414 days (Cohort 1). The median duration of exposure to CFZ533 450 mg was 372 days & to TAC was 389.5 days (Cohort 2).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	De Novo Cohort: CFZ533 300 mg + MMF + CS
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Reporting group description:

De Novo Cohort: CFZ533 300 mg + MMF + CS

Reporting group title	De Novo Cohort: CFZ533 600 mg + MMF + CS
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Reporting group description:

De Novo Cohort: CFZ533 600 mg + MMF + CS

Reporting group title	Maintenance Cohort: CFZ533 450 mg + MMF +/- CS
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Reporting group description:

Maintenance Cohort: CFZ533 450 mg + MMF +/- CS

Reporting group title	Maintenance Cohort: TAC + MMF +/- CS
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Reporting group description:

Maintenance Cohort: TAC + MMF +/- CS

Reporting group title	De Novo Cohort: TAC + MMF + CS
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Reporting group description:

De Novo Cohort: TAC + MMF + CS

Serious adverse events	De Novo Cohort: CFZ533 300 mg + MMF + CS	De Novo Cohort: CFZ533 600 mg + MMF + CS	Maintenance Cohort: CFZ533 450 mg + MMF +/- CS
Total subjects affected by serious adverse events			
subjects affected / exposed	76 / 109 (69.72%)	71 / 108 (65.74%)	25 / 70 (35.71%)
number of deaths (all causes)	1	9	1
number of deaths resulting from adverse events	1	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma			

subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial stenosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial thrombosis			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery stenosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery stenosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			

subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			

subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	5 / 109 (4.59%)	4 / 108 (3.70%)	4 / 70 (5.71%)
occurrences causally related to treatment / all	3 / 7	0 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant rejection			
subjects affected / exposed	10 / 109 (9.17%)	16 / 108 (14.81%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	6 / 11	10 / 18	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	3 / 109 (2.75%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 109 (0.00%)	4 / 108 (3.70%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose increased			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			

subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Arteriovenous fistula thrombosis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complications of transplanted kidney			
subjects affected / exposed	3 / 109 (2.75%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delayed graft function			
subjects affected / exposed	3 / 109 (2.75%)	6 / 108 (5.56%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft ischaemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft loss			

subjects affected / exposed	3 / 109 (2.75%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve injury			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 109 (0.00%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative lymphocele			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound complication			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural shock			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant dysfunction			
subjects affected / exposed	0 / 109 (0.00%)	4 / 108 (3.70%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			

subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 109 (0.00%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive encephalopathy			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic neuropathy			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mononeuropathy multiplex			

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadrantanopia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculitis brachial			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 109 (0.00%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 109 (1.83%)	2 / 108 (1.85%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	4 / 109 (3.67%)	1 / 108 (0.93%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	3 / 4	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphopenia			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Eye disorders			
Photophobia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain upper				
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Ascites				
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Colitis				
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Constipation				
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Diarrhoea				
subjects affected / exposed	2 / 109 (1.83%)	1 / 108 (0.93%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Enteritis				
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Food poisoning				
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Ileus				
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Inguinal hernia				

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stasis dermatitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	4 / 109 (3.67%)	3 / 108 (2.78%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 4	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric collection			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst haemorrhage			

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal ischaemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric stenosis			

subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary fistula			
subjects affected / exposed	0 / 109 (0.00%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract disorder			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperaldosteronism			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism secondary			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BK virus infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchitis			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	3 / 109 (2.75%)	5 / 108 (4.63%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral toxoplasmosis			

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Clostridium difficile colitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptococcal meningoencephalitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cytomegalovirus chorioretinitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus gastritis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus hepatitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			

subjects affected / exposed	11 / 109 (10.09%)	16 / 108 (14.81%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	9 / 23	13 / 23	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cytomegalovirus infection reactivation			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected lymphocele			

subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus B19 infection			

subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 109 (0.00%)	3 / 108 (2.78%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyomavirus-associated nephropathy			
subjects affected / exposed	5 / 109 (4.59%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	4 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis Escherichia coli			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	2 / 70 (2.86%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Septic shock			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			

subjects affected / exposed	1 / 109 (0.92%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxoplasmosis			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Upper respiratory tract infection			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	6 / 109 (5.50%)	5 / 108 (4.63%)	5 / 70 (7.14%)
occurrences causally related to treatment / all	3 / 6	1 / 11	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	2 / 109 (1.83%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic complication			

subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercreatininaemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 109 (0.00%)	0 / 108 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Maintenance Cohort: TAC + MMF +/- CS	De Novo Cohort: TAC + MMF + CS	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 42 (26.19%)	39 / 73 (53.42%)	
number of deaths (all causes)	2	1	
number of deaths resulting from adverse events	0	0	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian adenoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	2 / 42 (4.76%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Arterial stenosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haematoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery stenosis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant rejection			
subjects affected / exposed	0 / 42 (0.00%)	6 / 73 (8.22%)	
occurrences causally related to treatment / all	0 / 0	3 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			

subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood glucose increased subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Arteriovenous fistula thrombosis subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complications of transplanted kidney subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delayed graft function subjects affected / exposed	0 / 42 (0.00%)	4 / 73 (5.48%)	
occurrences causally related to treatment / all	0 / 0	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft complication subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Graft ischaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft loss			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve injury			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative lymphocele			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural shock			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant dysfunction			

subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial infarction			

subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic neuropathy			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononeuropathy multiplex			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadrantanopia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculitis brachial			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilia			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphopenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Photophobia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 42 (2.38%)	7 / 73 (9.59%)	
occurrences causally related to treatment / all	0 / 1	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinephric collection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst haemorrhage			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal ischaemia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal vein thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcapsular renal haematoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary fistula			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract disorder			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperaldosteronism			

subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BK virus infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bacteraemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	2 / 42 (4.76%)	3 / 73 (4.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral toxoplasmosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptococcal meningoencephalitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus chorioretinitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus colitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus gastritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus hepatitis			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected lymphocele			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			

subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parvovirus B19 infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 42 (4.76%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyomavirus-associated nephropathy			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis Escherichia coli			

subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected COVID-19			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxoplasmosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 42 (2.38%)	6 / 73 (8.22%)	
occurrences causally related to treatment / all	0 / 1	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			

subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetic complication			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercreatininaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	De Novo Cohort: CFZ533 300 mg + MMF + CS	De Novo Cohort: CFZ533 600 mg + MMF + CS	Maintenance Cohort: CFZ533 450 mg + MMF +/- CS
Total subjects affected by non-serious adverse events			
subjects affected / exposed	102 / 109 (93.58%)	105 / 108 (97.22%)	54 / 70 (77.14%)
Vascular disorders			
Haematoma			
subjects affected / exposed	3 / 109 (2.75%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences (all)	3	1	0
Hypertension			
subjects affected / exposed	29 / 109 (26.61%)	36 / 108 (33.33%)	12 / 70 (17.14%)
occurrences (all)	36	48	14
Hypotension			
subjects affected / exposed	5 / 109 (4.59%)	12 / 108 (11.11%)	1 / 70 (1.43%)
occurrences (all)	5	13	1
Lymphocele			
subjects affected / exposed	7 / 109 (6.42%)	4 / 108 (3.70%)	0 / 70 (0.00%)
occurrences (all)	7	4	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 109 (2.75%)	2 / 108 (1.85%)	4 / 70 (5.71%)
occurrences (all)	3	2	4
Fatigue			
subjects affected / exposed	4 / 109 (3.67%)	10 / 108 (9.26%)	0 / 70 (0.00%)
occurrences (all)	4	12	0
Oedema peripheral			
subjects affected / exposed	13 / 109 (11.93%)	21 / 108 (19.44%)	4 / 70 (5.71%)
occurrences (all)	18	29	4
Pyrexia			
subjects affected / exposed	17 / 109 (15.60%)	20 / 108 (18.52%)	7 / 70 (10.00%)
occurrences (all)	18	22	9
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 109 (6.42%)	11 / 108 (10.19%)	6 / 70 (8.57%)
occurrences (all)	8	13	10

Dyspnoea subjects affected / exposed occurrences (all)	5 / 109 (4.59%) 5	9 / 108 (8.33%) 11	1 / 70 (1.43%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	5 / 109 (4.59%) 6	10 / 108 (9.26%) 10	2 / 70 (2.86%) 4
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	8 / 109 (7.34%) 8	9 / 108 (8.33%) 14	1 / 70 (1.43%) 3
Investigations Blood creatinine increased subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 7	4 / 108 (3.70%) 4	3 / 70 (4.29%) 6
Cytomegalovirus test positive subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3	1 / 108 (0.93%) 1	1 / 70 (1.43%) 1
Lymphocyte count decreased subjects affected / exposed occurrences (all)	5 / 109 (4.59%) 6	10 / 108 (9.26%) 14	3 / 70 (4.29%) 4
Neutrophil count decreased subjects affected / exposed occurrences (all)	5 / 109 (4.59%) 7	13 / 108 (12.04%) 23	1 / 70 (1.43%) 2
SARS-CoV-2 test negative subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 10	1 / 108 (0.93%) 1	0 / 70 (0.00%) 0
Injury, poisoning and procedural complications Delayed graft function subjects affected / exposed occurrences (all)	8 / 109 (7.34%) 8	7 / 108 (6.48%) 7	0 / 70 (0.00%) 0
Transplant dysfunction subjects affected / exposed occurrences (all)	4 / 109 (3.67%) 5	8 / 108 (7.41%) 10	1 / 70 (1.43%) 1
Procedural pain subjects affected / exposed occurrences (all)	19 / 109 (17.43%) 19	13 / 108 (12.04%) 15	0 / 70 (0.00%) 0

Nervous system disorders	Dizziness			
	subjects affected / exposed	3 / 109 (2.75%)	3 / 108 (2.78%)	1 / 70 (1.43%)
	occurrences (all)	3	4	1
	Tremor			
	subjects affected / exposed	5 / 109 (4.59%)	2 / 108 (1.85%)	0 / 70 (0.00%)
	occurrences (all)	6	2	0
Headache	subjects affected / exposed	11 / 109 (10.09%)	15 / 108 (13.89%)	6 / 70 (8.57%)
	occurrences (all)	18	21	7
Blood and lymphatic system disorders				
Anaemia	subjects affected / exposed	23 / 109 (21.10%)	36 / 108 (33.33%)	4 / 70 (5.71%)
	occurrences (all)	27	37	4
Leukocytosis	subjects affected / exposed	3 / 109 (2.75%)	6 / 108 (5.56%)	0 / 70 (0.00%)
	occurrences (all)	3	6	0
Leukopenia	subjects affected / exposed	31 / 109 (28.44%)	31 / 108 (28.70%)	9 / 70 (12.86%)
	occurrences (all)	40	44	11
Lymphopenia	subjects affected / exposed	16 / 109 (14.68%)	14 / 108 (12.96%)	3 / 70 (4.29%)
	occurrences (all)	20	17	3
Polycythaemia	subjects affected / exposed	1 / 109 (0.92%)	2 / 108 (1.85%)	0 / 70 (0.00%)
	occurrences (all)	1	2	0
Neutropenia	subjects affected / exposed	13 / 109 (11.93%)	9 / 108 (8.33%)	7 / 70 (10.00%)
	occurrences (all)	16	9	9
Gastrointestinal disorders				
Abdominal pain upper	subjects affected / exposed	2 / 109 (1.83%)	3 / 108 (2.78%)	4 / 70 (5.71%)
	occurrences (all)	2	3	4
Constipation	subjects affected / exposed	21 / 109 (19.27%)	30 / 108 (27.78%)	3 / 70 (4.29%)
	occurrences (all)	26	41	3
Abdominal pain				

subjects affected / exposed	10 / 109 (9.17%)	8 / 108 (7.41%)	4 / 70 (5.71%)
occurrences (all)	12	10	4
Diarrhoea			
subjects affected / exposed	25 / 109 (22.94%)	19 / 108 (17.59%)	11 / 70 (15.71%)
occurrences (all)	31	26	13
Dyspepsia			
subjects affected / exposed	2 / 109 (1.83%)	4 / 108 (3.70%)	1 / 70 (1.43%)
occurrences (all)	3	5	1
Haemorrhoids			
subjects affected / exposed	5 / 109 (4.59%)	6 / 108 (5.56%)	1 / 70 (1.43%)
occurrences (all)	6	7	1
Nausea			
subjects affected / exposed	13 / 109 (11.93%)	13 / 108 (12.04%)	0 / 70 (0.00%)
occurrences (all)	17	13	0
Vomiting			
subjects affected / exposed	10 / 109 (9.17%)	12 / 108 (11.11%)	1 / 70 (1.43%)
occurrences (all)	10	12	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 109 (0.92%)	6 / 108 (5.56%)	1 / 70 (1.43%)
occurrences (all)	1	8	1
Rash			
subjects affected / exposed	2 / 109 (1.83%)	6 / 108 (5.56%)	2 / 70 (2.86%)
occurrences (all)	2	8	2
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	11 / 109 (10.09%)	3 / 108 (2.78%)	0 / 70 (0.00%)
occurrences (all)	11	4	0
Haematuria			
subjects affected / exposed	7 / 109 (6.42%)	5 / 108 (4.63%)	1 / 70 (1.43%)
occurrences (all)	7	6	1
Perinephric collection			
subjects affected / exposed	2 / 109 (1.83%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences (all)	2	1	0
Proteinuria			

subjects affected / exposed occurrences (all)	7 / 109 (6.42%) 7	6 / 108 (5.56%) 6	6 / 70 (8.57%) 6
Renal impairment subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 6	3 / 108 (2.78%) 3	0 / 70 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 7	6 / 108 (5.56%) 6	3 / 70 (4.29%) 6
Back pain subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 3	5 / 108 (4.63%) 5	3 / 70 (4.29%) 3
Groin pain subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	1 / 108 (0.93%) 1	0 / 70 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	3 / 108 (2.78%) 3	2 / 70 (2.86%) 2
Infections and infestations			
BK virus infection subjects affected / exposed occurrences (all)	11 / 109 (10.09%) 11	13 / 108 (12.04%) 14	1 / 70 (1.43%) 1
Bronchitis subjects affected / exposed occurrences (all)	4 / 109 (3.67%) 6	7 / 108 (6.48%) 11	0 / 70 (0.00%) 0
COVID-19 subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 7	9 / 108 (8.33%) 10	2 / 70 (2.86%) 2
Herpes zoster subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	4 / 108 (3.70%) 6	3 / 70 (4.29%) 3
Cytomegalovirus infection subjects affected / exposed occurrences (all)	8 / 109 (7.34%) 14	15 / 108 (13.89%) 19	2 / 70 (2.86%) 2
Gastroenteritis			

subjects affected / exposed	1 / 109 (0.92%)	3 / 108 (2.78%)	4 / 70 (5.71%)
occurrences (all)	1	3	5
Upper respiratory tract infection			
subjects affected / exposed	6 / 109 (5.50%)	8 / 108 (7.41%)	2 / 70 (2.86%)
occurrences (all)	11	8	2
Oral herpes			
subjects affected / exposed	1 / 109 (0.92%)	7 / 108 (6.48%)	4 / 70 (5.71%)
occurrences (all)	1	12	6
Nasopharyngitis			
subjects affected / exposed	6 / 109 (5.50%)	8 / 108 (7.41%)	5 / 70 (7.14%)
occurrences (all)	10	11	6
Urinary tract infection			
subjects affected / exposed	27 / 109 (24.77%)	19 / 108 (17.59%)	5 / 70 (7.14%)
occurrences (all)	39	27	8
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	3 / 109 (2.75%)	6 / 108 (5.56%)	1 / 70 (1.43%)
occurrences (all)	3	6	1
Dyslipidaemia			
subjects affected / exposed	4 / 109 (3.67%)	1 / 108 (0.93%)	2 / 70 (2.86%)
occurrences (all)	5	1	2
Gout			
subjects affected / exposed	1 / 109 (0.92%)	1 / 108 (0.93%)	0 / 70 (0.00%)
occurrences (all)	1	1	0
Hypercalcaemia			
subjects affected / exposed	7 / 109 (6.42%)	5 / 108 (4.63%)	1 / 70 (1.43%)
occurrences (all)	8	5	1
Hyperkalaemia			
subjects affected / exposed	8 / 109 (7.34%)	18 / 108 (16.67%)	1 / 70 (1.43%)
occurrences (all)	8	19	1
Hyperglycaemia			
subjects affected / exposed	16 / 109 (14.68%)	12 / 108 (11.11%)	1 / 70 (1.43%)
occurrences (all)	18	13	1
Hypervolaemia			
subjects affected / exposed	3 / 109 (2.75%)	6 / 108 (5.56%)	0 / 70 (0.00%)
occurrences (all)	3	6	0

Hypocalcaemia subjects affected / exposed occurrences (all)	7 / 109 (6.42%) 10	5 / 108 (4.63%) 5	0 / 70 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	13 / 109 (11.93%) 13	21 / 108 (19.44%) 23	1 / 70 (1.43%) 1
Hypophosphataemia subjects affected / exposed occurrences (all)	14 / 109 (12.84%) 15	12 / 108 (11.11%) 12	3 / 70 (4.29%) 3
Hypomagnesaemia subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3	7 / 108 (6.48%) 8	0 / 70 (0.00%) 0
Hypovolaemia subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3	4 / 108 (3.70%) 4	0 / 70 (0.00%) 0
Iron deficiency subjects affected / exposed occurrences (all)	7 / 109 (6.42%) 7	1 / 108 (0.93%) 1	1 / 70 (1.43%) 1
Metabolic acidosis subjects affected / exposed occurrences (all)	7 / 109 (6.42%) 7	5 / 108 (4.63%) 6	0 / 70 (0.00%) 0
Steroid diabetes subjects affected / exposed occurrences (all)	7 / 109 (6.42%) 7	9 / 108 (8.33%) 10	0 / 70 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	6 / 108 (5.56%) 6	1 / 70 (1.43%) 1

Non-serious adverse events	Maintenance Cohort: TAC + MMF +/- CS	De Novo Cohort: TAC + MMF + CS	
Total subjects affected by non-serious adverse events subjects affected / exposed	26 / 42 (61.90%)	67 / 73 (91.78%)	
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	4 / 73 (5.48%) 4	
Hypertension			

subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	15 / 73 (20.55%) 15	
Hypotension subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	5 / 73 (6.85%) 6	
Lymphocele subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 73 (0.00%) 0	
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	1 / 73 (1.37%) 1	
Fatigue subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	2 / 73 (2.74%) 2	
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	7 / 73 (9.59%) 9	
Pyrexia subjects affected / exposed occurrences (all)	4 / 42 (9.52%) 4	4 / 73 (5.48%) 5	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2	2 / 73 (2.74%) 2	
Dyspnoea subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2	5 / 73 (6.85%) 6	
Oropharyngeal pain subjects affected / exposed occurrences (all)	4 / 42 (9.52%) 4	2 / 73 (2.74%) 2	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	7 / 73 (9.59%) 9	
Investigations			

Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	5 / 73 (6.85%) 9	
Cytomegalovirus test positive subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	4 / 73 (5.48%) 5	
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 73 (2.74%) 2	
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 73 (0.00%) 0	
SARS-CoV-2 test negative subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	3 / 73 (4.11%) 5	
Injury, poisoning and procedural complications			
Delayed graft function subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 73 (2.74%) 2	
Transplant dysfunction subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	0 / 73 (0.00%) 0	
Procedural pain subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	4 / 73 (5.48%) 4	
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	2 / 73 (2.74%) 2	
Tremor subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 4	11 / 73 (15.07%) 11	
Headache subjects affected / exposed occurrences (all)	4 / 42 (9.52%) 4	8 / 73 (10.96%) 10	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	3 / 42 (7.14%)	12 / 73 (16.44%)	
occurrences (all)	3	13	
Leukocytosis			
subjects affected / exposed	0 / 42 (0.00%)	3 / 73 (4.11%)	
occurrences (all)	0	3	
Leukopenia			
subjects affected / exposed	1 / 42 (2.38%)	16 / 73 (21.92%)	
occurrences (all)	1	16	
Lymphopenia			
subjects affected / exposed	1 / 42 (2.38%)	5 / 73 (6.85%)	
occurrences (all)	1	6	
Polycythaemia			
subjects affected / exposed	1 / 42 (2.38%)	4 / 73 (5.48%)	
occurrences (all)	1	4	
Neutropenia			
subjects affected / exposed	1 / 42 (2.38%)	2 / 73 (2.74%)	
occurrences (all)	1	2	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 42 (0.00%)	6 / 73 (8.22%)	
occurrences (all)	0	7	
Constipation			
subjects affected / exposed	1 / 42 (2.38%)	12 / 73 (16.44%)	
occurrences (all)	1	12	
Abdominal pain			
subjects affected / exposed	3 / 42 (7.14%)	5 / 73 (6.85%)	
occurrences (all)	3	7	
Diarrhoea			
subjects affected / exposed	4 / 42 (9.52%)	20 / 73 (27.40%)	
occurrences (all)	5	23	
Dyspepsia			
subjects affected / exposed	0 / 42 (0.00%)	4 / 73 (5.48%)	
occurrences (all)	0	5	
Haemorrhoids			

subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	4 / 73 (5.48%) 4	
Nausea subjects affected / exposed occurrences (all)	4 / 42 (9.52%) 4	11 / 73 (15.07%) 12	
Vomiting subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	7 / 73 (9.59%) 7	
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	1 / 73 (1.37%) 1	
Rash subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	1 / 73 (1.37%) 1	
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	8 / 73 (10.96%) 8	
Haematuria subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	5 / 73 (6.85%) 5	
Perinephric collection subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	4 / 73 (5.48%) 4	
Proteinuria subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 2	1 / 73 (1.37%) 1	
Renal impairment subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 73 (2.74%) 3	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	2 / 73 (2.74%) 2	
Back pain			

subjects affected / exposed	1 / 42 (2.38%)	4 / 73 (5.48%)	
occurrences (all)	1	5	
Groin pain			
subjects affected / exposed	0 / 42 (0.00%)	5 / 73 (6.85%)	
occurrences (all)	0	5	
Pain in extremity			
subjects affected / exposed	3 / 42 (7.14%)	2 / 73 (2.74%)	
occurrences (all)	3	2	
Infections and infestations			
BK virus infection			
subjects affected / exposed	0 / 42 (0.00%)	9 / 73 (12.33%)	
occurrences (all)	0	9	
Bronchitis			
subjects affected / exposed	1 / 42 (2.38%)	2 / 73 (2.74%)	
occurrences (all)	1	2	
COVID-19			
subjects affected / exposed	4 / 42 (9.52%)	7 / 73 (9.59%)	
occurrences (all)	4	7	
Herpes zoster			
subjects affected / exposed	0 / 42 (0.00%)	4 / 73 (5.48%)	
occurrences (all)	0	4	
Cytomegalovirus infection			
subjects affected / exposed	1 / 42 (2.38%)	8 / 73 (10.96%)	
occurrences (all)	1	13	
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	3 / 73 (4.11%)	
occurrences (all)	0	3	
Upper respiratory tract infection			
subjects affected / exposed	1 / 42 (2.38%)	2 / 73 (2.74%)	
occurrences (all)	2	2	
Oral herpes			
subjects affected / exposed	2 / 42 (4.76%)	1 / 73 (1.37%)	
occurrences (all)	2	1	
Nasopharyngitis			
subjects affected / exposed	2 / 42 (4.76%)	2 / 73 (2.74%)	
occurrences (all)	2	2	

Urinary tract infection subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 4	17 / 73 (23.29%) 30	
Metabolism and nutrition disorders			
Acidosis subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 73 (2.74%) 2	
Dyslipidaemia subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	5 / 73 (6.85%) 5	
Gout subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	4 / 73 (5.48%) 9	
Hypercalcaemia subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2	2 / 73 (2.74%) 2	
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	18 / 73 (24.66%) 18	
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	17 / 73 (23.29%) 18	
Hypervolaemia subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	1 / 73 (1.37%) 2	
Hypocalcaemia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	10 / 73 (13.70%) 10	
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	3 / 73 (4.11%) 3	
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	7 / 73 (9.59%) 8	
Hypomagnesaemia			

subjects affected / exposed	1 / 42 (2.38%)	4 / 73 (5.48%)	
occurrences (all)	1	4	
Hypovolaemia			
subjects affected / exposed	0 / 42 (0.00%)	4 / 73 (5.48%)	
occurrences (all)	0	5	
Iron deficiency			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Metabolic acidosis			
subjects affected / exposed	0 / 42 (0.00%)	6 / 73 (8.22%)	
occurrences (all)	0	6	
Steroid diabetes			
subjects affected / exposed	0 / 42 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Vitamin D deficiency			
subjects affected / exposed	0 / 42 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 May 2019	This amendment extended the study by 48 months to 60 months. Kidney biopsies at Baseline and at Month 12 were made mandatory in both Cohort 1 and 2 which were to be sent to the central blinded reader for assessment
10 December 2019	This amendment introduced changes related to objectives and sample size.
15 December 2020	The key purpose of the amendment was to allow potential adaptations to study visits and study drug shipments during the COVID-19 pandemic.
18 March 2021	The primary purpose of this amendment was to incorporate feedback from the US Food and Drug Administration (FDA) on objectives.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.

Notes: