Clinical trial results:
An Open Label, Long-Term Extension Study to Investigate the Safety of PF-06823859 Administered to Adult Participants >=18 and <=80 With Active Dermatomyositis

Summary

EudraCT number	2021-004787-10
Trial protocol	HU PL ES DE
Global end of trial date	20 November 2023

Results information

Result version number	v1 (current)
This version publication date	29 November 2024
First version publication date	29 November 2024

Trial information

Trial identification

Sponsor protocol code	C0251008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05192200
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and tolerability of PF-06823859.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Poland: 4
Country: Number of subjects enrolled	United States: 17
Worldwide total number of subjects	24
EEA total number of subjects	7

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)	20
From 65 to 84 years	4

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Eligible participants with moderate to severe dermatomyositis (DM) who completed treatment period of study C0251002 [NCT03181893] and had agreement from their study doctor to continue treatment were enrolled in this study.

Pre-assignment

Screening details:

Total of 24 participants (9 from skin cohort [Amended Stage 2] and 15 from muscle cohort [Stage 3]) of study C0251002 were enrolled in study. As planned, in subject disposition discontinuations were reported by treatment.

Period 1

Period 1 title	Treatment Period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	PF-06823859 600mg: All Participants

Arm description:

Participants with DM received PF-06823859 600 milligrams (mg) intravenously (IV) once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Arm type	Experimental
Investigational medicinal product name	PF-06823859
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Participants with DM received PF-06823859 600 mg intravenously IV once every 4 weeks.

Number of subjects in period 1	PF-06823859 600mg: All Participants
Started	24
Safety Analysis Set	24
Skin Analysis Set	9 [1]
Muscle Analysis Set	15 [2]
Completed	21
Not completed	3
Consent withdrawn by subject	1
Unspecified	1
Lack of efficacy	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in this milestone is as per the number of participants in the specified cohort.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in this milestone is as per the number of participants in the specified cohort.

Period 2

Period 2 title	Follow-up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	PF-06823859 600mg: All Participants

Arm description:

Participants with DM received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	PF-06823859 600mg: All Participants
Started	21
Completed	21
Not completed	1
Consent withdrawn by subject	1
Joined	1
For Follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	PF-06823859 600mg: All Participants

Reporting group description:

Participants with DM received PF-06823859 600 milligrams (mg) intravenously (IV) once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Reporting group values	PF-06823859 600mg: All Participants	Total	
Number of subjects	24	24	
Age categorical Units: Participants			
Adults (18-64 years)	20	20	
From 65-84 years	4	4	
Age Continuous Units: Years			
arithmetic mean	49.79		
standard deviation	± 12.73	-	
Sex: Female, Male Units: Participants			
Female	20	20	
Male	4	4	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	24	24	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	5	
Not Hispanic or Latino	19	19	
Unknown or Not Reported	0	0	

Subject analysis sets

Subject analysis set title	PF-06823859 600mg: Skin Cohort
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with skin predominant DM entering from amended stage 2 of study C0251002 [NCT03181893] received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Subject analysis set title	PF-06823859 600mg: Muscle Cohort
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with muscle predominant DM entering from stage 3 of study C0251002 [NCT03181893] received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Reporting group values	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort	
Number of subjects	9	15	
Age categorical Units: Participants			
Adults (18-64 years)	8	12	
From 65-84 years	1	3	
Age Continuous Units: Years			
arithmetic mean	51.78	48.60	
standard deviation	± 10.32	± 14.19	
Sex: Female, Male Units: Participants			
Female	9	11	
Male	0	4	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	9	15	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	4	
Not Hispanic or Latino	8	11	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	PF-06823859 600mg: All Participants

Reporting group description:

Participants with DM received PF-06823859 600 milligrams (mg) intravenously (IV) once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Reporting group title	PF-06823859 600mg: All Participants

Reporting group description:

Participants with DM received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Subject analysis set title	PF-06823859 600mg: Skin Cohort
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with skin predominant DM entering from amended stage 2 of study C0251002 [NCT03181893] received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Subject analysis set title	PF-06823859 600mg: Muscle Cohort
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with muscle predominant DM entering from stage 3 of study C0251002 [NCT03181893] received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Primary: Number of Participants With Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs)[1]

End point description:

AE: any untoward medical occurrence in participant or clinical study participant, temporally associated with use of study intervention, whether or not considered related to study intervention. SAE: any untoward medical occurrence at any dose that: resulted in death, was life threatening, required hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, resulted in congenital anomaly/birth defect or considered to be important medical event. AE considered treatment emergent relative to given treatment if event occurred for first time during effective duration of treatment & was not seen prior to the start of treatment, or event was seen prior to the start of treatment but increased severity during treatment. AEs included both SAEs & all non-SAEs. Safety analysis set was evaluated. In this endpoint, data planned to be reported for skin cohort/analysis set, muscle cohort/analysis set & all participants/safety analysis set.

End point type	Primary

End point timeframe:

From Day 1 of dosing maximum up to Week 68

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned for this endpoint.

End point values	PF-06823859 600mg: All Participants	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	9	15	
Units: Participants	20	7	13	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Laboratory Abnormalities

End point title	Number of Participants With Laboratory Abnormalities[2]

End point description:

Hematology laboratory parameters: hemoglobin (g/dL); haematocrit (%); lymphocytes (10^3/millimetre[mm]^3); lymphocytes/leukocytes (%); neutrophils (10^3/mm^3)<0.8*lower limit of normal (LLN), leukocytes (10^3/mm^3)<0.6*LLN, neutrophils (10^3/mm^3); basophils (10^3/mm^3); basophils/leukocytes (%); monocytes/leukocytes (%); activated partial thromboplastin time (seconds [sec]); prothrombin time (sec)>1.2*upper limit of normal (ULN). Clinical chemistry: potassium (mEq/L); bicarbonate (mEq/L)<0.9*LLN, creatine kinase (units per liter [U/L])>2.0*ULN, glucose (mg/dl); glucose-fasting (mg/dl)>1.5*ULN. Urinalysis: Urine glucose; ketones; urine protein; urine hemoglobin; nitrite; leukocyte esterase; hyaline casts (1/per leukocytosis promoting factor (>= 1, urine erythrocytes (scalar); urine leukocytes (scalar)>=20. Safety analysis set evaluated. In this endpoint, data was planned to be reported for skin cohort/analysis set, muscle cohort/analysis set and all participants/safety analysis set.

End point type	Primary

End point timeframe:

From Day 1 of dosing maximum up to Week 68

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned for this endpoint.

End point values	PF-06823859 600mg: All Participants	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	9	15	
Units: Participants	22	8	14	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants According to Categorisation of Changes in Vital Signs

End point title	Number of Participants According to Categorisation of Changes in Vital Signs[3]

End point description:

Vital signs included the following parameters: sitting diastolic blood pressure (millimetres of mercury [mmHg]) change >=20 mmHg increase; sitting systolic blood pressure (mmHg) change >=30 mmHg increase, sitting diastolic blood pressure (mmHg) change >=20 mmHg decrease and sitting systolic

blood pressure (mmHg) change >=30 mmHg decrease. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for skin cohort/analysis set, muscle cohort/analysis set and all participants/safety analysis set. Here, Increase= Inc. and Decrease= Dec.

End point type	Primary

End point timeframe:

From Day 1 of dosing maximum up to Week 68

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned for this endpoint.

End point values	PF-06823859 600mg: All Participants	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	9	15	
Units: Participants				
Inc.: sitting diastolic blood pressure (mmHg)	8	4	4	
Inc.: sitting systolic blood pressure (mmHg)	6	4	2	
Dec.: sitting diastolic blood pressure (mmHg)	5	1	4	
Dec.: sitting systolic blood pressure (mmHg)	4	1	3	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants According to Categorisation of Electrocardiogram (ECG) Findings

End point title	Number of Participants According to Categorisation of Electrocardiogram (ECG) Findings[4]

End point description:

ECG parameters evaluated were: PR interval value >=300 milliseconds (msec); QRS duration value >=200 msec; QT interval value >=500 msec; corrected QT Interval using Fridericia's formula (QTCF) 450 <= value<480 msec; 480 <=value<500 msec and value>=500 msec. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for skin cohort/analysis set, muscle cohort/analysis set and all participants/safety analysis set.

End point type	Primary

End point timeframe:

From Day 1 of dosing maximum up to Week 68

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned for this endpoint.

End point values	PF-06823859 600mg: All Participants	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	9	15	
Units: Participants				
PR interval: value >=300 msec	0	0	0	
QRS duration: value >=200 msec	0	0	0	
QT interval: >=500 msec	0	0	0	
QTCF: 450<=value<480 msec	3	2	1	
QTCF: 480<=value<500 msec	0	0	0	
QTCF: value>=500 msec	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) Activity Score at Week 52

End point title	Change From Baseline in Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) Activity Score at Week 52

End point description:

CDASI is a validated DM-specific instrument designed to systematically quantify the extent of cutaneous disease. Disease involvement in 15 different anatomical locations was rated using three activity (erythema, scale, erosion/ulceration) and two damage (poikiloderma, calcinosis) measures. The presence and severity of Gottron's papules, periungual changes and alopecia were also captured. Total CDASI activity score was based on the physician's evaluation of three activities (erythema, scale, erosion/ulceration), presence and severity of Gottron's papules, periungual changes and alopecia. Total CDASI activity score ranged from 0 to 100, where higher scores indicated higher levels of disability. Safety analysis set was evaluated. In this endpoint, data was planned to be reported for skin cohort/analysis set and muscle cohort/analysis set. Here, ‘Number of Participants Analysed’ signifies number evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Week 52

End point values	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	12		
Units: Units on a scale				
least squares mean (confidence interval 90%)	-4.67 (-7.41 to -1.92)	-2.51 (-3.40 to -1.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CDASI Activity Score at Weeks 12, 24, 36, and 48

End point title	Change From Baseline in CDASI Activity Score at Weeks 12, 24, 36, and 48

End point description:

CDASI is a validated DM-specific instrument designed to systematically quantify the extent of cutaneous disease. Disease involvement in 15 different anatomical locations was rated using three activity (erythema, scale, erosion/ulceration) and two damage (poikiloderma, calcinosis) measures. The presence and severity of Gottron's papules, periungual changes and alopecia were also captured. Total CDASI activity score was based on the physician's evaluation of three activities (erythema, scale, erosion/ulceration), presence and severity of Gottron's papules, periungual changes and alopecia. Total CDASI activity score ranged from 0 to 100, where higher scores indicated higher levels of disability. Safety analysis set was evaluated. In this endpoint, data was planned to be reported for skin cohort/analysis set and muscle cohort/analysis set. Here, 'Number Analysed (n)' signifies number evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36 and 48

End point values	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	15		
Units: Units on a scale				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=8,15)	-5.28 (-7.67 to -2.90)	-0.87 (-1.98 to 0.25)		
Change at Week 24 (n=9,15)	-4.11 (-6.47 to -1.75)	-0.67 (-2.09 to 0.75)		
Change at Week 36 (n=8,15)	-4.51 (-7.90 to -1.11)	-1.40 (-2.40 to -0.40)		
Change at Week 48 (n=9,12)	-4.56 (-7.27 to -1.84)	-1.70 (-2.70 to -0.70)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of CDASI Activity Score at Weeks 12, 24, 36, 48, and 52

End point title	Absolute Values of CDASI Activity Score at Weeks 12, 24, 36, 48, and 52

End point description:

CDASI is a validated DM-specific instrument designed to systematically quantify the extent of cutaneous disease. Disease involvement in 15 different anatomical locations was rated using three activity (erythema, scale, erosion/ulceration) and two damage (poikiloderma, calcinosis) measures. The presence and severity of Gottron's papules, periungual changes and alopecia were also captured. Total CDASI activity score was based on the physician's evaluation of three activities (erythema, scale, erosion/ulceration), presence and severity of Gottron's papules, periungual changes and alopecia. Total CDASI activity score ranged from 0 to 100, where higher scores indicated higher levels of disability. Safety analysis set was evaluated. In this endpoint, data was planned to be reported for skin cohort/analysis set and muscle cohort/analysis set. Here, 'n' signifies number evaluable for specified rows.

End point type	Secondary
End point timeframe: Weeks 12, 24, 36, 48 and 52	

End point values	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	15		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 12 (n=8,15)	4.4 (± 2.45)	4.4 (± 3.44)		
Week 24 (n=9,15)	5.0 (± 3.71)	4.6 (± 3.81)		
Week 36 (n=8,15)	5.5 (± 5.13)	3.9 (± 3.27)		
Week 48 (n=9,12)	4.6 (± 4.45)	3.1 (± 3.03)		
Week 52 (n=9,12)	4.4 (± 4.85)	2.2 (± 2.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CDASI Damage Score at Weeks 12, 24, 36, 48, and 52

End point title	Change From Baseline in CDASI Damage Score at Weeks 12, 24, 36, 48, and 52

End point description:

CDASI is a validated DM-specific instrument designed to systematically quantify the extent of cutaneous disease. Disease involvement in 15 different anatomical locations was rated using three activity (erythema, scale, erosion/ulceration) and two damage (poikiloderma, calcinosis) measures. The presence and severity of Gottron's papules, periungual changes and alopecia were also captured. Total CDASI damage score was based on the physician's evaluation of two damage (poikiloderma, calcinosis) measures, and presence and severity of Gottron's papules. Total CDASI damage score ranged from 0 to 32, where higher scores indicated higher level of skin damage. Safety analysis set: all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for skin cohort/analysis set and muscle cohort/analysis set. n= Number of participants evaluable for specified rows.

End point type	Secondary
End point timeframe: Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52	

End point values	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	15		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 12 (n=8,15)	-2.4 (± 2.77)	-0.8 (± 1.15)		

Change at Week 24 (n=9,15)	-1.8 (± 2.33)	-0.5 (± 1.19)		
Change at Week 36 (n=8,15)	-2.3 (± 2.25)	-0.5 (± 1.06)		
Change at Week 48 (n=9,12)	-2.0 (± 2.00)	-0.9 (± 1.24)		
Change at Week 52 (n=9,12)	-2.1 (± 2.09)	-0.9 (± 1.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of CDASI Damage Score at Weeks 12, 24, 36, 48, and 52

End point title	Absolute Values of CDASI Damage Score at Weeks 12, 24, 36, 48, and 52

End point description:

CDASI is a validated DM-specific instrument designed to systematically quantify the extent of cutaneous disease. Disease involvement in 15 different anatomical locations was rated using three activity (erythema, scale, erosion/ulceration) and two damage (poikiloderma, calcinosis) measures. The presence and severity of Gottron's papules, periungual changes and alopecia were also captured. Total CDASI damage score was based on the physician's evaluation of two damage (poikiloderma, calcinosis) measures, and presence and severity of Gottron's papules. Total CDASI damage score ranged from 0 to 32, where higher scores indicated higher level of skin damage. Safety analysis set: all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for skin cohort/analysis set and muscle cohort/analysis set. n= Number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: Muscle Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	15		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 12 (n=8,15)	0.9 (± 1.25)	1.6 (± 3.07)		
Week 24 (n=9,15)	1.9 (± 2.26)	1.9 (± 3.41)		
Week 36 (n=8,15)	1.4 (± 2.33)	1.9 (± 3.43)		
Week 48 (n=9,12)	1.7 (± 2.12)	1.3 (± 2.83)		
Week 52 (n=9,12)	1.6 (± 1.59)	1.3 (± 3.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Total Improvement Score (TIS) at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Total Improvement Score (TIS) at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

TIS: 1) PhGA (from the MDAAT, 0-100 mm or 0-10 cm on a visual analogue scale [VAS], higher scores = worse health status); 2) PtGA (0-100 mm or 0-10 cm on VAS, higher scores = worse status); 3) MMT-8 designated muscle groups (0-80, lower scores = higher level of disability); 4) HAQ-DI (0-3, higher scores = worse status); 5) Global Extramuscular Disease Activity (from MDAAT, 0-10 cm on VAS, higher scores = higher level of disability); 6) Participant's most elevated muscle enzymes. TIS was sum of all 6 improvement scores associated with change in each core set measure. TIS range: 0-100; where TIS>=20 shows minimal improvement, TIS >=40 shows moderate improvement & TIS >= 60 shows major improvement. Safety analysis set: All participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. Data was planned to be reported for muscle cohort/analysis set. n= Number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Units on a scale				
least squares mean (confidence interval 90%)				
Week 12 (n=14)	15.03 (8.36 to 21.70)			
Week 24 (n=15)	15.67 (8.96 to 22.37)			
Week 36 (n=15)	18.17 (10.84 to 25.49)			
Week 48 (n=12)	19.61 (10.58 to 28.63)			
Week 52 (n=12)	23.66 (14.05 to 33.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PhGA) Score at Week 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Change From Baseline in Physician Global Assessment (PhGA) Score at Week 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

PhGA: investigator was asked to evaluate the participant's overall disease activity on a VAS of 0 (very good) to 10 (very poor) centimetre (cm), higher scores indicated worse health status. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for muscle cohort/analysis set. Here, 'n' signifies number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Centimetre				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=14)	0.17 (-0.54 to 0.87)			
Change at Week 24 (n=15)	0.29 (-0.39 to 0.98)			
Change at Week 36 (n=15)	-0.18 (-0.59 to 0.23)			
Change at Week 48 (n=12)	-0.48 (-0.85 to -0.10)			
Change at Week 52 (n=12)	-0.60 (-0.97 to -0.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient Global Assessment (PtGA) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Change From Baseline in Patient Global Assessment (PtGA) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

PtGA was the assessment of the severity of disease by the participant/participant's guardian, using a VAS from 0 mm (no evidence of disease activity) to 100 mm (extremely active or severe disease activity). Higher score indicated worse status. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for muscle cohort/analysis set. Here, 'n' signifies number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Millimetre				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=15)	3.70 (-6.55 to 13.95)			

Change at Week 24 (n=15)	-9.63 (-18.18 to -1.08)			
Change at Week 36 (n=15)	-9.10 (-16.47 to -1.73)			
Change at Week 48 (n=12)	-8.36 (-14.74 to -1.97)			
Change at Week 52 (n=12)	-6.28 (-16.79 to 4.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Manual Muscle Testing-8 Designated Muscle Groups (MMT-8) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Change From Baseline in Manual Muscle Testing-8 Designated Muscle Groups (MMT-8) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

MMT-8 is a tool that assesses muscle strength using manual muscle testing. Eight designated muscles are tested unilaterally with a total potential summed score of 0-80. Lower scores indicated a higher level of disability. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for muscle cohort/analysis set. Here 'n' signifies number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Units on a scale				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=14)	-0.06 (-5.93 to 5.82)			
Change at Week 24 (n=15)	1.85 (-3.11 to 6.81)			
Change at Week 36 (n=15)	4.92 (0.61 to 9.22)			
Change at Week 48 (n=12)	8.00 (5.69 to 10.30)			
Change at Week 52 (n=12)	9.84 (7.38 to 12.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire and Disease Index (HAQ-DI) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Change From Baseline in Health Assessment Questionnaire and Disease Index (HAQ-DI) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

HAQ-DI consisted of eight sections (including dressing & grooming, arising, eating, walking, hygiene, grip, reach, and activities). Each section had multiple questions that the participant used to rank their functionality and ranged from 0 to 3 where 0 = without any difficulty and 3 = unable to do. For each participant, the average ranking was calculated for each of the eight sections. HAQ-DI had a score range of 0 to 3, where higher score reflected worse status. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for muscle cohort/analysis set. Here 'n' signifies number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Units on a scale				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=15)	0.00 (-0.13 to 0.13)			
Change at Week 24 (n=15)	-0.10 (-0.21 to 0.01)			
Change at Week 36 (n=15)	-0.07 (-0.23 to 0.08)			
Change at Week 48 (n=12)	-0.12 (-0.24 to 0.00)			
Change at Week 52 (n=12)	-0.18 (-0.32 to -0.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Creatine Kinase at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Change From Baseline in Creatine Kinase at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

Creatine kinase is a muscle enzyme measured in units per liter (U/L). Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for muscle cohort/analysis set. Here, 'n' signifies number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Units per litre				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=15)	-98.93 (-163.76 to -34.11)			
Change at Week 24 (n=15)	-58.53 (-127.24 to 10.17)			
Change at Week 36 (n=14)	-97.62 (-150.82 to -44.42)			
Change at Week 48 (n=12)	-72.04 (-161.48 to 17.39)			
Change at Week 52 (n=12)	-94.04 (-147.13 to -40.95)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Extramuscular Global Assessment From the Myositis Disease Activity Assessment Tool (MDAAT) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point title	Change From Baseline in Extramuscular Global Assessment From the Myositis Disease Activity Assessment Tool (MDAAT) Score at Weeks 12, 24, 36, 48 and 52: Muscle Cohort

End point description:

MDAAT tool measures the degree of disease activity of extramuscular organ systems and muscle on a VAS of 0 to 10 centimetre (cm), higher scores indicated higher level of disability. Safety analysis set included all participants enrolled who took at least 1 dose of study intervention, regardless of which stage the participant entered from. In this endpoint, data was planned to be reported for muscle cohort/analysis set. Here 'n' signifies number of participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline (before dose on Day 1), Weeks 12, 24, 36, 48 and 52

End point values	PF-06823859 600mg: Muscle Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Centimetre				
least squares mean (confidence interval 90%)				
Change at Week 12 (n=14)	0.05 (-0.40 to 0.50)			
Change at Week 24 (n=15)	0.23 (-0.23 to 0.68)			
Change at Week 36 (n=15)	0.01 (-0.51 to 0.53)			
Change at Week 48 (n=12)	-0.16 (-0.91 to 0.59)			
Change at Week 52 (n=12)	-0.56 (-1.07 to -0.06)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day 1 of dosing maximum up to Week 68

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE. What is presented are distinct events. An event may be categorised as serious in 1 participant and non-serious in other participant, or a participant may have experienced both SAE and non-SAE. Safety analysis set was used.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	PF-06823859 600mg: Skin Cohort

Reporting group description:

Participants with skin predominant DM entering from amended stage 2 of study C0251002 [NCT03181893] received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Reporting group title	PF-06823859 600mg: All Participants

Reporting group description:

Participants with DM received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Reporting group title	PF-06823859 600mg: Muscle Cohort

Reporting group description:

Participants with muscle predominant DM entering from stage 3 of study C0251002 [NCT03181893] received PF-06823859 600 mg IV once every 4 weeks. The treatment duration was up to 48 weeks (treatment period was up through and including Week 52). There was a follow-up period of 16 weeks post treatment period, however participants were assessed for safety from Day 1 of treatment up to end of study (Week 68).

Serious adverse events	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: All Participants	PF-06823859 600mg: Muscle Cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 9 (11.11%)	3 / 24 (12.50%)	2 / 15 (13.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (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
Hepatobiliary disorders			

Cholelithiasis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	PF-06823859 600mg: Skin Cohort	PF-06823859 600mg: All Participants	PF-06823859 600mg: Muscle Cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 9 (77.78%)	20 / 24 (83.33%)	13 / 15 (86.67%)
Vascular disorders			
Peripheral venous disease			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Hypotension			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Lymphoedema			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
Infusion site rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Infusion site extravasation			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1

Calcinosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 9 (22.22%)	2 / 24 (8.33%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Investigations			
Blood potassium decreased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Blood pressure increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Crystal urine present			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Sunburn			

subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Tooth fracture			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Presyncope			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Mental impairment			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	0 / 9 (0.00%)	2 / 24 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	9	9
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 24 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	2	1
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	2	2
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 24 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	2	2
Diarrhoea			

subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Faeces discoloured			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Nail pigmentation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Dermatitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Cutaneous calcification			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Urticaria			
subjects affected / exposed	1 / 9 (11.11%)	2 / 24 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	3	2
Skin ulcer			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Proteinuria			

subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Acute kidney injury			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 9 (11.11%)	2 / 24 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	2	1
Bursitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Compartment syndrome			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Plantar fasciitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Myositis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	2 / 24 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	2	2
Pain in jaw			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Periarthritis			

subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Infections and infestations			
COVID-19			
subjects affected / exposed	3 / 9 (33.33%)	6 / 24 (25.00%)	3 / 15 (20.00%)
occurrences (all)	3	6	3
Bronchitis			
subjects affected / exposed	1 / 9 (11.11%)	2 / 24 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	2	1
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Fungal infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Laryngitis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 24 (4.17%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Respiratory tract infection viral			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0

Sinusitis			
subjects affected / exposed	1 / 9 (11.11%)	2 / 24 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	2	1
Tooth infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 9 (22.22%)	2 / 24 (8.33%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	3 / 24 (12.50%)	2 / 15 (13.33%)
occurrences (all)	1	3	2
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 24 (4.17%)	0 / 15 (0.00%)
occurrences (all)	1	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported