Clinical trial results:
A Phase 2a, Randomized, Double Blind, Vehicle Controlled, Parallel Group Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of PF-07038124 Ointment for 6 Weeks in Subjects With Mild to Moderate Atopic Dermatitis or Plaque Psoriasis

Summary

EudraCT number	2020-003977-23
Trial protocol	PL
Global end of trial date	18 August 2021

Results information

Result version number	v1 (current)
This version publication date	17 August 2022
First version publication date	17 August 2022

Trial information

Trial identification

Sponsor protocol code	C3941002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04664153
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., +1 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	18 August 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 August 2021
Global end of trial reached?	Yes
Global end of trial date	18 August 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the study were to compare the efficacy of PF-07038124 versus vehicle on percent change from baseline in EASI in subjects with mild or moderate AD, and to compare the efficacy of PF-07038124 versus vehicle on change from baseline in PASI score in subjects with mild to moderate plaque psoriasis.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 December 2020
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	Australia: 4
Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	Poland: 19
Country: Number of subjects enrolled	United States: 69
Worldwide total number of subjects	104
EEA total number of subjects	19

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)	95
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 152 subjects were screened for this study and 104 subjects were assigned to study treatment (70 for atopic dermatitis [AD] group and 34 for plaque psoriasis group).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	AD Vehicle Once Daily (QD)

Arm description:

Subjects in AD group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

Placebo was administered topically with QD dosing for 6 weeks.

Arm title	AD PF-07038124 0.01% QD

Arm description:

Subjects in AD group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Arm type	Experimental
Investigational medicinal product name	PF-07038124
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

PF-07038124 was administered topically with QD dosing for 6 weeks.

Arm title	Psoriasis Vehicle QD

Arm description:

Subjects in plaque psoriasis group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose
at Week 6 visit.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

Placebo was administered topically with QD dosing for 6 weeks.

Arm title	Psoriasis PF-07038124 0.01% QD

Arm description:

Subjects in plaque psoriasis group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Arm type	Experimental
Investigational medicinal product name	PF-07038124
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

PF-07038124 was administered topically with QD dosing for 6 weeks.

Number of subjects in period 1	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD
Started	34	36	17
Completed	27	33	13
Not completed	7	3	4
Consent withdrawn by subject	3	2	1
Physician decision	-	-	1
Adverse event, non-fatal	4	-	1
Unspecified	-	1	-
Lack of efficacy	-	-	1

Number of subjects in period 1	Psoriasis PF-07038124 0.01% QD
Started	17
Completed	15
Not completed	2
Consent withdrawn by subject	2
Physician decision	-
Adverse event, non-fatal	-
Unspecified	-
Lack of efficacy	-

Baseline characteristics

Reporting groups	
Reporting group title	AD Vehicle Once Daily (QD)
Reporting group description:	
Subjects in AD group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	
Reporting group title	AD PF-07038124 0.01% QD
Reporting group description:	
Subjects in AD group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	
Reporting group title	Psoriasis Vehicle QD
Reporting group description:	
Subjects in plaque psoriasis group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	
Reporting group title	Psoriasis PF-07038124 0.01% QD
Reporting group description:	
Subjects in plaque psoriasis group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	

Reporting group values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD
Number of subjects	34	36	17
Age Categorical Units: Subjects			
18-44	25	23	4
45-64	9	8	12
>=65	0	5	1
Age Continuous Units: Years			
arithmetic mean	36.1	41.4	51.2
standard deviation	± 13.93	± 16.61	± 10.83
Sex: Female, Male Units: Subjects			
Female	21	20	7
Male	13	16	10
Race/Ethnicity, Customized Units: Subjects			
White	25	29	17
Black or African American	8	5	0
Asian	1	2	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	8	11	7
Not Hispanic or Latino	26	25	10
Unknown or Not Reported	0	0	0

Reporting group values	Psoriasis PF-07038124 0.01% QD	Total	
Number of subjects	17	104	

Age Categorical Units: Subjects			
18-44	4	56	
45-64	10	39	
>=65	3	9	
Age Continuous Units: Years			
arithmetic mean	51.8		
standard deviation	± 12.32	-	
Sex: Female, Male Units: Subjects			
Female	7	55	
Male	10	49	
Race/Ethnicity, Customized Units: Subjects			
White	16	87	
Black or African American	0	13	
Asian	1	4	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	31	
Not Hispanic or Latino	12	73	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	AD Vehicle Once Daily (QD)
Reporting group description:	
Subjects in AD group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	
Reporting group title	AD PF-07038124 0.01% QD
Reporting group description:	
Subjects in AD group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	
Reporting group title	Psoriasis Vehicle QD
Reporting group description:	
Subjects in plaque psoriasis group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	
Reporting group title	Psoriasis PF-07038124 0.01% QD
Reporting group description:	
Subjects in plaque psoriasis group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.	

Primary: Percent Change From Baseline in Eczema Area and Severity Index (EASI) Total Score at Week 6 for AD Participants

End point title	Percent Change From Baseline in Eczema Area and Severity Index (EASI) Total Score at Week 6 for AD Participants[1]
End point description:	
EASI evaluated severity of subjects' AD based on severity of AD clinical signs and % of body surface area (BSA) affected. Severity of clinical signs of AD scored on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, where higher scores = greater severity of AD. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of Psoriasis Vehicle QD and Psoriasis PF-07038124 0.01% QD.	
End point type	Primary
End point timeframe:	
Baseline, Week 6	

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: This endpoint was summarized for specified reporting arms only.

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	36		
Units: Percent Change				
least squares mean (confidence interval 90%)	-35.5 (-48.95 to -22.03)	-74.9 (-88.81 to -61.06)		

Statistical analyses

Statistical analysis title	Difference From Vehicle
Comparison groups	AD Vehicle Once Daily (QD) v AD PF-07038124 0.01% QD
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004
Method	t-test, 1-sided
Parameter estimate	Mean difference (final values)
Point estimate	-39.4
Confidence interval	
level	90 %
sides	2-sided
lower limit	-58.76
upper limit	-20.12
Variability estimate	Standard error of the mean
Dispersion value	11.74

Primary: Change From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 6 for Plaque Psoriasis Participants

End point title	Change From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 6 for Plaque Psoriasis Participants[2]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0= 0% to 6= 90–100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0= none to 4= maximum. Final PASI = sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0= no disease to 72= maximal disease, where higher scores = greater severity of psoriasis. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Primary

End point timeframe:

Baseline, Week 6

Notes:

[2] - 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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: Units on a Scale				
least squares mean (confidence interval 90%)	0.1 (-1.47 to 1.68)	-4.8 (-6.21 to -3.37)		

Statistical analyses

Statistical analysis title	Difference From Vehicle
Comparison groups	Psoriasis Vehicle QD v Psoriasis PF-07038124 0.01% QD
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	t-test, 1-sided
Parameter estimate	Mean difference (final values)
Point estimate	-4.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.02
upper limit	-2.77
Variability estimate	Standard error of the mean
Dispersion value	1.29

Secondary: Percentage of AD Subjects Achieving Investigator's Global Assessment (IGA) Score of Clear (0) or Almost Clear (1) (on a 5-Point Scale) and a Reduction From Baseline of >=2 Points at Week 6

End point title	Percentage of AD Subjects Achieving Investigator's Global Assessment (IGA) Score of Clear (0) or Almost Clear (1) (on a 5-Point Scale) and a Reduction From Baseline of >=2 Points at Week 6[3]

End point description:

IGA assessed severity of AD on a 5 point scale (0 to 4, higher scores indicate more severity). Scores: 0= clear, no inflammatory signs of AD; 1= almost clear, AD not fully cleared-light pink residual lesions, just perceptible erythema, papulation/induration lichenification, excoriation, and no oozing/crusting; 2= mild AD with light red lesions, slight but definite erythema, papulation/induration, lichenification, excoriation and no oozing/crusting; 3= moderate AD with red lesions, moderate erythema, papulation/induration, lichenification, excoriation and slight oozing/crusting; 4= severe AD with deep dark red lesions, severe erythema, papulation/induration, lichenification, excoriation and moderate to severe oozing/crusting. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of Psoriasis Vehicle QD and Psoriasis PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Week 6

Notes:

[3] - 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: This endpoint was summarized for specified reporting arms only.

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	36		
Units: Percentage of Subjects				
number (confidence interval 90%)	8.8 (3.3 to 19.7)	44.4 (30.2 to 59.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of AD Subjects Achieving EASI 75 (75% Improvement From Baseline) at Weeks 1, 2, 4, 6 and Follow-up (FUP)/End of Study (EOS)

End point title	Percentage of AD Subjects Achieving EASI 75 (75% Improvement From Baseline) at Weeks 1, 2, 4, 6 and Follow-up (FUP)/End of Study (EOS)[4]

End point description:

EASI evaluated severity of subjects' AD based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD scored on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, higher scores = greater severity. EASI 75 response was defined as at least a 75% reduction in EASI relative to Baseline. Analysis population included all subjects who received at least 1 dose. Data collection was not planned for the 2 arms of Psoriasis Vehicle QD and Psoriasis PF-

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

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: This endpoint was summarized for specified reporting arms only.

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34[5]	36		
Units: Percentage of Subjects				
number (confidence interval 90%)				
Week 1	0 (0.0 to 8.0)	8.3 (3.1 to 18.9)		
Week 2	0 (0.0 to 8.2)	27.8 (15.9 to 40.9)		
Week 4	11.8 (5.2 to 24.3)	33.3 (21.3 to 47.0)		

Week 6	20.6 (11.3 to 34.9)	61.1 (47.0 to 74.6)		
FUP/EOS	8.8 (3.3 to 19.7)	44.4 (30.2 to 59.1)		

Notes:

[5] - Number of subjects analyzed for Week 2 was 33.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of AD Subjects Having >=4 Points of Reduction in Weekly Averages of Peak Pruritus Numerical Rating Scale (PP-NRS) From Baseline at Weeks 1, 2, 4 and 6

End point title	Percentage of AD Subjects Having >=4 Points of Reduction in Weekly Averages of Peak Pruritus Numerical Rating Scale (PP-NRS) From Baseline at Weeks 1, 2, 4 and 6[6]

End point description:

The PP-NRS was a daily patient-reported assessment of intensity of pruritus on an 11-point numerical rating scale, ranging from 0 ('No Itch) to 10 ('Worst Itch Imaginable') with a 24 hour recall period. For the PP-NRS score, baseline was defined as the average of all values recorded between Day -7 and Day -1. In this OM, percentages of AD subjects with >=4 points of reduction in weekly averages of PP-NRS from baseline are reported (percentage based on number of subjects with baseline >=4). Analysis population included all subjects who received at least 1 dose of study treatment with PP-NRS baseline >=4. For this end point, data collection was not planned for the 2 arms of Psoriasis Vehicle QD and Psoriasis PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4 and 6

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: This endpoint was summarized for specified reporting arms only.

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	34		
Units: Percentage of Subjects				
number (confidence interval 90%)				
Week 1	0 (0.0 to 9.4)	8.8 (3.3 to 19.7)		
Week 2	3.4 (0.4 to 14.5)	23.5 (12.3 to 37.7)		
Week 4	6.9 (1.8 to 20.0)	41.2 (26.9 to 56.7)		
Week 6	13.8 (6.2 to 27.9)	41.2 (26.9 to 56.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EASI Total Score at Weeks 1, 2, 4, 6 and FUP/EOS for AD Participants

End point title	Change From Baseline in EASI Total Score at Weeks 1, 2, 4, 6 and FUP/EOS for AD Participants[7]

End point description:

EASI evaluated severity of subjects' AD based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD scored on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, where higher scores = greater severity of AD. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of Psoriasis Vehicle QD and Psoriasis PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

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: This endpoint was summarized for specified reporting arms only.

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34[8]	36[9]		
Units: Units on a Scale				
least squares mean (confidence interval 90%)				
Week 1	-1.7 (-2.59 to -0.85)	-3.4 (-4.28 to -2.59)		
Week 2	-2.4 (-3.42 to -1.45)	-5.6 (-6.51 to -4.66)		
Week 4	-2.5 (-3.63 to -1.31)	-7.0 (-8.06 to -5.90)		
Week 6	-3.3 (-4.59 to -1.93)	-8.2 (-9.39 to -6.94)		
FUP/EOS	-2.8 (-4.26 to -1.39)	-6.9 (-8.19 to -5.54)		

Notes:

[8] - Numbers of subjects analyzed for Week 2, Week 4, Week 6 and FUP/EOS were 30, 28, 30 and 27.

[9] - Numbers of subjects analyzed for Week 4, Week 6 and FUP/EOS were 35, 34 and 32, respectively.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of AD Subjects Achieving IGA Score of Clear (0) or Almost Clear (1) at Weeks 1, 2, 4, 6 and FUP/EOS

End point title	Percentage of AD Subjects Achieving IGA Score of Clear (0) or Almost Clear (1) at Weeks 1, 2, 4, 6 and FUP/EOS[10]

End point description:

IGA assessed severity of AD on a 5 point scale (0 to 4, higher scores indicate more severity). Scores: 0= clear, no inflammatory signs of AD; 1= almost clear, AD not fully cleared- light pink residual lesions, just perceptible erythema, papulation/induration lichenification, excoriation, and no oozing/crusting; 2= mild AD with light red lesions, slight but definite erythema, papulation/induration, lichenification, excoriation and no oozing/crusting; 3= moderate AD with red lesions, moderate erythema,

papulation/induration, lichenification, excoriation and slight oozing/crusting; 4= severe AD with deep dark red lesions, severe erythema, papulation/induration, lichenification, excoriation and moderate to severe oozing/crusting. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of Psoriasis Vehicle QD and Psoriasis PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

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: This endpoint was summarized for specified reporting arms only.

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34[11]	36		
Units: Percentage of Subjects				
number (confidence interval 90%)				
Week 1	2.9 (0.3 to 12.3)	11.1 (4.9 to 22.9)		
Week 2	9.1 (3.4 to 20.2)	36.1 (22.9 to 50.0)		
Week 4	14.7 (7.3 to 26.9)	44.4 (30.2 to 59.1)		
Week 6	17.6 (8.0 to 30.7)	52.8 (38.0 to 67.2)		
FUP/EOS	5.9 (1.6 to 16.9)	38.9 (25.4 to 53.0)		

Notes:

[11] - Number of subjects analyzed for Week 2 was 33.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Psoriasis Subjects with Physician Global Assessment (PGA) Score Clear (0) or Almost Clear (1) (on a 5-Point Scale) and >=2 Points Improvement From Baseline at Week 6

End point title	Percentage of Psoriasis Subjects with Physician Global Assessment (PGA) Score Clear (0) or Almost Clear (1) (on a 5-Point Scale) and >=2 Points Improvement From Baseline at Week 6[12]

End point description:

The PGA of psoriasis was scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling were scored separately over the whole body according to a 5-point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear). In this end point, percentages of subjects with a PGA score of 0 or 1 and an improvement of >=2 from Baseline in PGA score are reported. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Week 6

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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: Percentage of Subjects				
number (confidence interval 90%)	5.9 (0.6 to 22.5)	17.6 (6.7 to 36.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Psoriasis Subjects Achieving PASI 75 (75% or Greater Improvement From Baseline) at Weeks 1, 2, 4, 6 and FUP/EOS

End point title	Percentage of Psoriasis Subjects Achieving PASI 75 (75% or Greater Improvement From Baseline) at Weeks 1, 2, 4, 6 and FUP/EOS[13]

End point description:

The PASI quantified the severity of a subject's psoriasis based on both, "lesion severity" and the "percent of BSA" affected. PASI was a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score could vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 75 response was defined as at least a 75 percent (%) reduction in PASI relative to Baseline. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

Notes:

[13] - 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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: Percentage of Subjects				
number (confidence interval 90%)				
Week 1	0 (0.0 to 14.0)	5.9 (0.6 to 22.5)		
Week 2	0 (0.0 to 14.0)	5.9 (0.6 to 22.5)		

Week 4	0 (0.0 to 14.0)	17.6 (6.7 to 36.4)		
Week 6	5.9 (0.6 to 22.5)	35.3 (17.5 to 56.8)		
FUP/EOS	0 (0.0 to 14.0)	23.5 (10.7 to 43.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Psoriasis Subjects Who Achieved a Psoriasis Symptoms Inventory (PSI) Score of 0 (Not at All) or 1 (Mild) on Every Item at Weeks 1, 2, 4, 6 and FUP/EOS

End point title	Percentage of Psoriasis Subjects Who Achieved a Psoriasis Symptoms Inventory (PSI) Score of 0 (Not at All) or 1 (Mild) on Every Item at Weeks 1, 2, 4, 6 and FUP/EOS[14]

End point description:

PSI was a self-administered 8 item questionnaire that measured the severity of psoriasis symptoms over the past 24 hours and the past 7 days. The measure included concepts of itch, pain, burning, stinging, cracking, scaling, flaking, and redness. Subjects were asked to respond to each item using a 5 point Likert response scale: 0: not all severe, 1: mild, 2: moderate, 3: severe and 4: very severe. In this end point, percentages of subjects with a PSI score of 0 or 1 on every item at weeks 1, 2, 4, 6 and FUP/EOS are reported. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

Notes:

[14] - 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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17[15]		
Units: Percentage of Subjects				
number (confidence interval 90%)				
Week 1	0 (0.0 to 14.0)	11.8 (3.2 to 31.1)		
Week 2	5.9 (0.6 to 22.5)	18.8 (7.1 to 39.1)		
Week 4	23.5 (10.7 to 43.2)	43.8 (23.5 to 66.7)		
Week 6	29.4 (14.0 to 50.0)	58.8 (36.4 to 77.5)		
FUP/EOS	41.2 (22.5 to 63.6)	41.2 (22.5 to 63.6)		

Notes:

[15] - Numbers of subjects analyzed for Week 2 and Week 4 were both 16.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Scores at Weeks 1, 2, 4 and FUP/EOS

End point title	Change From Baseline in PASI Scores at Weeks 1, 2, 4 and FUP/EOS[16]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0= 0% to 6= 90–100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0= none to 4= maximum. Final PASI = sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0= no disease to 72= maximal disease, where higher scores = greater severity of psoriasis. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4 and FUP/EOS (28-35 days post-last dose)

Notes:

[16] - 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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[17]	17[18]		
Units: Units on a Scale				
least squares mean (confidence interval 90%)				
Week 1	-0.6 (-1.23 to 0.03)	-1.9 (-2.50 to -1.24)		
Week 2	-0.7 (-1.51 to 0.11)	-3.2 (-3.97 to -2.35)		
Week 4	-0.1 (-1.49 to 1.19)	-4.1 (-5.44 to -2.80)		
FUP/EOS	0.2 (-1.59 to 1.97)	-3.7 (-5.35 to -2.00)		

Notes:

[17] - Numbers of subjects analyzed for Week 4 and FUP/EOS were 16 and 13, respectively.

[18] - Number of subjects analyzed for FUP/EOS was 15.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in PASI Scores at Weeks 1, 2, 4, 6 and FUP/EOS

End point title	Percent Change From Baseline in PASI Scores at Weeks 1, 2, 4, 6 and FUP/EOS[19]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0= 0% to 6= 90–100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0= none to 4= maximum. Final PASI = sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0= no disease to 72=

maximal disease, where higher scores = greater severity of psoriasis. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

Notes:

[19] - 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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[20]	17[21]		
Units: Percent Change				
least squares mean (confidence interval 90%)				
Week 1	-6.8 (-15.28 to 1.78)	-25.6 (-34.11 to -17.04)		
Week 2	-9.0 (-19.14 to 1.09)	-37.8 (-47.92 to -27.68)		
Week 4	-9.0 (-22.73 to 4.73)	-49.4 (-62.93 to -35.79)		
Week 6	-5.4 (-21.35 to 10.65)	-58.1 (-73.52 to -42.70)		
FUP/EOS	-8.4 (-27.02 to 10.25)	-45.6 (-63.02 to -28.10)		

Notes:

[20] - Numbers of subjects analyzed for Week 4, Week 6 and FUP/EOS were 16, 14 and 13, respectively.
[21] - Number of subjects analyzed for FUP/EOS was 15.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Psoriasis Subjects With PGA Score Clear (0) or Almost Clear (1) at Weeks 1, 2, 4, 6 and FUP/EOS

End point title	Percentage of Psoriasis Subjects With PGA Score Clear (0) or Almost Clear (1) at Weeks 1, 2, 4, 6 and FUP/EOS[22]

End point description:

The PGA of psoriasis was scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling were scored separately over the whole body according to a 5-point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear). In this end point, percentages of subjects with a PGA score of 0 or 1 are reported. Analysis population included all subjects who received at least 1 dose of study treatment. For this end point, data collection was not planned for the 2 arms of AD Vehicle QD and AD PF-07038124 0.01% QD.

End point type	Secondary

End point timeframe:

Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

Notes:

[22] - 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: This endpoint was summarized for specified reporting arms only.

End point values	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: Percentage of Subjects				
number (confidence interval 90%)				
Week 1	0 (0.0 to 14.0)	11.8 (3.2 to 31.1)		
Week 2	0 (0.0 to 14.0)	17.6 (6.7 to 36.4)		
Week 4	0 (0.0 to 14.0)	23.5 (10.7 to 43.2)		
Week 6	5.9 (0.6 to 22.5)	23.5 (10.7 to 43.2)		
FUP/EOS	11.8 (3.2 to 31.1)	17.6 (6.7 to 36.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in affected Body Surface Area (BSA) at Weeks 1, 2, 4, 6 and FUP/EOS

End point title	Percent Change From Baseline in affected Body Surface Area (BSA) at Weeks 1, 2, 4, 6 and FUP/EOS

End point description:

Four body regions were evaluated: head and neck, upper limbs, trunk (including axillae and groin) and lower limbs (including buttocks). Scalp, palms and soles were excluded. BSA was calculated using handprint method. Number of handprints fitting in the affected area of a body region was estimated. Maximum number of handprints were 10 for head and neck, 20 for upper limbs, 30 for trunk and 40 for lower limbs. Surface area of body region equivalent to 1 handprint: 1 handprint was equal to 10% for head and neck, 5% for upper limbs, 3.33% for trunk and 2.5% for lower limbs. Percent BSA for a body region was calculated as = total number of handprints in a body region * % surface area equivalent to 1 handprint. Overall % BSA for an individual: arithmetic mean of % BSA of all 4 body regions, ranges from 0 to 100%, with higher values representing greater severity of AD. Analysis population included all subjects who received at least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6 and FUP/EOS (28-35 days post-last dose)

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[23]	36[24]	17[25]	17[26]
Units: Percent Change				
least squares mean (confidence interval 90%)				
Week 1	-6.6 (-13.56 to 0.44)	-20.2 (-27.01 to -13.44)	2.5 (-5.50 to 10.49)	-14.5 (-22.46 to -6.56)
Week 2	-10.5 (-19.71 to -1.27)	-32.2 (-40.83 to -23.62)	7.2 (-2.68 to 17.17)	-13.8 (-23.70 to -3.91)
Week 4	-2.9 (-15.80 to 9.94)	-43.9 (-55.73 to -32.00)	19.8 (3.80 to 35.79)	-24.7 (-40.52 to -8.89)
Week 6	-4.9 (-23.07 to 13.28)	-61.2 (-78.01 to -44.42)	29.0 (4.46 to 53.46)	-32.6 (-56.32 to -8.84)
FUP/EOS	-5.1 (-20.70 to 10.56)	-48.7 (-63.05 to -34.27)	15.8 (-12.26 to 43.76)	-31.9 (-58.60 to -5.21)

Notes:

[23] - Numbers of subjects analyzed for Week 2, Week 4, Week 6 and FUP/EOS were 30, 28, 30, and 27.
[24] - Numbers of subjects analyzed for Week 4, Week 6 and FUP/EOS were 35, 34 and 32, respectively.
[25] - Numbers of subjects analyzed for Week 4, Week 6 and FUP/EOS were 16, 14 and 13, respectively.
[26] - Number of subjects analyzed for FUP/EOS was 15.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With All-Causality Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects With All-Causality Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical investigation where subjects administered a product or medical device; the event needed not necessarily have a causal relationship with the treatment or usage. TEAEs were events between first dose of study drug and up to discharge from study that were absent before treatment or that worsened relative to pretreatment state. An SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, or resulted in congenital anomaly/birth defect.

End point type	Secondary

End point timeframe:

Day 1 through Week 6

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	36	17	17
Units: Subjects				
Subjects With All-Causality TEAEs	9	9	6	3
Subjects With All-Causality SAEs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Vital Signs Data Meeting Pre-defined Criteria

End point title	Number of Subjects With Vital Signs Data Meeting Pre-defined Criteria

End point description:

Abnormality in vital signs: increase and decrease of change of supine diastolic blood pressure (SDBP) from baseline >=20 mmHg, supine systolic blood pressure (SSBP) <90 mmHg, and increase in change of SSBP from baseline >=30 mmHg. Analysis population included all subjects evaluated against criteria.

End point type	Secondary

End point timeframe:

Day 1 through Week 6

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	36	17	16
Units: Subjects				
Change of SDBP >=20 mmHg Increase	2	1	0	2
Change of SDBP >=20 mmHg Decrease	1	0	0	0
Value of SSBP <90 mmHg	0	0	0	1
Change of SSBP >=30 mmHg Increase	1	1	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Electrocardiogram (ECG) Data Meeting Pre-defined Criteria

End point title	Number of Subjects With Electrocardiogram (ECG) Data Meeting Pre-defined Criteria

End point description:

ECG abnormalities criteria included: value of PR interval >=300 msec, percent change of PR interval >=25/50% and change of corrected QT interval using Fridericia's Formula (QTcF) >=30 msec and <60 msec. Analysis population included all subjects evaluated against criteria.

End point type	Secondary

End point timeframe:

Day 1 through Week 6

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	33	13	15
Units: Subjects				
Value of PR Interval >=300 msec	0	1	0	0
Percent Change of PR Interval >=25/50%	0	0	1	0
Change of Corrected QTcF >=30 msec and <60 msec	3	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Test Abnormalities

End point title	Number of Subjects With Laboratory Test Abnormalities

End point description:

Laboratory parameters included: hematology (hemoglobin, hematocrit, red blood cell, platelet and white blood cell count, neutrophils, eosinophils, monocytes, basophils and lymphocytes), chemistry (blood urea nitrogen, creatinine, sodium, potassium, aspartate aminotransferase, alanine aminotransferase, total bilirubin, alkaline phosphatase, albumin, total protein and serum pregnancy test [for all female subjects]) and urine (urine pregnancy test [for all female subjects]). Analysis population included subjects with at least 1 observation of the given laboratory test while on study treatment or during lag time.

End point type	Secondary

End point timeframe:

Day 1 through Week 6

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[27]	36[28]	17[29]	17[30]
Units: Subjects				
Hemoglobin <0.8 × LLN	0	1	0	0
Ery. Mean Corpuscular Volume <0.9 × LLN	0	1	0	0
Ery. Mean Corpuscular Hemoglobin <0.9 × LLN	0	1	0	0
Leukocytes >1.5 × ULN	0	0	0	1
Lymphocytes <0.8 × LLN	1	0	0	0
Lymphocytes >1.2 × ULN	0	1	0	0
Lymphocytes/Leukocytes <0.8 × LLN	3	2	2	1
Lymphocytes/Leukocytes >1.2 × ULN	1	0	0	0
Neutrophils <0.8 × LLN	2	0	0	0

Neutrophils >1.2 × ULN	0	1	1	1
Neutrophils/Leukocytes <0.8 × LLN	1	1	0	0
Basophils/Leukocytes >1.2 × ULN	0	0	0	1
Eosinophils >1.2 × ULN	2	1	0	1
Eosinophils/Leukocytes >1.2 × ULN	3	4	0	1
Monocytes >1.2 × ULN	0	1	0	0
Monocytes/Leukocytes >1.2 × ULN	0	2	0	1
Potassium >1.1 × ULN	0	0	2	1
Bicarbonate <0.9 × LLN	2	0	1	0
Glucose >1.5 × ULN	2	3	4	1
Fibrinogen >1.25 × ULN	3	11	4	1
URINE Glucose >=1	2	2	1	0
Ketones >=1	0	2	1	3
URINE Protein >=1	1	0	0	1
URINE Hemoglobin >=1	4	4	2	2
URINE Bilirubin >=1	0	0	1	0
Nitrite >=1	2	0	0	0
Leukocyte Esterase >=1	3	9	5	3
URINE Erythrocytes (/HPF) >=20	2	1	0	3
URINE Leukocytes (/HPF) >=20	0	1	2	2
Hyaline Casts (/LPF) >1	0	3	2	0

Notes:

[27] - Numbers of subjects analyzed for URINE Erythrocytes/Leukocytes and Hyaline Casts were 15, 18 and 0.
[28] - Numbers of subjects analyzed for URINE Erythrocytes/ Leukocytes and Hyaline Casts were 16, 20 and 4.
[29] - Numbers of subjects analyzed for URINE Erythrocytes/Leukocytes and Hyaline Casts were 12, 13 and 2.
[30] - Numbers of subjects analyzed for URINE Erythrocytes/Leukocytes and Hyaline Casts were 8, 10 and 0.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Different Severity Grades in Skin Tolerability at Day 1, Weeks 1, 2, 4, 6, Early Termination (ET) and FUP

End point title	Number of Subjects With Different Severity Grades in Skin Tolerability at Day 1, Weeks 1, 2, 4, 6, Early Termination (ET) and FUP

End point description:

The investigator or designee assessed tolerability at the site of investigational product application (pre-dose and immediately post-dose). This assessment focused on the treated non-lesional skin using the scale: none = no evidence of local intolerance; mild = minimal erythema and/or oedema, slight glazed appearance; moderate = definite erythema and/or oedema with peeling and/or cracking but needs no adaptation of posology; severe (to be reported as an AE) = erythema, oedema glazing with fissures, few vesicles or papules: consider removing topical agent (if still in place); very severe (to be reported as an AE) = strong reaction spreading beyond the treated area, bullous reaction, erosions: removal of topical agent (if still in place). Analysis population included all subjects who received at least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

Day 1, Weeks 1, 2, 4, 6, ET and FUP (28-35 days post-last dose)

End point values	AD Vehicle Once Daily (QD)	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD	Psoriasis PF-07038124 0.01% QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	36	17	17
Units: Subjects				
Day 1 None	33	35	17	17
Day 1 Mild	0	1	0	0
Day 1 Moderate	1	0	0	0
Day 1 Severe	0	0	0	0
Day 1 Very Severe	0	0	0	0
Week 1 None	25	33	17	16
Week 1 Mild	4	3	0	0
Week 1 Moderate	2	0	0	1
Week 1 Severe	0	0	0	0
Week 1 Very Severe	0	0	0	0
Week 2 None	26	34	15	16
Week 2 Mild	1	2	0	0
Week 2 Moderate	1	0	1	1
Week 2 Severe	0	0	0	0
Week 2 Very Severe	0	0	0	0
Week 4 None	22	32	13	16
Week 4 Mild	4	2	1	0
Week 4 Moderate	1	0	0	0
Week 4 Severe	0	0	0	0
Week 4 Very Severe	0	0	0	0
Week 6 None	24	33	11	14
Week 6 Mild	3	0	0	1
Week 6 Moderate	0	0	2	0
Week 6 Severe	0	0	0	0
Week 6 Very Severe	0	0	0	0
ET None	3	2	3	1
ET Mild	1	0	0	0
ET Moderate	1	0	0	1
ET Severe	2	0	0	0
ET Very Severe	0	0	0	0
FUP None	25	29	12	15
FUP Mild	1	1	1	0
FUP Moderate	1	0	1	1
FUP Severe	0	0	0	0
FUP Very Severe	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 through Week 6

Adverse event reporting additional description:

The same event may appear as both an AE and an SAE. An event may be categorized as serious in 1 subject and as non-serious in another subject, or 1 subject may have experienced both a serious and non-serious event during the study. Total number at risk below refers to the number of subjects evaluable for SAEs or AEs.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	AD Vehicle QD

Reporting group description:

Subjects in AD group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Reporting group title	AD PF-07038124 0.01% QD

Reporting group description:

Subjects in AD group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Reporting group title	Psoriasis Vehicle QD

Reporting group description:

Subjects in plaque psoriasis group received vehicle ointment in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Reporting group title	Psoriasis PF-07038124 0.01% QD

Reporting group description:

Subjects in plaque psoriasis group received PF-07038124 ointment at 0.01% in 60 g tube with QD dosing beginning on Day 1 through the final dose at Week 6 visit.

Serious adverse events	AD Vehicle QD	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	0 / 17 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Psoriasis PF-07038124 0.01% QD		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	AD Vehicle QD	AD PF-07038124 0.01% QD	Psoriasis Vehicle QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 34 (17.65%)	1 / 36 (2.78%)	6 / 17 (35.29%)
Investigations			
Blood glucose increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 34 (2.94%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Muscle strain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Application site pruritus			
subjects affected / exposed	2 / 34 (5.88%)	0 / 36 (0.00%)	0 / 17 (0.00%)
occurrences (all)	4	0	0
Respiratory, thoracic and mediastinal disorders			
Sinus congestion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	3 / 34 (8.82%)	1 / 36 (2.78%)	0 / 17 (0.00%)
occurrences (all)	3	1	0

Pruritus			
subjects affected / exposed	1 / 34 (2.94%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Psoriasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 36 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Non-serious adverse events	Psoriasis PF-07038124 0.01% QD		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 17 (17.65%)		
Investigations			

Blood glucose increased subjects affected / exposed occurrences (all) SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0 0 / 17 (0.00%) 0		
Injury, poisoning and procedural complications Muscle strain subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
General disorders and administration site conditions Application site pruritus subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Sinus congestion subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Skin and subcutaneous tissue disorders Dermatitis atopic subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0		
Psychiatric disorders Suicidal ideation subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Infections and infestations			
Herpes zoster			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	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