Clinical trial results:
Patient insights following use of LEO 90100 aerosol foam and Daivobet® gel in subjects with psoriasis vulgaris

Summary

EudraCT number	2014-003072-24
Trial protocol	DE
Global end of trial date	03 August 2015

Results information

Result version number	v2 (current)
This version publication date	16 November 2016
First version publication date	17 August 2016
Version creation reason	• Correction of full data set Minor updates for better read flow.

Trial information

Trial identification

Sponsor protocol code	LP0053-1030

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02310646
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	LEO Pharma A/S
Sponsor organisation address	Industriparken 55, Ballerup, Denmark, 2750
Public contact	Clinical Trial Disclosure Manager, LEO Pharma A/S, 45 44945888, ctr.disclosure@leo-pharma.com
Scientific contact	Clinical Trial Disclosure Manager, LEO Pharma A/S, 45 44945888, ctr.disclosure@leo-pharma.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	29 June 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 August 2015
Global end of trial reached?	Yes
Global end of trial date	03 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To gather insight on how product attributes affect usability by investigating the factors that are thought to influence patient preference to topical anti-psoriatic treatments.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 February 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 122
Country: Number of subjects enrolled	Germany: 97
Worldwide total number of subjects	219
EEA total number of subjects	97

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)	167
From 65 to 84 years	52
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

219 subjects from Canada (8 sites) and Germany (7 sites) were enrolled into the trial. First Subject First Visit:10-Feb-2015 and Last Subject Last Visit: 03-Aug-2015 (last visit, including follow-up). 6 enrolled subjects were not randomised.

Pre-assignment

Screening details:

Screening assessments were performed at the Screening Visit which could occur up to 28 days prior to Baseline (Day 1; Visit 1). A washout period of up to 4 weeks was to be completed if the subject was treated or had recently been treated with anti-psoriatic treatments or other relevant medication, as defined by the exclusion criteria.

Period 1

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

Blinding implementation details:

This was an open-label, cross-over study. All subjects received both treatments, each for 1 week, and hence served as their own control. A cross-over design was selected to be able to test if the sequence of applying the treatments had an influence on preference.

Arms

Are arms mutually exclusive?	Yes
Arm title	Foam - Gel

Arm description:

Day 1 to 7: LEO 90100 aerosol foam
Day 8 to 14: Daivobet® gel

Arm type	Experimental
Investigational medicinal product name	Daivobet® gel
Investigational medicinal product code	
Other name	Dovobet®
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) gel 60 g per bottle, applied once daily for one week. Applied to psoriasis lesions on the trunk and/or limbs. Subjects were instructed not to apply the IMP on the face, scalp, genitals, and skin folds.

Investigational medicinal product name	LEO 90100 aerosol foam
Investigational medicinal product code	LEO 90100
Other name	Enstilar® foam
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use

Dosage and administration details:

Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) aerosol foam 60 g per can, applied once daily for one week. Applied to psoriasis lesions on the trunk and/or limbs. Subjects were instructed not to apply the IMP on the face, scalp, genitals, and skin folds.

Arm title	Gel - Foam

Arm description:

Day 1 to 7: Daivobet® gel
Day 8 to 14: LEO 90100 aerosol foam

Arm type	Experimental

Investigational medicinal product name	LEO 90100 aerosol foam
Investigational medicinal product code	LEO 90100
Other name	Enstilar® foam
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use

Dosage and administration details:

Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) aerosol foam 60 g per can, applied once daily for one week. Applied to psoriasis lesions on the trunk and/or limbs. Subjects were instructed not to apply the IMP on the face, scalp, genitals, and skin folds.

Investigational medicinal product name	Daivobet® gel
Investigational medicinal product code	
Other name	Dovobet®
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) gel 60 g per bottle, applied once daily for one week. Applied to psoriasis lesions on the trunk and/or limbs. Subjects were instructed not to apply the IMP on the face, scalp, genitals, and skin folds.

Number of subjects in period 1[1]	Foam - Gel	Gel - Foam
Started	109	104
First Intervention (Day 1 - Day 7)	109	104
Second Intervention (Day 8 - Day 14)	107	104
Completed	107	104
Not completed	2	0
Consent withdrawn by subject	1	-
Lost to follow-up	1	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 6 enrolled subjects were not randomised due to inclusion/exclusion criteria.

Baseline characteristics

Reporting groups	
Reporting group title	Foam - Gel
Reporting group description: Day 1 to 7: LEO 90100 aerosol foam Day 8 to 14: Daivobet® gel	
Reporting group title	Gel - Foam
Reporting group description: Day 1 to 7: Daivobet® gel Day 8 to 14: LEO 90100 aerosol foam	

Reporting group values	Foam - Gel	Gel - Foam	Total
Number of subjects	109	104	213
Age categorical Units: Subjects			
Adults (18-39 years)	26	23	49
Adults (40-59 years)	43	49	92
From 60-84 years	40	32	72
Age continuous Units: years			
arithmetic mean	52	51.6	
standard deviation	± 14	± 14.2	-
Gender categorical Units: Subjects			
Female	46	34	80
Male	63	70	133

End points

End points reporting groups

Reporting group title	Foam - Gel
Reporting group description:	
Day 1 to 7: LEO 90100 aerosol foam Day 8 to 14: Daivobet® gel	
Reporting group title	Gel - Foam
Reporting group description:	
Day 1 to 7: Daivobet® gel Day 8 to 14: LEO 90100 aerosol foam	
Subject analysis set title	Latest topical treatment
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Comparison to Latest Topical Treatment (CLTT) analysis set was defined by including all randomised subjects who had used topical anti-psoriatic medication on the treatment area (trunk and/or limbs) within 3 months prior to Baseline.	
Subject analysis set title	All subjects foam
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects that received both treatments (foam and gel) are included in the full analysis set (FAS). One subject in the foam-gel group discontinued from the trial prior to the Week 1 visit (after 7 days of treatment with LEO 90100) and did not complete any on-treatment questionnaires, and was excluded from the FAS which hence comprised 212 subjects: 108 subjects in the foam-gel group and 104 subjects in the gel-foam group. All subjects foam=All subjects gel=All randomized subjects. These 3 different names are used for endpoint reporting to clarify the treatment referred to.	
Subject analysis set title	All subjects gel
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects that received both treatments (foam and gel) are included in the full analysis set (FAS). One subject in the foam-gel group discontinued from the trial prior to the Week 1 visit (after 7 days of treatment with LEO 90100) and did not complete any on-treatment questionnaires, and was excluded from the FAS which hence comprised 212 subjects: 108 subjects in the foam-gel group and 104 subjects in the gel-foam group. All subjects foam=All subjects gel=All randomized subjects. These 3 different names are used for endpoint reporting to clarify the treatment referred to.	
Subject analysis set title	All randomised subjects
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects that received both treatments (foam and gel) are included in the full analysis set (FAS). One subject in the foam-gel group discontinued from the trial prior to the Week 1 visit (after 7 days of treatment with LEO 90100) and did not complete any on-treatment questionnaires, and was excluded from the FAS which hence comprised 212 subjects: 108 subjects in the foam-gel group and 104 subjects in the gel-foam group. All subjects foam=All subjects gel=All randomized subjects. These 3 different names are used for endpoint reporting to clarify the treatment referred to.	
Subject analysis set title	Prefer Foam (very important factor)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Created for response criteria results representation purposes - applicable to endpoint 6.	
Subject analysis set title	Prefer Foam (fairly important factor)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Created for response criteria results representation purposes - applicable to endpoint 6.	
Subject analysis set title	Prefer Foam (not very important factor)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Created for response criteria results representation purposes - applicable to endpoint 6.

Subject analysis set title	Prefer Foam (not at all important factor)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Created for response criteria results representation purposes - applicable to endpoint 6.

Subject analysis set title	Prefer Gel (very important factor)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Created for response criteria results representation purposes - applicable to endpoint 6.

Subject analysis set title	Prefer Gel (fairly important factor)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Created for response criteria results representation purposes - applicable to endpoint 6.

Subject analysis set title	Prefer Gel (not very important factor)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Created for response criteria results representation purposes - applicable to endpoint 6.

Subject analysis set title	Prefer Gel (not at all important factor)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Created for response criteria results representation purposes - applicable to endpoint 6.

Primary: Overall treatment preference by Subject's Preference Assessment (SPA) at Week 2 and association with baseline characteristics

End point title	Overall treatment preference by Subject's Preference Assessment (SPA) at Week 2 and association with baseline characteristics

End point description:

The SPA questionnaire was completed at Week 2 and consisted of 2 parts:
(i) the subject indicated if they preferred LEO 90100 foam or Daivobet® gel based on their experience using these products for 1 week each during the 2-weeks treatment period;
(ii) the subject indicated how much each of the 22 items under the application, formulation, and container domains contributed to their overall decision of which product they preferred. This part of the SPA tool used a 4-point scale ranging from 'very important factor' to 'not at all important factor'.

The statistical significance of each of the following 7 baseline characteristics (gender, age, disease severity, distribution, plaque size, skin thickness, onset) was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.

Results for multiple regression analyses are provided in the Clinical Study Report found on the LEO Pharma website.

End point type	Primary

End point timeframe:

Baseline to Week 2

End point values	Foam - Gel	Gel - Foam	All randomised subjects	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	108	104	212	
Units: percent				
number (not applicable)				
Overall, I preferred the aerosol foam	52.9	46.2	49.5	

Overall, I preferred the gel in a bottle	47.1	53.8	50.5	

Statistical analyses

Statistical analysis title	Treatment sequence and gender

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: gender (male, female).

Comparison groups	Foam - Gel v Gel - Foam
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2 [1]
Method	Regression, Logistic

Notes:

[1] - Treatment sequence effect: p=0.28; gender effect: p=0.20; threshold for statistical significance: p<0.05

Statistical analysis title	Treatment sequence and age

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: age (18-39 years, 40-59 years, ≥60 years).

Comparison groups	Foam - Gel v Gel - Foam
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [2]
Method	Regression, Logistic

Notes:

[2] - Treatment sequence effect: p=0.34; age effect: p=0.001; threshold for statistical significance: p<0.05.

Statistical analysis title	Treatment sequence and baseline disease severity

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: Baseline disease severity (mild, moderate, severe).

Comparison groups	Foam - Gel v Gel - Foam
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.29 [3]
Method	Regression, Logistic

Notes:

[3] - Treatment sequence effect: p=0.34; baseline disease severity effect: p=0.29; threshold for statistical significance: p<0.05

Statistical analysis title	Treatment sequence and distribution phenotype

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: distribution phenotype (localised, widespread).

Comparison groups	Foam - Gel v Gel - Foam
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.55 [4]
Method	Regression, Logistic

Notes:

[4] - Treatment sequence effect: p=0.33; distribution phenotype (localised, widespread) effect: p=0.55; threshold for statistical significance: p<0.05

Statistical analysis title	Treatment sequence and plaque size

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: plaque size (≤3 mm diameter, >3 mm diameter).

Comparison groups	Foam - Gel v Gel - Foam
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.25 [5]
Method	Regression, Logistic

Notes:

[5] - Treatment sequence effect: p=0.32; plaque size (≤3 mm diameter, >3 mm diameter): p=0.25; threshold for statistical significance: p<0.05

Statistical analysis title	Treatment sequence and thickness

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: skin thickness phenotype (≤0.75 mm, >0.75 mm).

Comparison groups	Foam - Gel v Gel - Foam
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41 [6]
Method	Regression, Logistic

Notes:

[6] - Treatment sequence effect: p=0.34; skin thickness phenotype (≤0.75 mm, >0.75 mm) effect: p=0.41; threshold for statistical significance: p<0.05

Statistical analysis title	Treatment sequence and age onset phenotype

Statistical analysis description:

The statistical significance of each of the 7 baseline characteristics was tested in a 2-factor logistic regression model with treatment sequence and each baseline characteristic as factors.
Baseline factor: onset phenotype (≤40 years of age, >40 years of age).

Comparison groups	Foam - Gel v Gel - Foam

Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2 [7]
Method	Regression, Logistic

Notes:

[7] - Treatment sequence effect: p=0.30; onset phenotype (≤40 years of age, >40 years of age) effect: p=0.20; threshold for statistical significance: p<0.05

Other pre-specified: Within subject difference in response to Topical Product Usability Questionnaire (TPUQ) items between trial treatments

End point title	Within subject difference in response to Topical Product Usability Questionnaire (TPUQ) items between trial treatments

End point description:

Each response category (item 1 to 25) was assigned a numeric score (-2=strongly disagree, -1=slightly disagree, 0=neither agree nor disagree, 1=slightly agree, 2=strongly agree). For item 26, each response category was assigned a score (from -2=very dissatisfied to 2=very satisfied).
Summary scores were calculated by summing numeric scores for items under each domain, i.e., application (items 1-9; score range -18 to +18), formulation (items 10-18; score range -18 to +18), container (items 19-22; score range -8 to +8), and satisfaction (items 23-25; score range -6 to +6). Positive scores indicate agreement with domains' items.
A total TPUQ summary score (item 1-25; score range -50 to +50) was also calculated. The summary scores were analysed in the same way as the individual questions. The higher score signifies higher preference in that domain.

Results of multiple regression analyses are provided in the Clinical Study Report which can be found on the LEO Pharma website.

End point type	Other pre-specified

End point timeframe:

Baseline to Week 2

End point values	All subjects foam	All subjects gel		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	212	212		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
1. Ease of application	1.1 (± 1.2)	1.5 (± 0.9)		
2. Ease of application on psoriasis lesions only	0.9 (± 1.3)	1.4 (± 0.9)		
3. Ease of spreading	1.5 (± 0.8)	1.7 (± 0.7)		
4. Lack of mess when applying	0.8 (± 1.2)	1 (± 1.2)		
5. Good for use on smaller areas	1 (± 1.2)	1.4 (± 0.9)		
6. Good for use on larger areas	1.4 (± 0.9)	1.5 (± 0.8)		
7. Quick to apply	1.4 (± 0.8)	1.4 (± 0.9)		
8. Total time spent acceptable	1.5 (± 0.7)	1.5 (± 0.8)		
9. Easily incorporated into daily routine	1.4 (± 0.9)	1.5 (± 0.9)		
Total application score (summary score)	11.1 (± 6.9)	12.8 (± 6.1)		
10. Quickly absorbed	0.7 (± 1.3)	0.7 (± 1.3)		
11. Dried quickly	0.5 (± 1.3)	0.5 (± 1.3)		
12. Gave an immediate feeling of relief	1 (± 1)	0.7 (± 1)		
13. Felt soothing to my skin	1.2 (± 1)	1 (± 0.9)		
14. Appealing to touch	0.9 (± 1.1)	0.9 (± 1.1)		
15. Felt moisturising to my skin	1.1 (± 1)	1.2 (± 0.9)		

16. Not greasy	0 (± 1.5)	0.3 (± 1.4)		
17. Odourless	1.3 (± 1)	1.6 (± 0.7)		
18. Lack of staining of clothes/bed linen	1 (± 1.3)	1 (± 1.3)		
Total formulation score (summary score)	7.7 (± 7.2)	8 (± 7.4)		
19. Easy to get medication out of container	1.1 (± 1.2)	1.3 (± 1)		
20. Easy to use container	1.1 (± 1.2)	1.4 (± 0.9)		
21. Easy to keep container clean	1.2 (± 1.1)	1.4 (± 1)		
22. Accurately dispense wanted amount	0.9 (± 1.2)	1.5 (± 0.9)		
Total container score (summary score)	4.3 (± 3.8)	5.6 (± 3.3)		
23.Confidence in using the product	1.2 (± 1.1)	1.2 (± 1)		
24. Would regularly use the product	1.3 (± 1.2)	1.3 (± 1)		
25. Would recommend the product	1.2 (± 1.1)	1.1 (± 1.1)		
Total satisfaction score (summary score)	3.6 (± 3.2)	3.7 (± 2.9)		
Total TPUQ (summary score item 1-25)	26.8 (± 17.8)	29.9 (± 16.9)		
26. Overall satisfaction score	1.1 (± 1)	1.2 (± 1)		

Statistical analyses

Statistical analysis title	Comparison Gel versus Foam
Comparison groups	All subjects foam v All subjects gel
Number of subjects included in analysis	424
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.007 [9]
Method	Wilcoxon (Mann-Whitney)

Notes:

[8] - Subjects in the analysis are 212 - full analysis set. All subjects received both study treatments. Wilcoxon rank sum test comparing the period difference (within subject difference between study treatments) between both treatment sequences.
[9] - The total TPUQ score for the gel and the foam (mean score 29.9 vs. mean score 26.8; p=0.007). Threshold for statistical significance: p<0.05.

Other pre-specified: Within subject difference in response to TPUQ between the latest topical anti-psoriatic treatment and each of the 2 trial treatments

End point title	Within subject difference in response to TPUQ between the latest topical anti-psoriatic treatment and each of the 2 trial treatments

End point description:

The TPUQ tool was used to evaluate the subject's latest topical treatment at Baseline (used within 3 months prior Baseline). TPUQ assessments of trial treatments at Week 1 and Week 2.
Each response category was assigned a numeric score as described in Primary endpoint.
For each subject and each item, the latest topical treatment score was compared with each study treatment by calculating the difference between the scores, i.e., by subtracting the latest topical treatment score from each study medication score.

End point type	Other pre-specified

End point timeframe:

Baseline to Week 2

End point values	Latest topical treatment	All subjects foam	All subjects gel	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	118	118	118	
Units: Score on a scale				
arithmetic mean (standard deviation)				
Total application score (summary score)	9.9 (± 6.7)	11.5 (± 6.7)	12.5 (± 6.7)	
Total formulation score (summary score)	2.8 (± 7.5)	8.3 (± 7.2)	7.5 (± 8)	
Total container score (summary score)	4.6 (± 3.7)	4.6 (± 3.4)	5.5 (± 3.4)	
Total satisfaction score (summary score)	2 (± 3)	4 (± 3)	3.4 (± 3.2)	
Total TPUQ score (items 1-25)	19.4 (± 16.9)	28.4 (± 17.1)	29 (± 18.6)	
26. Overall satisfaction score	0.3 (± 1.1)	1.2 (± 1)	1.1 (± 1.1)	

Statistical analyses

Statistical analysis title	Comparison Gel vs. latest treatment

Statistical analysis description:

Statistical analysis for total TPUQ score (summary score item 1-25): superiority comparison gel versus latest topical treatment.

Comparison groups	All subjects gel v Latest topical treatment
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [10]
Method	Wilcoxon (Mann-Whitney)

Notes:

[10] - Wilcoxon signed rank test comparing within subject difference to latest topical treatment.

Statistical analysis title	Comparison Foam vs. latest treatment

Statistical analysis description:

Statistical analysis for total TPUQ score (summary score item 1-25): superiority comparison foam versus latest topical treatment.

Comparison groups	All subjects foam v Latest topical treatment
Number of subjects included in analysis	236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [11]
Method	Wilcoxon (Mann-Whitney)

Notes:

[11] - Wilcoxon signed rank test comparing within subject difference to latest topical treatment.

Other pre-specified: Responses to Comparison to Last Topical Treatment Questionnaire (CLTT) for each of the 2 trial treatments

End point title	Responses to Comparison to Last Topical Treatment

	Questionnaire (CLTT) for each of the 2 trial treatments

End point description:

Subjects in both arms (foam-gel; gel-foam) indicated whether they preferred latest topical treatment, LEO 90100 aerosol foam, Daivobet® gel, or did not have any preference.

The subject compared the trial treatment used the previous week with the latest topical treatment (used within 3 months prior to baseline; CLTT analysis set). Each item was scored with either 'prefer latest treatment', 'no preference', or 'prefer trial medication (foam or gel)'. A subject could prefer both study treatments over the latest topical treatment. The percentage is given for the number of subjects preferring foam and number of subjects preferring gel.

End point type	Other pre-specified

End point timeframe:

At Week 1 and Week 2

End point values	All subjects foam	All subjects gel		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	118	118		
Units: Percent				
number (not applicable)				
Total - Prefer trial medication (Foam or Gel)	76.5	70.2		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Within subject difference in response to vehicle preference measure (VPM) items between trial treatments

End point title	Within subject difference in response to vehicle preference measure (VPM) items between trial treatments

End point description:

The VPM questionnaire was analysed the same way as the TPUQ. Numeric scores were calculated by assigning the following values to each response category: -3 = Extremely unappealing, -2 = Moderately unappealing, -1 = Slightly unappealing, 0 = Neutral, 1 = Slightly appealing, 2 = Moderately appealing, 3 = Extremely appealing. A summary score was defined as the sum of all questions and could range from -21 to 21.

End point type	Other pre-specified

End point timeframe:

Week 1 and Week 2

End point values	All subjects foam	All subjects gel		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	212	212		
Units: Scores on a scale				
number (not applicable)				
Ease of application	1.5	1.9		
Time it takes to apply	1.9	2		
How well it is absorbed	1.4	1.4		
How it feels to touch	1.4	1.6		
How it smells	1.6	1.9		
How it feels on the skin	1.8	1.8		
How much it stains	1.4	1.3		
Total VPM score (summary score)	11.1	12		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Reasons for overall preference as assessed by SPA at Week 2

End point title	Reasons for overall preference as assessed by SPA at Week 2
End point description:	
Comparison of contribution of each product attribute in the stated preference between trial treatments (foam and gel).	
End point type	Other pre-specified
End point timeframe:	
Baseline to Week 2	

End point values	Prefer Foam (very important factor)	Prefer Foam (fairly important factor)	Prefer Foam (not very important factor)	Prefer Foam (not at all important factor)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	103	103	103
Units: Percent				
number (not applicable)				
1. The medication was easy to apply	51.5	30.1	12.6	5.8
2. Easy application on psoriasis lesions only	48.5	31.1	14.6	5.8
3. Easy to spread	65	24.3	4.9	5.8
4. Applying the medication was not messy	47.6	34	15.5	2.9
5. Overall good for smaller areas	53.6	29.9	8.2	8.2
6. Overall good for larger areas	61.8	25.8	5.6	6.7
7. Treatment was quick to apply	55.3	34	7.8	2.9
8. Total time spent on treatment acceptable	57.3	26.2	11.7	4.9
9. Applying treatment easy in daily routine	61.2	24.3	10.7	3.9

10. Treatment quickly absorbed	51.5	32	11.7	4.9
11. Treatment dried quickly	45.6	35	17.5	1.9
12. Treatment gave immediate feeling of relief	48.5	31.1	18.4	1.9
13. The medication felt soothing to my skin	50.5	36.9	8.7	3.9
14. The medication was appealing to touch	44.7	34	14.6	6.8
15. Treatment felt moisturising to my skin	45.6	38.8	11.7	3.9
16. Treatment not too greasy	48.5	30.1	17.5	3.9
17. Treatment was odourless	46.6	26.2	18.4	8.7
18. Absence of staining of clothes/bed linen	53.4	31.1	11.7	3.9
19. Easy to get medication out of container	52.4	32	10.7	4.9
20. Container was easy to use	55.3	31.1	10.7	2.9
21. Easy to keep container container clean	42.7	33	16.5	7.8
22. Dispensing the desired amount	54.4	34	8.7	2.9

End point values	Prefer Gel (very important factor)	Prefer Gel (fairly important factor)	Prefer Gel (not very important factor)	Prefer Gel (not at all important factor)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	105	105	105	105
Units: Percent				
number (not applicable)				
1. The medication was easy to apply	54.3	37.1	4.8	3.8
2. Easy application on psoriasis lesions only	61	30.5	4.8	3.8
3. Easy to spread	52.4	41	2.9	3.8
4. Applying the medication was not messy	45.7	44.8	4.8	4.8
5. Overall good for smaller areas	50.5	38.4	7.1	4
6. Overall good for larger areas	44.2	42.1	10.5	3.2
7. Treatment was quick to apply	45.7	45.7	4.8	3.8
8. Total time spent on treatment acceptable	48.6	41.9	6.7	2.9
9. Applying treatment easy in daily routine	56.2	36.2	3.8	3.8
10. Treatment quickly absorbed	50.5	39	9.5	1
11. Treatment dried quickly	50.5	39	9.5	1
12. Treatment gave immediate feeling of relief	39	41	17.1	2.9
13. The medication felt soothing to my skin	46.7	39	12.4	1.9
14. The medication was appealing to touch	34.3	39	21	5.7
15. Treatment felt moisturising to my skin	41	43.8	12.4	2.9
16. Treatment not too greasy	43.8	38.1	15.2	2.9
17. Treatment was odourless	38.1	41	16.2	4.8

18. Absence of staining of clothes/bed linen	54.3	36.2	7.6	1.9
19. Easy to get medication out of container	52.4	41	2.9	3.8
20. Container was easy to use	57.1	36.2	4.8	1.9
21. Easy to keep container container clean	45.7	38.1	16.2	0
22. Dispensing the desired amount	59	33.3	5.7	1.9

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

2 weeks

Adverse event reporting additional description:

21 subjects (9.9%) experienced a total of 21 treatment-emergent AEs. No SAEs, severe AEs or AEs leading to withdrawal were observed. 2 subjects had AEs which were assessed as related to study treatment by the investigator: one subject in the foam-gel group experienced folliculitis, and one subject in the gel-foam group experienced dermatitis.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	Gel - Foam

Reporting group description:

Day 1 to 7: Daivobet® gel
Day 8 to 14: LEO 90100 aerosol foam

LEO 90100 Aerosol Foam: Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) Aerosol Foam 60 g per can, applied once daily for one week

Daivobet® gel: Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) Gel 60 g per bottle, applied once daily for one week.

Reporting group title	Foam - Gel

Reporting group description:

Day 1 to 7: LEO 90100 aerosol foam
Day 8 to 14: Daivobet® gel

LEO 90100 Aerosol Foam: Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) Aerosol Foam 60 g per can, applied once daily for one week

Daivobet® gel: Calcipotriol 50 mcg/g (as hydrate) and betamethasone 0.5 mg/g (as dipropionate) Gel 60 g per bottle, applied once daily for one week.

Serious adverse events	Gel - Foam	Foam - Gel	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 104 (0.00%)	0 / 109 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Gel - Foam	Foam - Gel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 104 (7.69%)	13 / 109 (11.93%)	
Investigations			
Arthroscopy			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Excoriation			
subjects affected / exposed	1 / 104 (0.96%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Ligament rupture			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Application site pruritus			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 104 (0.96%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	1 / 104 (0.96%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

Rhinitis allergic			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	1 / 104 (0.96%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 104 (1.92%)	2 / 109 (1.83%)	
occurrences (all)	2	2	
Bronchitis			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Folliculitis			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Gastrointestinal infection			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Oral herpes			
subjects affected / exposed	1 / 104 (0.96%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 104 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	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

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

None reported

Notes: