Clinical trial results:
A Randomised, Double-blind, Placebo-Controlled, Phase II Study to Assess the Efficacy and Safety of Topically Applied DGLA Cream in Patients with Mild to Moderate Acne Vulgaris

Summary

EudraCT number	2012-004965-41
Trial protocol	DE HU SK
Global end of trial date	10 February 2014

Results information

Result version number	v2 (current)
This version publication date	24 September 2022
First version publication date	25 May 2022
Version creation reason	• Correction of full data set Correction of full data set

Trial information

Trial identification

Sponsor protocol code	DS107E-03

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dignity Sciences Limited
Sponsor organisation address	Trintech Building, South County Business Park, Dublin 18, Ireland, Dublin 18
Public contact	David Coughlan, Dignity Sciences Limited, +353 12933590, david.coughlan@dignitysciences.com
Scientific contact	David Coughlan, Dignity Sciences Limited, +353 12933590, david.coughlan@dignitysciences.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	27 June 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 January 2014
Global end of trial reached?	Yes
Global end of trial date	10 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this proof-of-concept study was to compare the efficacy of different concentrations of the study treatment (DS107E,dihomo-gamma-linolenic acid [DGLA]cream) on facial papulopustular acne in comparison to a placebo control. The secondary objective of this study was to assess the safety and tolerability of topically applied DS107E DGLA cream in different concentrations.

Protection of trial subjects:

The study was managed and conducted according to the latest International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice (GCP) and applicable regulatory requirement(s) (specifically the principles of GCP in ICH topic E6, as laid down by the Commission Directive 2005/28/EC and in accordance with applicable local laws and guidelines).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 June 2013
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	Slovakia: 56
Country: Number of subjects enrolled	Germany: 34
Country: Number of subjects enrolled	Hungary: 64
Worldwide total number of subjects	154
EEA total number of subjects	154

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)	32
Adults (18-64 years)	122

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study was carried out in 3 countries (Germany, Slovakia, and Hungary) across 16 investigational sites.

Pre-assignment

Screening details:

The study consisted of a wash out period of maximum 14 days; a 12-week treatment period and a 4 week follow up period.

Period 1

Period 1 title	Overall Study Period (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	DS107E Placebo cream

Arm description:

DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance.

Arm type	Placebo
Investigational medicinal product name	Placebo matching DS107E DGLA Cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical

Dosage and administration details:

DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks.

Arm title	DS107E DGLA 1% cream

Arm description:

DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	DS107E DGLA Cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical

Dosage and administration details:

DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.

Arm title	DS107E DGLA 5% cream

Arm description:

DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks

Arm type	Experimental

Investigational medicinal product name	DS107E DGLA 5% cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical

Dosage and administration details:

DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks.

Number of subjects in period 1	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream
Started	49	53	52
Completed	46	49	44
Not completed	3	4	8
Adverse event, non-fatal	1	-	-
Other	-	1	1
Subject request	-	1	4
Lost to follow-up	-	2	-
Lack of efficacy	2	-	1
Protocol deviation	-	-	2

Baseline characteristics

Reporting groups	
Reporting group title	DS107E Placebo cream
Reporting group description:	
DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance.	
Reporting group title	DS107E DGLA 1% cream
Reporting group description:	
DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.	
Reporting group title	DS107E DGLA 5% cream
Reporting group description:	
DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks	

Reporting group values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream
Number of subjects	49	53	52
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	14	7	11
Adults (18-64 years)	35	46	41
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	22.7	23.1	22.8
standard deviation	± 6.33	± 6.06	± 5.78
Gender categorical Units: Subjects			
Female	35	45	34
Male	14	8	18
Race Units: Subjects			
White	48	52	50
Black	0	1	0
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Other	0	0	1
Mixed	1	0	1
Missing	0	0	0

Reporting group values	Total		
Number of subjects	154		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	32		
Adults (18-64 years)	122		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	114		
Male	40		
Race Units: Subjects			
White	150		
Black	1		
Asian	0		
American Indian or Alaska Native	0		
Native Hawaiian or other Pacific Islander	0		
Other	1		
Mixed	2		
Missing	0		

End points

End points reporting groups

Reporting group title	DS107E Placebo cream
Reporting group description:	
DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance.	
Reporting group title	DS107E DGLA 1% cream
Reporting group description:	
DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.	
Reporting group title	DS107E DGLA 5% cream
Reporting group description:	
DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks	

Primary: Change in Investigators Global Assessment (IGA) of acne severity from baseline to the end of week 12.

End point title	Change in Investigators Global Assessment (IGA) of acne severity from baseline to the end of week 12.
End point description:	
Mean Change from Baseline of IGA Score to Week 12.	
End point type	Primary
End point timeframe:	
Up to 12 weeks.	

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	50	44	
Units: IGA scores				
arithmetic mean (standard deviation)	-0.4 (± 0.75)	-0.3 (± 0.64)	-0.3 (± 0.56)	

Statistical analyses

Statistical analysis title	DS107E DGLA 1% Cream V Placebo
Comparison groups	DS107E Placebo cream v DS107E DGLA 1% cream
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.74
Method	ANCOVA
Parameter estimate	Mean Change in IGA Score
Point estimate	0.1

Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.1
upper limit	0.3

Statistical analysis title	DS107E DGLA 5% Cream V Placebo
Comparison groups	DS107E Placebo cream v DS107E DGLA 5% cream
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.909
Method	ANCOVA
Parameter estimate	Mean Change in IGA Score
Point estimate	0.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	0
upper limit	0.4

Primary: Change of total count of acne lesions from baseline to the end of week 12

End point title	Change of total count of acne lesions from baseline to the end of week 12

End point description:

Mean Change from Baseline of Total Lesion Count to Week 12.

End point type	Primary

End point timeframe:

Up to 12 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	50	44	
Units: Total lesion count				
arithmetic mean (standard deviation)	-32.5 (± 29.42)	-30.5 (± 32.03)	-27.1 (± 25.68)	

Statistical analyses

Statistical analysis title	DS107E DGLA 1% Cream V Placebo
Comparison groups	DS107E Placebo cream v DS107E DGLA 1% cream
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.651
Method	ANCOVA
Parameter estimate	Mean Change in Total Lesion Count
Point estimate	2.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-6.9
upper limit	11.2

Statistical analysis title	DS107E DGLA 5% Cream V Placebo
Comparison groups	DS107E Placebo cream v DS107E DGLA 5% cream
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.876
Method	ANCOVA
Parameter estimate	Mean Change in Total Lesion Count
Point estimate	6.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.8
upper limit	15.9

Secondary: Change in Investigators Global Assessment (IGA) of acne severity after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment).

End point title	Change in Investigators Global Assessment (IGA) of acne severity after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment).

End point description:

Change in Investigators Global Assessment (IGA) of acne severity after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment).

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: IGA Scores				
arithmetic mean (standard deviation)				
Week 2	-0.1 (± 0.47)	-0.1 (± 0.43)	-0.1 (± 0.38)	
Week 4	-0.1 (± 0.47)	-0.1 (± 0.39)	-0.2 (± 0.43)	
Week 8	-0.4 (± 0.69)	-0.3 (± 0.55)	-0.3 (± 0.52)	
Week 12	-0.4 (± 0.75)	-0.3 (± 0.64)	-0.3 (± 0.56)	
Week 16	-0.3 (± 0.84)	-0.4 (± 0.79)	-0.4 (± 0.66)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total Lesion Count).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total Lesion Count).

End point description:

Mean Change from Baseline of Total Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total lesion count				
arithmetic mean (standard deviation)				
Change from Baseline to Week 2	-12.4 (± 16.27)	-14.8 (± 17.32)	-10.6 (± 19.09)	
Observed value Week 2	67.4 (± 46.41)	59.6 (± 34.06)	68.8 (± 37.95)	
Change from Baseline to Week 4	-22.4 (± 19.08)	-23.0 (± 19.58)	-17.0 (± 21.80)	
Observed value Week 4	52.6 (± 30.01)	51.4 (± 34.42)	60.8 (± 36.55)	
Change from Baseline to Week 8	-30.7 (± 28.81)	-26.5 (± 29.07)	-20.5 (± 42.98)	
Observed value Week 8	43.2 (± 29.97)	47.5 (± 40.8)	56.3 (± 42.98)	
Change from Baseline to Week 12	-32.5 (± 29.42)	-30.5 (± 32.03)	-27.1 (± 25.68)	
Observed value Week 12	41.5 (± 34.27)	43.8 (± 39.01)	50.4 (± 34.29)	
Change from Baseline to Week 16	-28.5 (± 30.99)	-34.3 (± 40.55)	-24.8 (± 35.53)	

Observed value Week 16	51.3 (± 48.17)	40.8 (± 32.00)	54.6 (± 41.63)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory Lesion Count).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory Lesion Count).

End point description:

Mean change from baseline of Inflammatory Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total count				
arithmetic mean (standard deviation)				
Week 2	-6.3 (± 8.38)	-7.0 (± 12.85)	-5.4 (± 10.00)	
Week 4	-12.4 (± 10.62)	-12.0 (± 12.04)	-10.4 (± 12.75)	
Week 8	-14.4 (± 12.44)	-13.6 (± 12.14)	-12.8 (± 14.46)	
Week 12	-15.5 (± 12.67)	-15.1 (± 13.48)	-14.6 (± 12.92)	
Week 16	-13.8 (± 13.56)	-15.9 (± 15.31)	-12.4 (± 19.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory Lesion Count).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of

	treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory Lesion Count).

End point description:

Mean change from baseline of Non-inflammatory Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total count				
arithmetic mean (standard deviation)				
Week 2	-6.1 (± 11.45)	-7.8 (± 16.45)	-5.1 (± 16.55)	
Week 4	-9.9 (± 11.73)	-10.9 (± 21.13)	-6.5 (± 18.34)	
Week 8	-16.2 (± 20.46)	-12.9 (± 26.40)	-7.6 (± 20.83)	
Week 12	-17.0 (± 22.72)	-15.4 (± 30.84)	-12.4 (± 19.16)	
Week 16	-14.9 (± 23.45)	-18.4 (± 38.74)	-12.4 (± 23.13)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory)

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory)

End point description:

Mean change from baseline of Inflammatory and Non-inflammatory Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total count				
arithmetic mean (standard deviation)				
Week 2	-12.4 (± 16.18)	-14.8 (± 17.34)	-10.5 (± 19.16)	
Week 4	-22.3 (± 19.17)	-22.9 (± 19.55)	-16.9 (± 21.85)	
Week 8	-30.6 (± 28.71)	-26.5 (± 28.98)	-20.4 (± 28.25)	
Week 12	-32.5 (± 29.22)	-30.5 (± 31.84)	-27.0 (± 25.61)	
Week 16	-28.8 (± 30.63)	-34.3 (± 40.47)	-24.7 (± 35.33)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total lesion count).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total lesion count).

End point description:

Mean Percent Change from Baseline of Total Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total lesion count				
arithmetic mean (standard deviation)				
Week 2	-16.9 (± 19.53)	-19.0 (± 21.19)	-14.1 (± 21.82)	
Week 4	-29.3 (± 24.52)	-31.8 (± 22.87)	-21.4 (± 25.72)	
Week 8	-41.4 (± 28.84)	-37.2 (± 33.55)	-26.4 (± 36.94)	
Week 12	-45.8 (± 27.37)	-40.0 (± 45.74)	-33.3 (± 36.02)	
Week 16	-37.3 (± 30.30)	-37.9 (± 63.23)	-30.0 (± 39.28)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory lesion count).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory lesion count).

End point description:

Mean Percent Change from Baseline of Inflammatory Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total count				
arithmetic mean (standard deviation)				
Week 2	-23.2 (± 32.41)	-12.3 (± 73.59)	-18.3 (± 27.01)	
Week 4	-41.7 (± 30.56)	-33.9 (± 54.63)	-32.3 (± 34.59)	
Week 8	-50.1 (± 36.89)	-43.6 (± 40.37)	-42.4 (± 38.84)	
Week 12	-53.3 (± 37.14)	-46.5 (± 73.84)	-47.6 (± 32.10)	
Week 16	-48.5 (± 39.47)	-52.4 (± 47.30)	-40.6 (± 42.96)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory lesion count).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory lesion count).

End point description:

Mean Percent Change from Baseline of Non-inflammatory Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total count				
arithmetic mean (standard deviation)				
Week 2	-4.4 (± 64.80)	-4.2 (± 82.82)	-1.7 (± 61.51)	
Week 4	-19.6 (± 36.05)	-13.3 (± 81.70)	36.9 (± 365.18)	
Week 8	-33.9 (± 33.64)	-14.9 (± 93.07)	27.2 (± 280.62)	
Week 12	-40.9 (± 32.07)	-11.7 (± 113.97)	10.9 (± 236.25)	
Week 16	-23.6 (± 54.52)	0.2 (± 157.74)	11.8 (± 225.53)	

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory).

End point title	Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory).

End point description:

Mean Percent Change from Baseline of Inflammatory and Non-inflammatory Lesion Count by Visit.

End point type	Secondary

End point timeframe:

Up to 16 weeks.

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Total count				
arithmetic mean (standard deviation)				
Week 2	-17.1 (± 19.76)	-19.1 (± 21.26)	-14.1 (± 21.92)	
Week 4	-29.2 (± 24.70)	-31.8 (± 22.86)	-21.4 (± 25.73)	
Week 8	-41.4 (± 29.00)	-37.2 (± 33.43)	-26.4 (± 36.93)	
Week 12	-45.9 (± 27.17)	-40.00 (± 45.60)	-33.3 (± 36.01)	
Week 16	-37.7 (± 30.07)	-38.0 (± 63.14)	-30.0 (± 39.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reduction of acne lesions by >30%

End point title	Time to Reduction of acne lesions by >30%

End point description:

Analysis of Time to Reduction of Total Lesion Count by >30% from Baseline.

End point type	Secondary

End point timeframe:

Up to 16 weeks

End point values	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	53	51	
Units: Events observed				
Event observed	40	42	34	
Censored	9	11	17	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 16 weeks.

Adverse event reporting additional description:

Any undesirable experience occurring to a patient that has signed the ICF, whether or not considered related to the investigational treatment. All Adverse Events must be recorded in the case report form, defining relationship to treatment and severity.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	DS107E Placebo cream

Reporting group description:

DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance.

Reporting group title	DS107E DGLA 1% cream

Reporting group description:

DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.

Reporting group title	DS107E DGLA 5% cream

Reporting group description:

DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks

Serious adverse events	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	DS107E Placebo cream	DS107E DGLA 1% cream	DS107E DGLA 5% cream
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 49 (42.86%)	18 / 53 (33.96%)	21 / 52 (40.38%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	1 / 49 (2.04%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	2 / 52 (3.85%)
occurrences (all)	0	1	2
Pyrexia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Oedema			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	3 / 49 (6.12%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	3	1	0
Menstrual discomfort			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	2	0
Premenstrual pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Premenstrual syndrome			

subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 49 (2.04%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Nasal congestion			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 49 (4.08%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Lymph node palpable			

subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Hand fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Road traffic accident			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 49 (10.20%)	1 / 53 (1.89%)	4 / 52 (7.69%)
occurrences (all)	6	2	9
Migraine			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	4
Gastrointestinal disorders			
Toothache			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	3 / 52 (5.77%)
occurrences (all)	0	1	3
Diarrhoea			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	6
Abdominal pain upper			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 49 (4.08%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0

Dermatitis allergic			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Alopecia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Angiokeratoma			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Muscle tightness			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 49 (8.16%)	3 / 53 (5.66%)	2 / 52 (3.85%)
occurrences (all)	4	4	2
Influenza			
subjects affected / exposed	0 / 49 (0.00%)	2 / 53 (3.77%)	2 / 52 (3.85%)
occurrences (all)	0	2	2

Pharyngitis			
subjects affected / exposed	1 / 49 (2.04%)	2 / 53 (3.77%)	1 / 52 (1.92%)
occurrences (all)	1	2	1
Gastroenteritis			
subjects affected / exposed	2 / 49 (4.08%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
Tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Viral infection			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Abscess			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Acute sinusitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Appendicitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1

Postoperative wound infection			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 May 2013	CRO name removed update to inclusion and exclusion criteria. Washout phase clarification Application of IMP clarification Baseline visit window clarification Concomitant medication clarification

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported