



Clinical trial results:

A Randomised, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Orally Administered DS107 in Adult Patients with Moderate to Severe Atopic Dermatitis

Summary

EudraCT number	2019-000932-25
Trial protocol	LV AT
Global end of trial date	14 September 2020

Results information

Result version number	v1
This version publication date	12 March 2022
First version publication date	12 March 2022

Trial information

Trial identification

Sponsor protocol code	DS107G-05-AD3
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03817190
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	DS Biopharma
Sponsor organisation address	Trintech Building, South County Business Park, Dublin 18, Ireland,
Public contact	Study Director, DS Biopharma, +353 1 2933590, dsbiopharma.regulatory@dsbiopharma.com
Scientific contact	Study Director, DS Biopharma, +353 1 2933590, dsbiopharma.regulatory@dsbiopharma.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 May 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 September 2020
Global end of trial reached?	Yes
Global end of trial date	14 September 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Efficacy Objective:

o To compare the efficacy of orally administered DS107 versus placebo, in the treatment of adult patients with moderate to severe Atopic Dermatitis (AD).

Safety Objective:

o To assess the safety of orally administered DS107 versus placebo, in adult patients with moderate to severe AD.

Protection of trial subjects:

The study was designed, conducted, and evaluated according to the study protocol and in compliance with the latest International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines on Good Clinical Practice (GCP) E6 and the ethical principles that have their origins in the World Medical Association Declaration of Helsinki, as well as with all national and local legal requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 September 2019
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	Poland: 47
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Germany: 63
Country: Number of subjects enrolled	Latvia: 31
Country: Number of subjects enrolled	United States: 75
Worldwide total number of subjects	219
EEA total number of subjects	144

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)	205
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in 50 sites across 5 countries.

Pre-assignment

Screening details:

The observation period per patient was 20 weeks (treatment duration: 16 weeks, follow-up period: 4 weeks). Nine visits were scheduled: Screening, Baseline, Week 1 (phone call), Week 4, 8, 12, 16 (end of treatment), 18 (follow-up 1) and 20 (follow-up 2).

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	Placebo

Arm description:

Patients randomised to placebo group received 4 placebo capsules administered orally once daily.

Arm type	Placebo
Investigational medicinal product name	Placebo capsules
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 placebo capsules orally administered once daily for 16 weeks.

Arm title	DS107 2000mg
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Arm description:

Patients randomised to DS107 2000mg group received 4 DS107 capsules administered orally once daily for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	DS107 Capsules
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2g DS107 (4 DS107 capsules) orally administered once daily for 16 weeks.

Number of subjects in period 1	Placebo	DS107 2000mg
Started	110	109
Completed	50	50
Not completed	60	59
Consent withdrawn by subject	12	8
Physician decision	5	1
Adverse Event	10	17
Early Termination by Sponsor	13	20
Other reason	2	1
Lost to follow-up	11	7
Lack of efficacy	7	5

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Patients randomised to placebo group received 4 placebo capsules administered orally once daily.	
Reporting group title	DS107 2000mg
Reporting group description:	
Patients randomised to DS107 2000mg group received 4 DS107 capsules administered orally once daily for 16 weeks.	

Reporting group values	Placebo	DS107 2000mg	Total
Number of subjects	110	109	219
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)	0	0	0
Adults (18-64 years)	105	100	205
From 65-84 years	5	9	14
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	37.95	38.83	
standard deviation	± 14.90	± 15.45	-
Gender categorical			
Units: Subjects			
Female	60	55	115
Male	50	54	104
Race			
Units: Subjects			
White	90	87	177
Black/African American	17	18	35
Asian	2	2	4
Other	1	2	3
Ethnicity			
Units: Subjects			
Hispanic or Latino	7	5	12
Not Hispanic or Latino	103	104	207

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Patients randomised to placebo group received 4 placebo capsules administered orally once daily.	
Reporting group title	DS107 2000mg
Reporting group description:	
Patients randomised to DS107 2000mg group received 4 DS107 capsules administered orally once daily for 16 weeks.	

Primary: Proportion of patients achieving a vIGA-ADTM score of 0 (clear) or 1 (almost clear) and a decrease of at least 2 points in vIGA-ADTM in treated population compared to placebo population from Baseline at Week 16.

End point title	Proportion of patients achieving a vIGA-ADTM score of 0 (clear) or 1 (almost clear) and a decrease of at least 2 points in vIGA-ADTM in treated population compared to placebo population from Baseline at Week 16.
End point description:	
Proportion of patients achieving a Validated Investigator Global Assessment Scale for Atopic Dermatitis score of 0 or 1 and a decrease of at least 2 points in vIGA-ADTM in treated population compared to placebo population from Baseline at Week 16 using GLMM.	
End point type	Primary
End point timeframe:	
Up to 16 Weeks.	

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	92		
Units: Number of Subjects				
Proportion of Patients	15	14		

Statistical analyses

Statistical analysis title	DS107 2000mg V Placebo
Comparison groups	Placebo v DS107 2000mg
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.688
Method	GLMM
Parameter estimate	Proportion of Subjects
Point estimate	-0.2277

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.0415
upper limit	0.586

Primary: Proportion of patients achieving EASI-75 ($\geq 75\%$ improvement from Baseline) in treated population compared to placebo population at Week 16.

End point title	Proportion of patients achieving EASI-75 ($\geq 75\%$ improvement from Baseline) in treated population compared to placebo population at Week 16.
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End point description:

End point type	Primary
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End point timeframe:

Up to 16 weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	93		
Units: Number of Subjects				
Proportion of Subjects	30	27		

Statistical analyses

Statistical analysis title	DS107 2000mg V Placebo
Comparison groups	Placebo v DS107 2000mg
Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4321
Method	GLMM
Parameter estimate	Proportion of Subjects
Point estimate	-0.276
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9185
upper limit	0.3665

Secondary: Proportion of patients achieving a vIGA-ADTM score of 0 (clear) or 1 (almost clear) and a decrease of at least 2 points in vIGA-ADTM in treated

population compared to placebo population from Baseline to Week 4, 8, 12, 18 and 20

End point title	Proportion of patients achieving a vIGA-ADTM score of 0 (clear) or 1 (almost clear) and a decrease of at least 2 points in vIGA-ADTM in treated population compared to placebo population from Baseline to Week 4, 8, 12, 18 and 20
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End point description:

Proportion of patients achieving a vIGA-ADTM score of 0 or 1 and a decrease of at least 2 points in vIGA-ADTM in treated population compared to placebo population from Baseline to Week 4, 8, 12, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point type	Secondary
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End point timeframe:

Up to 20 Weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	99		
Units: Number of Subjects				
Week 4	3	2		
Week 8	6	6		
Week 12	10	7		
Week 18	13	7		
Week 20	10	13		
Week 16 to Week 18	1	1		
Week 16 to Week 20	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients achieving EASI-75 ($\geq 75\%$ improvement from Baseline) in treated population compared to placebo population at Weeks 4, 8, 12, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point title	Proportion of patients achieving EASI-75 ($\geq 75\%$ improvement from Baseline) in treated population compared to placebo population at Weeks 4, 8, 12, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.
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End point description:

Proportion of patients achieving EASI-75 in treated population compared to placebo population at Weeks 4, 8, 12, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point type	Secondary
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End point timeframe:

Up to 20 Weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	99		
Units: Number of Subjects				
Week 4	8	8		
Week 8	15	7		
Week 12	19	10		
Week 18	21	20		
Week 20	23	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in vIGA-ADTM score in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.

End point title	Change from Baseline in vIGA-ADTM score in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.
End point description:	Change from Baseline in vIGA-ADTM score in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.
End point type	Secondary
End point timeframe:	Up to 20 Weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	109		
Units: vIGA-AD Score				
number (confidence interval 95%)				
Week 4	0.7843 (0.4869 to 1.0816)	-0.0454 (-0.4715 to 0.3807)		
Week 8	0.3487 (0.03437 to 0.6630)	0.2577 (-0.1929 to 0.7083)		
Week 12	0.1224 (-0.2109 to 0.4558)	0.3091 (-0.1687 to 0.7870)		
Week 16	0.2813 (-0.01342 to 0.5761)	0.1394 (-0.2781 to 0.5568)		
Week 18	0.0862 (-0.2366 to 0.4089)	0.1283 (-0.3349 to 0.5914)		
Week 18 V Last Visit	0.0689 (-0.2153 to 0.3531)	0.1024 (-0.3055 to 0.5102)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in EASI in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.

End point title	Change from Baseline in EASI in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.
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End point description:

End point type	Secondary
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End point timeframe:

Up to 20 Weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	109		
Units: EASI Score				
number (confidence interval 95%)				
Week 4	31.4509 (17.6525 to 45.2493)	3.5453 (- 16.1397 to 23.2303)		
Week 8	14.4747 (- 0.08487 to 29.0342)	8.8565 (- 11.9180 to 29.6310)		
Week 12	6.4487 (- 8.9305 to 21.8279)	10.4186 (- 11.6294 to 32.4667)		
Week 16	18.4269 (4.8107 to 32.0431)	3.5470 (- 15.6720 to 22.7661)		
Week 18	4.1677 (- 10.79008 to 19.1262)	3.1252 (- 18.2311 to 24.4815)		
Week 18 V Last Visit	2.6189 (- 53.4435 to 58.6812)	10.1487 (- 70.3673 to 90.6647)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients achieving a decrease of at least 4 points in worst

itch numeric rating scale (NRS) in treated population compared to placebo population from Baseline to Week 4, 8, 12, 16, 18 and 20.

End point title	Proportion of patients achieving a decrease of at least 4 points in worst itch numeric rating scale (NRS) in treated population compared to placebo population from Baseline to Week 4, 8, 12, 16, 18 and 20.
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End point description:

Proportion of patients achieving a decrease of at least 4 points in worst itch numeric rating scale in treated population compared to placebo population from Baseline to Week 4, 8, 12, 16, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point type	Secondary
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End point timeframe:

Up to 20 Weeks

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	99		
Units: Number of Patients				
Week 4	6	11		
Week 8	12	12		
Week 12	10	13		
Week 16	13	12		
Week 18	12	12		
Week 20	11	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients achieving a decrease of at least 3 points in worst itch NRS in treated population compared to placebo population from Baseline to Week 4, 8, 12, 16, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point title	Proportion of patients achieving a decrease of at least 3 points in worst itch NRS in treated population compared to placebo population from Baseline to Week 4, 8, 12, 16, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.
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End point description:

Proportion of patients achieving a decrease of at least 3 points in worst itch NRS in treated population compared to placebo population from Baseline to Week 4, 8, 12, 16, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point type	Secondary
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End point timeframe:

Up to 20 weeks

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	99		
Units: Number of Patients				
Week 4	12	19		
Week 8	18	22		
Week 12	21	21		
Week 16	20	22		
Week 18	17	16		
Week 20	16	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in worst itch NRS in treated population compared to placebo population to Week 4, 8, 12, 16, 18 and 20 and from Week 16 to Week 18 and 20.

End point title	Change from Baseline in worst itch NRS in treated population compared to placebo population to Week 4, 8, 12, 16, 18 and 20 and from Week 16 to Week 18 and 20.
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End point description:

End point type	Secondary
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End point timeframe:

Up to 20 weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	109		
Units: NRS				
number (confidence interval 95%)				
Week 4	1.9916 (1.1339 to 2.8493)	-0.5094 (-1.7037 to 0.6848)		
Week 8	1.2897 (0.4072 to 2.1723)	-0.2826 (-1.5060 to 0.9408)		
Week 12	0.8685 (-0.05200 to 1.7889)	-0.2133 (-1.4913 to 1.0646)		
Week 16	0.2244 (-0.7377 to 1.1865)	0.0258 (-1.3063 to 1.3579)		
Week 18	0.0905 (-0.9063 to 1.0873)	0.1468 (-1.2412 to 1.5348)		
Week 18 V Last Visit	0.0797 (-0.4720 to 0.6313)	0.1101 (-0.6686 to 0.8889)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients achieving EASI-50 ($\geq 50\%$ improvement from Baseline) in treated population compared to placebo population at Week 4, 8, 12, 16, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.

End point title	Proportion of patients achieving EASI-50 ($\geq 50\%$ improvement from Baseline) in treated population compared to placebo population at Week 4, 8, 12, 16, 18 and 20 and the change in proportion of patients from Week 16 to Week 18 and 20.
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End point description:

End point type	Secondary
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End point timeframe:

Up to 20 weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	99		
Units: Number of Participants				
Week 4	21	15		
Week 8	31	26		
Week 12	28	23		
Week 16	44	45		
Week 18	29	35		
Week 20	29	33		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Body Surface Area (BSA) affected by AD in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.

End point title	Change from Baseline in the Body Surface Area (BSA) affected by AD in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.
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End point description:

End point type	Secondary
End point timeframe:	
Up to 20 Weeks.	

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	109		
Units: BSA				
number (confidence interval 95%)				
Week 4	10.5575 (5.0467 to 16.0682)	-1.1911 (- 9.0736 to 6.6913)		
Week 8	7.0087 (1.1680 to 12.8495)	-0.2839 (- 8.6398 to 8.0720)		
Week 12	4.8296 (- 1.3215 to 10.9808)	-1.4232 (- 10.2908 to 7.4445)		
Week 16	6.5413 (1.1144 to 11.9681)	0.9244 (- 6.7736 to 8.6224)		
Week 18	1.4568 (- 4.4994 to 7.4129)	1.1470 (- 7.3990 to 9.6929)		
Week 18 V Last Visit	1.0590 (- 2.7322 to 4.8502)	0.7666 (- 4.7036 to 6.2369)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the SCORing Atopic Dermatitis (SCORAD) score in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.

End point title	Change from Baseline in the SCORing Atopic Dermatitis (SCORAD) score in treated population compared to placebo population to Weeks 4, 8, 12, 16, 18 and 20, and from Week 16 to Week 18 and 20.
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End point description:

End point type	Secondary
End point timeframe:	
Up to 20 Weeks.	

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	109		
Units: SCORAD Score				
number (confidence interval 95%)				
Week 4	15.7003 (8.8854 to 22.5153)	-0.9182 (- 10.6319 to 8.7955)		
Week 8	12.6334 (5.4389 to 19.8279)	-0.0799 (- 10.3366 to 10.1769)		
Week 12	4.0487 (- 3.5504 to 11.6478)	5.2956 (- 5.5928 to 16.1840)		
Week 16	7.3626 (0.6168 to 14.1084)	1.8419 (- 7.6580 to 11.3419)		
Week 18	1.8556 (- 5.5327 to 9.2439)	4.3232 (- 6.2245 to 14.8709)		
Week 18 V Last Visit	2.5318 (- 2.8807 to 7.9443)	2.2924 (- 5.4016 to 9.9865)		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of treatment emergent adverse events (TEAEs) and serious adverse events (SAEs).

End point title	Incidence of treatment emergent adverse events (TEAEs) and serious adverse events (SAEs).
End point description:	Incidence of treatment emergent adverse events (TEAEs) and serious adverse events (SAEs).
End point type	Secondary
End point timeframe:	Up to 20 Weeks.

End point values	Placebo	DS107 2000mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	109		
Units: Number of AEs				
All AEs	58	62		
Serious AEs	5	5		
AEs with relationship to study medication	23	42		
AEs leading to death	0	0		
AEs that led to withdrawal	12	17		
AEs before first administration of DS107	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 20 Weeks.

Adverse event reporting additional description:

An adverse event is any undesirable experience occurring to a patient that has signed the ICF and who has taken their first dose of the study drug, whether or not considered related to the investigational IMP(s). All Adverse Events (AEs) must be recorded in the CRF, defining relationship to IMP and severity. AEs should also be recorded by the Inves

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Patients randomised to placebo group received 4 placebo capsules administered orally once daily.

Reporting group title	DS107 2000mg
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Reporting group description:

Patients randomised to DS107 2000mg group received 4 DS107 capsules administered orally once daily for 16 weeks.

Serious adverse events	Placebo	DS107 2000mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 110 (4.55%)	5 / 109 (4.59%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis ulcerative			

subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	2 / 110 (1.82%)	2 / 109 (1.83%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Coronavirus infection			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	DS107 2000mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 110 (48.18%)	57 / 109 (52.29%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	

Fatigue			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Feeling abnormal			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
General physical health deterioration			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Peripheral swelling			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Sluggishness			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	2	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	2 / 110 (1.82%)	0 / 109 (0.00%)	
occurrences (all)	2	0	
Bronchitis			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Folliculitis			
subjects affected / exposed	1 / 110 (0.91%)	1 / 109 (0.92%)	
occurrences (all)	1	1	
Gastroenteritis			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Herpes simplex			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Herpes virus infection			

subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)
occurrences (all)	1	0
Hordeolum		
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)
occurrences (all)	0	1
Influenza		
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)
occurrences (all)	0	1
Nasal herpes		
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)
occurrences (all)	0	1
Nasopharyngitis		
subjects affected / exposed	3 / 110 (2.73%)	3 / 109 (2.75%)
occurrences (all)	3	4
Oral herpes		
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)
occurrences (all)	0	1
Otitis media		
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)
occurrences (all)	1	0
Pharyngitis		
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)
occurrences (all)	1	0
Pulpitis dental		
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)
occurrences (all)	1	0
Pyoderma		
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)
occurrences (all)	1	0
Respiratory tract infection		
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)
occurrences (all)	0	1
Respiratory tract infection viral		
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)
occurrences (all)	1	0
Rhinitis		

subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	1 / 109 (0.92%) 1	
Skin infection subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Superinfection bacterial subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	3 / 110 (2.73%) 3	0 / 109 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	1 / 109 (0.92%) 1	
Cough subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	2 / 109 (1.83%) 2	
Rhinitis allergic subjects affected / exposed occurrences (all)	2 / 110 (1.82%) 2	2 / 109 (1.83%) 2	
Throat tightness subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Psychiatric disorders Emotional distress subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Insomnia subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	2 / 109 (1.83%) 2	
Sleep disorder			

subjects affected / exposed occurrences (all)	2 / 110 (1.82%) 2	1 / 109 (0.92%) 1	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	1 / 109 (0.92%) 1	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	3 / 109 (2.75%) 3	
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Blood glucose increased subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Blood pressure increased subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Blood triglycerides increased subjects affected / exposed occurrences (all)	3 / 110 (2.73%) 3	1 / 109 (0.92%) 1	
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Foot fracture subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Heat stroke			

subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Sunburn subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Tooth injury subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Cardiac disorders Ventricular extrasystoles subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Dysgeusia subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Headache subjects affected / exposed occurrences (all)	10 / 110 (9.09%) 20	3 / 109 (2.75%) 4	
Hypoaesthesia subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	1 / 109 (0.92%) 1	
Eye disorders Conjunctivitis allergic subjects affected / exposed occurrences (all)	2 / 110 (1.82%) 2	1 / 109 (0.92%) 1	
Eczema eyelids subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Eye pain			

subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Macular oedema			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	3	
Abdominal distension			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	1 / 110 (0.91%)	3 / 109 (2.75%)	
occurrences (all)	1	3	
Abdominal pain upper			
subjects affected / exposed	1 / 110 (0.91%)	3 / 109 (2.75%)	
occurrences (all)	1	3	
Constipation			
subjects affected / exposed	1 / 110 (0.91%)	1 / 109 (0.92%)	
occurrences (all)	1	1	
Diarrhoea			
subjects affected / exposed	4 / 110 (3.64%)	21 / 109 (19.27%)	
occurrences (all)	5	27	
Dyspepsia			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Faeces soft			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Functional gastrointestinal disorder			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	

Gastroesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Haematochezia subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Haemorrhoids thrombosed subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Lip swelling subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Nausea subjects affected / exposed occurrences (all)	2 / 110 (1.82%) 2	6 / 109 (5.50%) 6	
Toothache subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Vomiting subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	1 / 109 (0.92%) 1	
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Alopecia areata subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Dermatitis atopic subjects affected / exposed occurrences (all)	26 / 110 (23.64%) 28	13 / 109 (11.93%) 15	
Diffuse alopecia subjects affected / exposed occurrences (all)	2 / 110 (1.82%) 2	0 / 109 (0.00%) 0	
Eczema			

subjects affected / exposed occurrences (all)	3 / 110 (2.73%) 3	13 / 109 (11.93%) 1	
Erythrodermic atopic dermatitis subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Intertrigo subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Pruritus subjects affected / exposed occurrences (all)	2 / 110 (1.82%) 2	2 / 109 (1.83%) 2	
Skin exfoliation subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Skin ulcer subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Solar dermatitis subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Renal and urinary disorders Urinary tract inflammation subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Infections and infestations Breast abscess subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	1 / 109 (0.92%) 1	
Metabolism and nutrition disorders Gout subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0	2 / 109 (1.83%) 2	
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	1 / 110 (0.91%) 1	0 / 109 (0.00%) 0	
Arthralgia			

subjects affected / exposed	0 / 110 (0.00%)	1 / 109 (0.92%)	
occurrences (all)	0	1	
Joint hyperextension			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Muscle spasms			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 110 (0.91%)	0 / 109 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 October 2019	Update to 24-hour contact number. Clarification of Inclusion Criteria. Clarification of Exclusion Criteria. Clarification of DGLA Plasma Concentration Sampling. Clarification of IMP administration and emollient use on day of visit. Clarification of AE and SAE reporting. Primary variables analysis updated. Open Label Safety Study Removed.
18 March 2020	Addition of Interim Analysis Section. Addition of COVID-19 Contingency section.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported