Clinical trial results:
A phase 2b randomized, double-blind, placebo controlled, multi-center 12-week study with an additional 40-week follow-up assessment of efficacy, safety and tolerability of M1095 in subjects with moderate to severe chronic plaque-type psoriasis

Summary

EudraCT number	2017-004611-38
Trial protocol	CZ BG HU
Global end of trial date	26 March 2020

Results information

Result version number	v1 (current)
This version publication date	12 April 2021
First version publication date	12 April 2021

Trial information

Trial identification

Sponsor protocol code	AV002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03384745
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bond Avillion 2 Development LP
Sponsor organisation address	Sarnia House, Le Truchot, St Peter Port, Guernsey, GY1 1GR
Public contact	Alun Morris, Avillion LLP , +44 (0)203 764 9530, avillion@avillionllp.com
Scientific contact	Alun Morris, Avillion LLP, +44 (0)203 764 9530, avillion@avillionllp.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	25 August 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of four dose regimens of M1095 (Solenokimab) compared to placebo on achievement of an Investigator's Global Assessment (IGA) score of 0 or 1 after 12 weeks of treatment in subjects with moderate to severe chronic plaque-type psoriasis.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles of the International Council for Harmonization (ICH) guideline for Good Clinical Practice (GCP) and the World Medical Association Declaration of Helsinki, 2013, as well as with applicable local regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 July 2018
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: 58
Country: Number of subjects enrolled	Bulgaria: 56
Country: Number of subjects enrolled	Czechia: 85
Country: Number of subjects enrolled	Germany: 14
Country: Number of subjects enrolled	Hungary: 39
Country: Number of subjects enrolled	Canada: 74
Country: Number of subjects enrolled	United States: 57
Worldwide total number of subjects	383
EEA total number of subjects	252

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)	347
From 65 to 84 years	36
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

47 sites were initiated in Europe (Bulgaria, Czech Republic, Germany, Hungary and Poland) and North America (USA and Canada). Subjects were screened at 42 sites and randomized at 41 sites.

Pre-assignment

Screening details:

The study consisted of a 4-week screening period (Week -4 to Week 0).

Period 1

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

Blinding implementation details:

The study was double-blind, with the subject, investigator and project team staff at the Contract Research Organization remaining blinded throughout.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo / M1095 120 mg

Arm description:

Placebo was given at Week 0, 1, 2, 3, 4, 6, 8 and 10, then M1095, 120 mg was given at Week 12, 14, 16, and every four weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo will be given at Week 0, 1, 2, 3, 4, 6, 8 and 10

Arm title	Secukinumab

Arm description:

Secukinumab 300 mg was given at Week 0, 1, 2, 3, 4, 8, 12 and every four weeks.

Arm type	Active comparator
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	SECUKINUMAB
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab, 300mg, given at Week 0, 1, 2, 3, 4, 8, 12 and every four weeks.

Arm title	M1095 30 mg

Arm description:

M1095 30 mg was given at Week 0, 2, 4, 8, 12 and every four weeks.

Arm type	Experimental

Investigational medicinal product name	M1095
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

M1095, 30 mg, given at Week 0, 2, 4, 8, 12 and every four weeks.

Arm title	M1095 60 mg

Arm description:

M1095 60 mg was given at Week 0, 2, 4, 8, 12 and every four weeks.

Arm type	Experimental
Investigational medicinal product name	M1095
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

M1095, 60 mg, given at Week 0, 2, 4, 8, 12 and every four weeks.

Arm title	M1095 120 mg - regimen 1

Arm description:

M1095 120 mg was given at Week 0, 2, 4, 8, 12 and every eight weeks.

Arm type	Experimental
Investigational medicinal product name	M1095
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

M1095, 120 mg, given at Week 0, 2, 4, 8, 12 and every eight weeks.

Arm title	M1095 120 mg - regimen 2

Arm description:

M1095 120 mg was given at Week 0, 2, 4, 6, 8, 10, 12 and every four weeks.

Arm type	Experimental
Investigational medicinal product name	M1095
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

M1095, 120 mg, given at Week 0, 2, 4, 8, 12 and every eight weeks.

Number of subjects in period 1[1]	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg
Started	52	53	52
Completed	45	49	51
Not completed	7	4	1
Consent withdrawn by subject	5	3	-

Worsening disease	-	-	-
Death	-	-	-
Adverse event	2	-	1
Lost to follow-up	-	1	-
Protocol deviation	-	-	-

Number of subjects in period 1[1]	M1095 60 mg	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2
Started	52	53	51
Completed	48	45	43
Not completed	4	8	8
Consent withdrawn by subject	1	2	2
Worsening disease	-	-	1
Death	1	-	-
Adverse event	1	4	3
Lost to follow-up	1	1	2
Protocol deviation	-	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: A total of 383 subjects were screened resulting in 313 randomized subjects.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo / M1095 120 mg
Reporting group description:	
Placebo was given at Week 0, 1, 2, 3, 4, 6, 8 and 10, then M1095, 120 mg was given at Week 12, 14, 16, and every four weeks.	
Reporting group title	Secukinumab
Reporting group description:	
Secukinumab 300 mg was given at Week 0, 1, 2, 3, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 30 mg
Reporting group description:	
M1095 30 mg was given at Week 0, 2, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 60 mg
Reporting group description:	
M1095 60 mg was given at Week 0, 2, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 120 mg - regimen 1
Reporting group description:	
M1095 120 mg was given at Week 0, 2, 4, 8, 12 and every eight weeks.	
Reporting group title	M1095 120 mg - regimen 2
Reporting group description:	
M1095 120 mg was given at Week 0, 2, 4, 6, 8, 10, 12 and every four weeks.	

Reporting group values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg
Number of subjects	52	53	52
Age categorical Units: Subjects			
<45 Years	20	24	20
≥45 -<65 Years	29	24	29
≥65 Years	3	5	3
Gender categorical Units: Subjects			
Female	13	15	16
Male	39	38	36

Reporting group values	M1095 60 mg	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2
Number of subjects	52	53	51
Age categorical Units: Subjects			
<45 Years	24	27	28
≥45 -<65 Years	23	23	20
≥65 Years	5	3	3
Gender categorical Units: Subjects			
Female	14	10	17
Male	38	43	34

Reporting group values	Total		

Number of subjects	313		
Age categorical Units: Subjects			
<45 Years	143		
≥45 -<65 Years	148		
≥65 Years	22		
Gender categorical Units: Subjects			
Female	85		
Male	228		

End points

End points reporting groups

Reporting group title	Placebo / M1095 120 mg
Reporting group description:	
Placebo was given at Week 0, 1, 2, 3, 4, 6, 8 and 10, then M1095, 120 mg was given at Week 12, 14, 16, and every four weeks.	
Reporting group title	Secukinumab
Reporting group description:	
Secukinumab 300 mg was given at Week 0, 1, 2, 3, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 30 mg
Reporting group description:	
M1095 30 mg was given at Week 0, 2, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 60 mg
Reporting group description:	
M1095 60 mg was given at Week 0, 2, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 120 mg - regimen 1
Reporting group description:	
M1095 120 mg was given at Week 0, 2, 4, 8, 12 and every eight weeks.	
Reporting group title	M1095 120 mg - regimen 2
Reporting group description:	
M1095 120 mg was given at Week 0, 2, 4, 6, 8, 10, 12 and every four weeks.	

Primary: IGA Response Rates (NRI) at Week 12

End point title	IGA Response Rates (NRI) at Week 12
End point description:	
End point type	Primary
End point timeframe:	
At Week 12	

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	53	52	52
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 6.8)	77.4 (63.8 to 87.7)	48.1 (34.0 to 62.4)	84.6 (71.9 to 93.1)

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: percentage of participants				

number (confidence interval 95%)	77.4 (63.8 to 87.7)	88.2 (76.1 to 95.6)		

Statistical analyses

Statistical analysis title	Secukinumab vs placebo
Comparison groups	Placebo / M1095 120 mg v Secukinumab
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Cochran-Mantel-Haenszel

Notes:

[1] - Confidence interval and P-value are derived from two-sided Cochran-Mantel-Haenszel test stratified by actual weight category and prior biologic use stratum. Confidence interval is not presented as it was not evaluable.

Statistical analysis title	M1095 30 mg vs placebo
Comparison groups	Placebo / M1095 120 mg v M1095 30 mg
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Cochran-Mantel-Haenszel

Notes:

[2] - Confidence interval and P-value are derived from two-sided Cochran-Mantel-Haenszel test stratified by actual weight category and prior biologic use stratum. Confidence interval is not presented as it was not evaluable.

Statistical analysis title	M1095 60 mg vs placebo
Comparison groups	M1095 60 mg v Placebo / M1095 120 mg
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Cochran-Mantel-Haenszel

Notes:

[3] - Confidence interval and P-value are derived from two-sided Cochran-Mantel-Haenszel test stratified by actual weight category and prior biologic use stratum. Confidence interval is not presented as it was not evaluable.

Statistical analysis title	M1095 120 mg - regimen 1 vs placebo
Comparison groups	Placebo / M1095 120 mg v M1095 120 mg - regimen 1
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Cochran-Mantel-Haenszel

Notes:

[4] - Confidence interval and P-value are derived from two-sided Cochran-Mantel-Haenszel test stratified by actual weight category and prior biologic use stratum. Confidence interval is not presented as it was not evaluable.

Statistical analysis title	M1095 120 mg - regimen 2 vs placebo
Comparison groups	Placebo / M1095 120 mg v M1095 120 mg - regimen 2
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	Cochran-Mantel-Haenszel

Notes:

[5] - Confidence interval and P-value are derived from two-sided Cochran-Mantel-Haenszel test stratified by actual weight category and prior biologic use stratum. Confidence interval is not presented as it was not evaluable.

Secondary: Number of subjects with treatment emergent adverse events

End point title	Number of subjects with treatment emergent adverse events

End point description:

End point type	Secondary

End point timeframe:

Screening until early discontinuation

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	53	52	52
Units: Number of subjects				
Any TEAE	27	41	40	36
Any trial drug related TEAE	10	17	15	10
Any serious TEAE	1	2	4	5
Any trial drug related serious TEAE	1	1	0	0
Any TEAE leading to treatment interruption	0	2	5	1
Any drug related TEAE-treatment interruptions	0	1	1	0
Any TEAE leading to treatment discontinuation	2	0	1	2
Any TEAE leading to death	0	0	0	1
Any trial drug related TEAE leading to death	0	0	0	0

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: Number of subjects				
Any TEAE	34	38		

Any trial drug related TEAE	13	16		
Any serious TEAE	3	3		
Any trial drug related serious TEAE	0	0		
Any TEAE leading to treatment interruption	3	1		
Any drug related TEAE-treatment interruptions	0	0		
Any TEAE leading to treatment discontinuation	4	3		
Any TEAE leading to death	0	0		
Any trial drug related TEAE leading to death	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Psoriasis Area Severity Index 100 Responses

End point title	Percentage of Participants with Psoriasis Area Severity Index 100 Responses

End point description:

End point type	Secondary

End point timeframe:

At Weeks 12, 24, 36, and 48

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	53	52	52
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12	0.0 (0.0 to 6.8)	28.3 (16.8 to 42.3)	17.3 (8.2 to 30.3)	23.1 (12.5 to 36.8)
Week 24	34.6 (22.0 to 49.1)	34.0 (21.5 to 48.3)	42.3 (28.7 to 56.8)	40.4 (27.0 to 54.9)
Week 36	30.8 (18.7 to 45.1)	39.6 (26.5 to 54.0)	30.8 (18.7 to 45.1)	34.6 (22.0 to 49.1)
Week 48	44.2 (30.5 to 58.7)	43.4 (29.8 to 57.7)	32.7 (20.3 to 47.1)	44.2 (30.5 to 58.7)

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: Percentage of participants				
number (confidence interval 95%)				

Week 12	37.7 (24.8 to 52.1)	33.3 (20.8 to 47.9)		
Week 24	43.4 (29.8 to 57.7)	56.9 (42.2 to 70.7)		
Week 36	35.8 (23.1 to 50.2)	45.1 (31.1 to 59.7)		
Week 48	49.1 (35.1 to 63.2)	52.9 (38.5 to 67.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Psoriasis Area Severity Index 90 Responses

End point title	Percentage of Participants with Psoriasis Area Severity Index 90 Responses

End point description:

End point type	Secondary

End point timeframe:

Art Week 12, 24, 36, 48

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	53	52	52
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12	0.0 (0.0 to 6.8)	64.2 (49.8 to 76.9)	36.5 (23.6 to 51.0)	65.4 (50.9 to 78.0)
Week 24	69.2 (54.9 to 81.3)	79.2 (65.9 to 89.2)	67.3 (52.9 to 79.7)	90.4 (79.0 to 96.8)
Week 36	71.2 (56.9 to 82.9)	69.8 (55.7 to 81.7)	69.2 (54.9 to 81.3)	73.1 (59.0 to 84.4)
Week 48	76.9 (63.2 to 87.5)	69.8 (55.7 to 81.7)	69.2 (54.9 to 81.3)	80.8 (67.5 to 90.4)

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12	69.8 (55.7 to 81.7)	76.5 (62.5 to 87.2)		
Week 24	79.2 (65.9 to 89.2)	84.3 (71.4 to 93.0)		

Week 36	73.6 (59.7 to 84.7)	80.4 (66.9 to 90.2)		
Week 48	75.5 (61.7 to 86.2)	72.5 (58.3 to 84.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Psoriasis Area Severity Index 75 Responses

End point title	Percentage of Participants with Psoriasis Area Severity Index 75 Responses
End point description:	
End point type	Secondary
End point timeframe: At Week 12, 24, 36, and 48	

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	53	52	52
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12	0.0 (0.0 to 6.8)	90.6 (79.3 to 96.9)	65.4 (50.9 to 78.0)	88.5 (76.6 to 95.6)
Week 24	84.6 (71.9 to 93.1)	88.7 (77.0 to 95.7)	94.2 (84.1 to 98.8)	98.1 (89.7 to 100.0)
Week 36	84.6 (71.9 to 93.1)	86.8 (74.7 to 94.5)	94.2 (84.1 to 98.8)	86.5 (74.2 to 94.4)
Week 48	84.6 (71.9 to 93.1)	84.9 (72.4 to 93.3)	84.6 (71.9 to 93.1)	90.4 (79.0 to 96.8)

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12	84.9 (72.4 to 93.3)	90.2 (78.6 to 96.7)		
Week 24	90.6 (79.3 to 96.9)	92.2 (81.1 to 97.8)		
Week 36	83.0 (70.2 to 91.9)	88.2 (76.1 to 95.6)		
Week 48	81.1 (68.0 to 90.6)	80.4 (66.9 to 90.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change from Baseline in Body Surface Area

End point title	Percentage Change from Baseline in Body Surface Area

End point description:

End point type	Secondary

End point timeframe:

At Week 12, 24, 36 and 48

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	53	52	52
Units: Change				
least squares mean (standard error)				
Week 12	2.0 (± 1.20)	-19.8 (± 1.21)	-18.6 (± 1.20)	-21.2 (± 1.21)
Week 24	-20.6 (± 0.85)	-22.2 (± 0.85)	-24.0 (± 0.85)	-24.3 (± 0.85)
Week 36	-22.7 (± 0.77)	-22.8 (± 0.77)	-23.7 (± 0.77)	-24.7 (± 0.77)
Week 48	-23.3 (± 0.77)	-23.0 (± 0.78)	-24.0 (± 0.77)	-24.7 (± 0.78)

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: Change				
least squares mean (standard error)				
Week 12	-20.6 (± 1.19)	-21.0 (± 1.22)		
Week 24	-23.3 (± 0.84)	-23.2 (± 0.86)		
Week 36	-23.3 (± 0.76)	-23.3 (± 0.78)		
Week 48	-23.5 (± 0.77)	-23.5 (± 0.78)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change from Baseline in Psoriasis Area Severity Index

End point title	Percentage Change from Baseline in Psoriasis Area Severity Index

End point description:

End point type	Secondary

End point timeframe:

At Week 12, 24, 36 and 48

End point values	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg	M1095 60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	53	52	52
Units: Percentage change				
least squares mean (standard error)				
Week 12	1.92 (± 2.725)	-89.72 (± 2.730)	-78.99 (± 2.724)	-91.50 (± 2.729)
Week 24	-86.78 (± 2.315)	-90.97 (± 2.320)	-92.48 (± 2.314)	-96.42 (± 2.319)
Week 36	-88.22 (± 2.503)	-90.01 (± 2.507)	-90.55 (± 2.502)	-95.05 (± 2.506)
Week 48	-89.92 (± 2.306)	-90.58 (± 2.310)	-92.13 (± 2.305)	-95.77 (± 2.309)

End point values	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	51		
Units: Percentage change				
least squares mean (standard error)				
Week 12	-88.80 (± 2.698)	-91.04 (± 2.755)		
Week 24	-91.80 (± 2.292)	-94.36 (± 2.340)		
Week 36	-90.32 (± 2.477)	-93.93 (± 2.530)		
Week 48	-91.95 (± 2.282)	-93.78 (± 2.330)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Screening until early discontinuation	
Adverse event reporting additional description:	
"Placebo/120mg" group includes data from active treatment only i.e., after Week 12.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups	
Reporting group title	Placebo / M1095 120 mg
Reporting group description:	
Placebo, given at Week 0, 1, 2, 3, 4, 6, 8 and 10, then M1095, 120 mg, given at Week 12, 14, 16, and every four weeks.	
Reporting group title	Secukinumab
Reporting group description:	
Secukinumab, 300 mg, given at Week 0, 1, 2, 3, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 30 mg
Reporting group description:	
M1095, 30 mg, given at Week 0, 2, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 60 mg
Reporting group description:	
M1095, 60 mg, given at Week 0, 2, 4, 8, 12 and every four weeks.	
Reporting group title	M1095 120 mg - regimen 1
Reporting group description:	
M1095, 120 mg, given at Week 0, 2, 4, 8, 12 and every eight weeks.	
Reporting group title	M1095 120 mg - regimen 2
Reporting group description:	
M1095, 120 mg, given at Week 0, 2, 4, 6, 8, 10, 12 and every four weeks.	

Serious adverse events	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 49 (2.04%)	2 / 53 (3.77%)	4 / 52 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Forearm Fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Upper Limb Fracture			

subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Atrial Fibrillation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary Failure			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Myocardial Infarction			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Nervous system disorders			
Neuroglycopenia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic Ischaemic Neuropathy			

subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Gastrointestinal disorders			
Salivary Gland Calculus			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Renal Colic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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
Infectious Pleural Effusion			

subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Candidiasis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal Candidiasis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	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

Serious adverse events	M1095 60 mg	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 52 (9.62%)	3 / 53 (5.66%)	3 / 51 (5.88%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Forearm Fracture			
subjects affected / exposed	1 / 52 (1.92%)	0 / 53 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Limb Fracture			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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

Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 52 (1.92%)	0 / 53 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Cardiopulmonary Failure			
subjects affected / exposed	1 / 52 (1.92%)	0 / 53 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	1 / 52 (1.92%)	0 / 53 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuroglycopenia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Eye disorders			
Optic Ischaemic Neuropathy			
subjects affected / exposed	1 / 52 (1.92%)	0 / 53 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Salivary Gland Calculus			

subjects affected / exposed	0 / 52 (0.00%)	1 / 53 (1.89%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 52 (0.00%)	1 / 53 (1.89%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 52 (0.00%)	1 / 53 (1.89%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Pleural Effusion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Oesophageal Candidiasis			

subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Oropharyngeal Candidiasis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	0 / 51 (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
Pneumonia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo / M1095 120 mg	Secukinumab	M1095 30 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 49 (32.65%)	31 / 53 (58.49%)	25 / 52 (48.08%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 49 (2.04%)	3 / 53 (5.66%)	3 / 52 (5.77%)
occurrences (all)	1	3	3
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 49 (4.08%)	3 / 53 (5.66%)	0 / 52 (0.00%)
occurrences (all)	2	6	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 49 (2.04%)	3 / 53 (5.66%)	4 / 52 (7.69%)
occurrences (all)	1	5	8
Vomiting			

subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	3 / 52 (5.77%)
occurrences (all)	0	1	6
Angular Cheilitis			
subjects affected / exposed	2 / 49 (4.08%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	5 / 52 (9.62%)
occurrences (all)	0	0	5
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 49 (2.04%)	2 / 53 (3.77%)	4 / 52 (7.69%)
occurrences (all)	1	2	5
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 49 (0.00%)	2 / 53 (3.77%)	5 / 52 (9.62%)
occurrences (all)	0	2	7
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	7 / 49 (14.29%)	12 / 53 (22.64%)	7 / 52 (13.46%)
occurrences (all)	7	15	12
Upper respiratory tract infection			
subjects affected / exposed	0 / 49 (0.00%)	5 / 53 (9.43%)	5 / 52 (9.62%)
occurrences (all)	0	6	5
Oral Candidiasis			
subjects affected / exposed	3 / 49 (6.12%)	0 / 53 (0.00%)	3 / 52 (5.77%)
occurrences (all)	5	0	4
Tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 53 (1.89%)	3 / 52 (5.77%)
occurrences (all)	0	2	3
Influenza			
subjects affected / exposed	1 / 49 (2.04%)	1 / 53 (1.89%)	2 / 52 (3.85%)
occurrences (all)	2	1	2
Rhinitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2

Oral Fungal Infection			
subjects affected / exposed	2 / 49 (4.08%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	4	0	0
Erysipelas			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Otitis Externa			
subjects affected / exposed	1 / 49 (2.04%)	1 / 53 (1.89%)	1 / 52 (1.92%)
occurrences (all)	1	1	1
Conjunctivitis			
subjects affected / exposed	1 / 49 (2.04%)	3 / 53 (5.66%)	1 / 52 (1.92%)
occurrences (all)	1	3	2
Fungal Skin Infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 53 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	M1095 60 mg	M1095 120 mg - regimen 1	M1095 120 mg - regimen 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 52 (53.85%)	24 / 53 (45.28%)	25 / 51 (49.02%)
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 52 (5.77%)	0 / 53 (0.00%)	3 / 51 (5.88%)
occurrences (all)	3	0	3
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 52 (7.69%)	4 / 53 (7.55%)	1 / 51 (1.96%)
occurrences (all)	5	6	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 52 (5.77%)	4 / 53 (7.55%)	2 / 51 (3.92%)
occurrences (all)	6	5	2
Vomiting			
subjects affected / exposed	0 / 52 (0.00%)	1 / 53 (1.89%)	2 / 51 (3.92%)
occurrences (all)	0	1	2
Angular Cheilitis			
subjects affected / exposed	0 / 52 (0.00%)	3 / 53 (5.66%)	0 / 51 (0.00%)
occurrences (all)	0	3	0

Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	3 / 52 (5.77%)	0 / 53 (0.00%)	1 / 51 (1.96%)
occurrences (all)	4	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	6 / 52 (11.54%)	3 / 53 (5.66%)	5 / 51 (9.80%)
occurrences (all)	6	4	6
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 52 (0.00%)	2 / 53 (3.77%)	3 / 51 (5.88%)
occurrences (all)	0	2	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	14 / 52 (26.92%)	12 / 53 (22.64%)	6 / 51 (11.76%)
occurrences (all)	15	16	6
Upper respiratory tract infection			
subjects affected / exposed	6 / 52 (11.54%)	6 / 53 (11.32%)	3 / 51 (5.88%)
occurrences (all)	8	7	3
Oral Candidiasis			
subjects affected / exposed	3 / 52 (5.77%)	3 / 53 (5.66%)	4 / 51 (7.84%)
occurrences (all)	3	11	5
Tonsillitis			
subjects affected / exposed	2 / 52 (3.85%)	4 / 53 (7.55%)	1 / 51 (1.96%)
occurrences (all)	3	5	1
Influenza			
subjects affected / exposed	3 / 52 (5.77%)	1 / 53 (1.89%)	1 / 51 (1.96%)
occurrences (all)	3	1	1
Rhinitis			
subjects affected / exposed	3 / 52 (5.77%)	2 / 53 (3.77%)	0 / 51 (0.00%)
occurrences (all)	3	2	0
Oral Fungal Infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 53 (0.00%)	3 / 51 (5.88%)
occurrences (all)	1	0	3
Erysipelas			

subjects affected / exposed	0 / 52 (0.00%)	3 / 53 (5.66%)	0 / 51 (0.00%)
occurrences (all)	0	3	0
Otitis Externa			
subjects affected / exposed	3 / 52 (5.77%)	0 / 53 (0.00%)	0 / 51 (0.00%)
occurrences (all)	3	0	0
Conjunctivitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 53 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Fungal Skin Infection			
subjects affected / exposed	0 / 52 (0.00%)	3 / 53 (5.66%)	0 / 51 (0.00%)
occurrences (all)	0	3	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 April 2018	Main updates included clarifications for IMP reconstitution, ICF use for skin evaluation and pregnant partners, and blinding methods, as well as changes to timings of scheduled assessments.
16 October 2018	Main updates as a result of this amendment included clarifications for eligibility criteria, study endpoints, null hypotheses, unblinding, prohibited treatments for psoriasis, contraception requirements, and ICF use for subject expense reimbursement system.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported