Clinical trial results:
A Phase 2 Multicenter, Randomized, Placebo- and Active-Comparator-Controlled, Dose-Ranging Trial to Evaluate CNTO1959 for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis (X-PLORE)

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2011-001066-17
Trial protocol	DE BE
Global end of trial date	05 August 2013

Results information

Result version number	v2 (current)
This version publication date	15 July 2016
First version publication date	15 August 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSO2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01483599
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.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	20 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 August 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of CNTO 1959 in the treatment of participants with moderate to severe plaque psoriasis.

Protection of trial subjects:

Safety evaluation of this study included physical examinations, detection of injection site and allergic reactions, electrocardiograms (ECGs), clinical laboratory tests, vital signs and concomitant medications. Safety was to be monitored through Week 52 for all participants. Adverse events (AEs) were reported throughout the study period.

Background therapy:

None

Evidence for comparator:

Adalimumab: Particpants receiving 80 mg adalimumab at Week 0, 40 mg at Week 1 and every other week to Week 39 as active comparator.

Actual start date of recruitment	25 October 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Canada: 83
Country: Number of subjects enrolled	Germany: 23
Country: Number of subjects enrolled	Poland: 55
Country: Number of subjects enrolled	United States: 127
Worldwide total number of subjects	293
EEA total number of subjects	83

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	272
From 65 to 84 years	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 394 participants were screened, however 293 participants were randomized to receive treatment.

Period 1

Period 1 title	Controlled period (Week 0 - 16)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (CP)

Arm description:

Participants received placebo at Week 0, 4 and 8.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo at Week 0, 4 and 8.

Arm title	5 mg CNTO1959 (CP)

Arm description:

Participants received CNTO1959 5 milligram (mg) subcutaneously at Weeks 0 and 4.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 5 milligram (mg) subcutaneously at Weeks 0 and 4.

Arm title	15 mg CNTO1959 (CP)

Arm description:

Participants received CNTO1959 15 milligram (mg) subcutaneously at Weeks 0 and 8.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 15 milligram (mg) subcutaneously at Weeks 0 and 8.

Arm title	50 mg CNTO1959 (CP)

Arm description:

Participants received CNTO1959 50 milligram (mg) subcutaneously at weeks 0 and 4.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 50 milligram (mg) subcutaneously at weeks 0 and 4.

Arm title	100 mg CNTO1959 (CP)

Arm description:

Participants received CNTO1959 100 milligram (mg) subcutaneously at weeks 0 and 8.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 100 milligram (mg) subcutaneously at weeks 0 and 8.

Arm title	200 mg CNTO1959 (CP)

Arm description:

Participants received CNTO1959 200 milligram (mg) subcutaneously at weeks 0 and 4.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 200 milligram (mg) subcutaneously at weeks 0 and 4.

Arm title	Adalimumab (CP)

Arm description:

Adalimumab (Week 0 - 16, Open label): Participants received Adalimumab 80 milligram (mg) as open label at week 0 followed by 40 mg at week 1 and every second week up to week 15. Efficacy for this arm was evaluated by a blinded assessor.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received Adalimumab 80 milligram (mg) at week 0 followed by 40 mg at week 1 and every

second week up to week 15 (i.e., Weeks 3, 5, 7, etc.)

Number of subjects in period 1	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)
Started	42	41	41
Completed	39	38	41
Not completed	3	3	0
Adverse event, non-fatal	2	-	-
Other	-	2	-
Lost to follow-up	-	1	-
Lack of efficacy	1	-	-

Number of subjects in period 1	50 mg CNTO1959 (CP)	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)
Started	42	42	42
Completed	39	40	38
Not completed	3	2	4
Adverse event, non-fatal	1	1	4
Other	1	1	-
Lost to follow-up	1	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Adalimumab (CP)
Started	43
Completed	39
Not completed	4
Adverse event, non-fatal	3
Other	-
Lost to follow-up	1
Lack of efficacy	-

Period 2

Period 2 title	After Controlled period (Week 16 - 52)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo --> 100 mg CNTO1959 (after CP)

Arm description:

Participants received 100 mg CNTO1959 at Week 16 and every 8 weeks (q8w) thereafter through Week 40.

Arm type	Experimental
Investigational medicinal product name	CNTO1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 100 mg CNTO1959 at Week 16 and every 8 weeks (q8w) thereafter through Week 40.

Arm title	5 mg CNTO1959 (after CP)

Arm description:

Participants received CNTO1959 5 milligram (mg) subcutaneously at week 16, then every 12 weeks through Week 40.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 5 milligram (mg) subcutaneously at week 16, then every 12 weeks through Week 40.

Arm title	15 mg CNTO1959 (after CP)

Arm description:

Participants received CNTO1959 15 milligram (mg) subcutaneously at week 16 and then every 8 weeks through Week 40.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 15 milligram (mg) subcutaneously at week 16 and then every 8 weeks through Week 40.

Arm title	50 mg CNTO1959 (after CP)

Arm description:

Participants received CNTO1959 50 mg subcutaneously at week 16, then every 12 weeks through Week 40.

Arm type	Experimental

Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 50 mg subcutaneously at week 16, then every 12 weeks through Week 40.

Arm title	100 mg CNTO1959 (after CP)

Arm description:

Participants received CNTO1959 100 milligram (mg) subcutaneously at week 16, then every 8 weeks through Week 40.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 100 milligram (mg) subcutaneously at week 16, then every 8 weeks through Week 40.

Arm title	200 mg CNTO1959 (after CP)

Arm description:

Participants received CNTO1959 200 mg subcutaneously at week 16, then every 12 weeks through Week 40.

Arm type	Experimental
Investigational medicinal product name	CNTO 1959
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received CNTO1959 200 mg subcutaneously at week 16, then every 12 weeks through Week 40.

Arm title	Adalimumab (after CP)

Arm description:

Participants received Adalimumab 40 milligram (mg) at week 17 and every second week through Week 39 (i.e., Weeks 19, 21, 23, etc.)

Arm type	Experimental
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received Adalimumab 40 milligram (mg) at week 17 and every second week through Week 39 (i.e., Weeks 19, 21, 23, etc.)

Number of subjects in period 2	Placebo --> 100 mg CNTO1959 (after CP)	5 mg CNTO1959 (after CP)	15 mg CNTO1959 (after CP)
Started	39	38	41
Completed	37	29	37
Not completed	2	9	4
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	1	1	-
Other	1	-	4
Lost to follow-up	-	1	-
Lack of efficacy	-	5	-

Number of subjects in period 2	50 mg CNTO1959 (after CP)	100 mg CNTO1959 (after CP)	200 mg CNTO1959 (after CP)
Started	39	40	38
Completed	37	39	35
Not completed	2	1	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	-	-
Adverse event, non-fatal	-	-	1
Other	-	-	1
Lost to follow-up	-	1	-
Lack of efficacy	-	-	1

Number of subjects in period 2	Adalimumab (after CP)
Started	39
Completed	32
Not completed	7
Adverse event, serious fatal	-
Consent withdrawn by subject	1
Adverse event, non-fatal	1
Other	-
Lost to follow-up	1
Lack of efficacy	4

Baseline characteristics

Reporting groups	
Reporting group title	Placebo (CP)
Reporting group description:	
Participants received placebo at Week 0, 4 and 8.	
Reporting group title	5 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 5 milligram (mg) subcutaneously at Weeks 0 and 4.	
Reporting group title	15 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 15 milligram (mg) subcutaneously at Weeks 0 and 8.	
Reporting group title	50 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 50 milligram (mg) subcutaneously at weeks 0 and 4.	
Reporting group title	100 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 100 milligram (mg) subcutaneously at weeks 0 and 8.	
Reporting group title	200 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 200 milligram (mg) subcutaneously at weeks 0 and 4.	
Reporting group title	Adalimumab (CP)
Reporting group description:	
Adalimumab (Week 0 - 16, Open label): Participants received Adalimumab 80 milligram (mg) as open label at week 0 followed by 40 mg at week 1 and every second week up to week 15. Efficacy for this arm was evaluated by a blinded assessor.	

Reporting group values	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)
Number of subjects	42	41	41
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	41	40	39
From 65 to 84 years	1	1	2
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	45	45.2	43.8
standard deviation	± 11.97	± 13.92	± 13.5
Title for Gender			
Units: subjects			
Female	14	13	13
Male	28	28	28

Reporting group values	50 mg CNTO1959 (CP)	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)
Number of subjects	42	42	42

Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	41	36	40
From 65 to 84 years	1	6	2
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	42.6	45.3	45.1
standard deviation	± 12.14	± 13.72	± 10.96
Title for Gender Units: subjects			
Female	12	10	11
Male	30	32	31

Reporting group values	Adalimumab (CP)	Total	
Number of subjects	43	293	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	35	272	
From 65 to 84 years	8	21	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	47.5		
standard deviation	± 14.91	-	
Title for Gender Units: subjects			
Female	13	86	
Male	30	207	

End points

End points reporting groups

Reporting group title	Placebo (CP)
Reporting group description:	
Participants received placebo at Week 0, 4 and 8.	
Reporting group title	5 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 5 milligram (mg) subcutaneously at Weeks 0 and 4.	
Reporting group title	15 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 15 milligram (mg) subcutaneously at Weeks 0 and 8.	
Reporting group title	50 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 50 milligram (mg) subcutaneously at weeks 0 and 4.	
Reporting group title	100 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 100 milligram (mg) subcutaneously at weeks 0 and 8.	
Reporting group title	200 mg CNTO1959 (CP)
Reporting group description:	
Participants received CNTO1959 200 milligram (mg) subcutaneously at weeks 0 and 4.	
Reporting group title	Adalimumab (CP)
Reporting group description:	
Adalimumab (Week 0 - 16, Open label): Participants received Adalimumab 80 milligram (mg) as open label at week 0 followed by 40 mg at week 1 and every second week up to week 15. Efficacy for this arm was evaluated by a blinded assessor.	
Reporting group title	Placebo --> 100 mg CNTO1959 (after CP)
Reporting group description:	
Participants received 100 mg CNTO1959 at Week 16 and every 8 weeks (q8w) thereafter through Week 40.	
Reporting group title	5 mg CNTO1959 (after CP)
Reporting group description:	
Participants received CNTO1959 5 milligram (mg) subcutaneously at week 16, then every 12 weeks through Week 40.	
Reporting group title	15 mg CNTO1959 (after CP)
Reporting group description:	
Participants received CNTO1959 15 milligram (mg) subcutaneously at week 16 and then every 8 weeks through Week 40.	
Reporting group title	50 mg CNTO1959 (after CP)
Reporting group description:	
Participants received CNTO1959 50 mg subcutaneously at week 16, then every 12 weeks through Week 40.	
Reporting group title	100 mg CNTO1959 (after CP)
Reporting group description:	
Participants received CNTO1959 100 milligram (mg) subcutaneously at week 16, then every 8 weeks through Week 40.	
Reporting group title	200 mg CNTO1959 (after CP)
Reporting group description:	
Participants received CNTO1959 200 mg subcutaneously at week 16, then every 12 weeks through Week 40.	
Reporting group title	Adalimumab (after CP)
Reporting group description:	
Participants received Adalimumab 40 milligram (mg) at week 17 and every second week through Week	

39 (i.e., Weeks 19, 21, 23, etc.)

Subject analysis set title	Randomised Population
Subject analysis set type	Full analysis

Subject analysis set description:

All randomized subjects were analyzed according to their assigned treatment group regardless of the actual treatment received (ie, adalimumab, placebo, CNTO 1959). For subjects randomized to placebo, only subjects who crossed over to receive CNTO 1959 100 mg q8w at Week 16 were included in the efficacy summaries after Week 16.

Primary: Number of Participants With Cleared or Minimal (0 or 1) Physician's Global Assessment (PGA) Score at Week 16

End point title	Number of Participants With Cleared or Minimal (0 or 1) Physician's Global Assessment (PGA) Score at Week 16

End point description:

Percentage of participants with cleared or minimal (0 or 1) at Week 16 was reported. The PGA score is a numeric scale which is completed by the physician and was designed to evaluate the physician's overall assessment of the participant's psoriasis. Overall lesions will be graded as: 0=cleared, 1=minimal, 2=mild, 3=moderate,4=marked, and 5=severe.

End point type	Primary

End point timeframe:

Up to Week 16

End point values	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)	50 mg CNTO1959 (CP)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[1]	41[2]	41[3]	42[4]
Units: Participants	3	14	25	33

Notes:

[1] - Randomised Population

[2] - Randomised Population

[3] - Randomised Population

[4] - Randomised Population

End point values	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)	Adalimumab (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	42[5]	42[6]	43[7]	
Units: Participants	36	35	25	

Notes:

[5] - Randomised Population

[6] - Randomised Population

[7] - Randomised Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (CP) v 5 mg CNTO1959 (CP)

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (CP) v 15 mg CNTO1959 (CP)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (CP) v 50 mg CNTO1959 (CP)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (CP) v 100 mg CNTO1959 (CP)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo (CP) v 200 mg CNTO1959 (CP)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Number of Participants With 75 Percent (%) Improvement in Psoriasis Area and Severity Index (PASI) Score

End point title	Number of Participants With 75 Percent (%) Improvement in Psoriasis Area and Severity Index (PASI) Score

End point description:

Percentage of participants with >=75% improvement in PASI score at Week 16 from Baseline was reported. PASI is a widely used tool for the measurement of severity of psoriasis. The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. The scale ranges from 0 (best) to 72 (worst).

End point type	Secondary

End point timeframe:

Up to week 16

End point values	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)	50 mg CNTO1959 (CP)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[8]	41[9]	41[10]	42[11]
Units: Participants	2	18	31	34

Notes:

[8] - Randomised Population

[9] - Randomised Population

[10] - Randomised Population

[11] - Randomised Population

End point values	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)	Adalimumab (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	42[12]	42[13]	43[14]	
Units: Participants	33	34	30	

Notes:

[12] - Randomised Population

[13] - Randomised Population

[14] - Randomised Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (CP) v 5 mg CNTO1959 (CP)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	Cochran-Mantel-Haenszel

Notes:

[15] - p-Value was based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 90 kg, > 90 kg).

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (CP) v 15 mg CNTO1959 (CP)

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	Cochran-Mantel-Haenszel

Notes:

[16] - P-value was based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 90 kg, > 90 kg).

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (CP) v 50 mg CNTO1959 (CP)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [17]
Method	Cochran-Mantel-Haenszel

Notes:

[17] - P-value is based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 90 kg, > 90 kg).

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (CP) v 100 mg CNTO1959 (CP)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [18]
Method	Cochran-Mantel-Haenszel

Notes:

[18] - P-value is based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 90 kg, > 90 kg).

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo (CP) v 200 mg CNTO1959 (CP)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [19]
Method	Cochran-Mantel-Haenszel

Notes:

[19] - P-value is based on the Cochran-Mantel-Haenszel chi-square test stratified by baseline weight (≤ 90 kg, > 90 kg).

Secondary: Percentage of Participants Achieving the Physician's Global Assessment (PGA) score of cleared (0) or minimal (1) at Week 16 and Week 40

End point title	Percentage of Participants Achieving the Physician's Global Assessment (PGA) score of cleared (0) or minimal (1) at Week 16 and Week 40[20]

End point description:

Difference and the 95% confidence intervals in the percentage of participants achieving a PGA score of cleared (0) or minimal (1) at Week 16 and Week 40 between each of the CNTO 1959 treatment groups and the adalimumab treatment group was calculated. The PGA score is a numeric scale which was completed by the physician and was designed to evaluate the physician's overall assessment of the participant's psoriasis. Overall lesions was graded as: 0=cleared, 1=minimal, 2=mild, 3=moderate,4=marked, and 5=severe. The proportion of subjects achieving a PGA score of cleared (0) or minimal (1) was lower in theCNTO 1959 5 mg q12w group as compared with the adalimumab group, however the 95% CI incudes 0. Here 'n' signifies the number of participants evaluated at this time point.

End point type	Secondary

End point timeframe:

Weeks 16 and 40

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Subjects randomized in placebo group were not evaluated for this endpoint.

End point values	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)	50 mg CNTO1959 (CP)	100 mg CNTO1959 (CP)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	41	42	42
Units: `Percentage of participants				
number (confidence interval 95%)				
Week 16 (n=41, 41, 42, 42, 42, 43)	-24 (-44 to -4)	2.8 (-17.9 to 23.5)	20.4 (1.5 to 39.3)	27.7 (9.8 to 45.6)
Week 40 (n=34, 37, 38, 39, 37,37)	-15.4 (-37.7 to 6.9)	10.8 (-10.7 to 32.4)	22.7 (1.8 to 43.6)	28.7 (8.5 to 49)

End point values	200 mg CNTO1959 (CP)	Adalimumab (CP)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	43		
Units: `Percentage of participants				
number (confidence interval 95%)				
Week 16 (n=41, 41, 42, 42, 42, 43)	25.4 (7.2 to 43.6)	0 (0 to 0)		
Week 40 (n=34, 37, 38, 39, 37,37)	32.9 (13 to 52.8)	0 (0 to 0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Dermatology Life Quality Index (DLQI) at Week 16

End point title	Change from baseline in Dermatology Life Quality Index (DLQI) at Week 16

End point description:

The DLQI is a self-administered 10-item questionnaire that is used to assess 6 different aspects of quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Scores range from 0 (no impairment in quality of life) to 30 (most impairment in quality of life).

End point type	Secondary

End point timeframe:

Up to week 16

End point values	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)	50 mg CNTO1959 (CP)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[21]	39[22]	41[23]	40[24]
Units: Units on a scale				
arithmetic mean (standard deviation)	-2.3 (± 6.8)	-6.2 (± 5.24)	-10.3 (± 5.49)	-11.1 (± 7.38)

Notes:

[21] - Randomised Population

[22] - Randomised Population

[23] - Randomised Population

[24] - Randomised Population

End point values	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)	Adalimumab (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40[25]	39[26]	39[27]	
Units: Units on a scale				
arithmetic mean (standard deviation)	-10.8 (± 7.34)	-11.4 (± 6.83)	-10.1 (± 9)	

Notes:

[25] - Randomised Population

[26] - Randomised Population

[27] - Randomised Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (CP) v 5 mg CNTO1959 (CP)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [28]
Method	ANOVA

Notes:

[28] - P-value was based on the analysis of variance (ANOVA) on the van der Waerden normal scores adjusted with baseline weight (≤90 kg, >90 kg) as a binary covariate.

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (CP) v 15 mg CNTO1959 (CP)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [29]
Method	ANOVA

Notes:

[29] - P-value was based on the analysis of variance (ANOVA) on the van der Waerden normal scores adjusted with baseline weight (≤90 kg, >90 kg) as a binary covariate.

Statistical analysis title	Statistical analysis 3

Comparison groups	Placebo (CP) v 50 mg CNTO1959 (CP)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [30]
Method	ANOVA

Notes:

[30] - P-value was based on the analysis of variance (ANOVA) on the van der Waerden normal scores adjusted with baseline weight (≤90 kg, >90 kg) as a binary covariate.

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (CP) v 100 mg CNTO1959 (CP)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [31]
Method	ANOVA

Notes:

[31] - P-value is based on the analysis of variance (ANOVA) on the van der Waerden normal scores adjusted with baseline weight (≤90 kg, >90 kg) as a binary covariate.

Statistical analysis title	Statistical analysis 5
Comparison groups	200 mg CNTO1959 (CP) v Placebo (CP)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [32]
Method	ANOVA

Notes:

[32] - P-value is based on the analysis of variance (ANOVA) on the van der Waerden normal scores adjusted with baseline weight (≤90 kg, >90 kg) as a binary covariate.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to followup (Week 52)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Placebo (CP)

Reporting group description:

Placebo (Week 0 - 16): Placebo SC administration at Week 0, Week 4, and Week 8

Reporting group title	5 mg CNTO1959 (CP)

Reporting group description:

5 mg CNTO 1959 (Week 0 - 16): 5 mg CNTO1959 SC administration at Week 0 and Week 4

Reporting group title	15 mg CNTO1959 (CP)

Reporting group description:

15 mg CNTO1959 (Week 0 - 16): 15 mg CNTO1959 SC administration at Week 0 and Week 8

Reporting group title	50 mg CNTO1959 (CP)

Reporting group description:

50 mg CNTO1959 (Week 0 - 16): 50 mg CNTO1959 SC administration at Week 0 and Week 4

Reporting group title	100 mg CNTO1959 (CP)

Reporting group description:

100 mg CNTO1959 (Week 0 - 16): 100 mg CNTO1959 SC administration at Week 0 and Week 8

Reporting group title	200 mg CNTO1959 (CP)

Reporting group description:

200 mg CNTO1959 (Week 0 - 16): 200 mg CNTO1959 SC administration at Week 0 and Week 4

Reporting group title	Adalimumab (CP)

Reporting group description:

Adalimumab (Week 0 - 16): Patients receiving 80 mg adalimumab at Week 0, 40 mg at Week 1 and every other week to week 15

Reporting group title	Placebo --> 100 mg CNTO1959 (after CP)

Reporting group description:

Placebo --> 100 mg CNTO1959 (Week 16 - 40): Patients receiving Placebo at Week 0, 4, and week 8 --> receiving 100 mg CNTO1959 at Week 16 and every 8 weeks (q8w) thereafter through Week 40

Reporting group title	5 mg CNTO1959 (after CP)

Reporting group description:

5 mg CNTO1959 (after CP): patients receiving 5 mg CNTO1959 at Week 0 and 4 --> receiving 5 mg CNTO1959 at Week 16 and every 12 weeks (q12w) thereafter through Week 40

Reporting group title	15 mg CNTO1959 (after CP)

Reporting group description:

15 mg CNTO1959 (after CP): patients receiving 15 mg CNTO1959 at Week 0 and 8 --> receiving 15 mg CNTO1959 at Week 16 and every 8 weeks (q8w) thereafter through Week 40

Reporting group title	50 mg CNTO1959 (after CP)

Reporting group description:

50 mg CNTO1959 (after CP): patients receiving 50 mg CNTO1959 at Week 0 and 4 --> receiving 50 mg CNTO1959 at Week 16 and every 12 weeks (q12w) thereafter through Week 40

Reporting group title	100 mg CNTO1959 (after CP)

Reporting group description:

100 mg CNTO1959 (after CP): patients receiving 100 mg CNTO1959 at Week 0 and 8 --> receiving 100 mg CNTO1959 at Week 16 and every 8 weeks (q8w) thereafter through Week 40

Reporting group title	200 mg CNTO1959 (after CP)
Reporting group description:	
200 mg CNTO1959 (after CP): patients receiving 200 mg CNTO1959 at Week 0 and 4 --> receiving 200 mg CNTO1959 at Week 16 and every 12 weeks (q12w) thereafter through Week 40	
Reporting group title	Adalimumab (after CP)
Reporting group description:	
Adalimumab (after CP): Patients receiving 80 mg adalimumab at Week 0, 40 mg at Week 1 and every other week to week 15 --> receiving 40 mg adalimumab at week 17 and every other week through Week 39	

Serious adverse events	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	0 / 41 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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			
Atrial Flutter			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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			
Cerebrovascular Accident			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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			
Oesophagitis Haemorrhagic			

subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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
Umbilical Hernia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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
Reproductive system and breast disorders			
Uterine Prolapse			
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	0 / 41 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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			
Appendicitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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
Lung Abscess			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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
Metabolism and nutrition disorders			
Hyperglycaemia			

subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (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	50 mg CNTO1959 (CP)	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	0 / 41 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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			
Atrial Flutter			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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			
Cerebrovascular Accident			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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			
Oesophagitis Haemorrhagic			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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
Umbilical Hernia			

subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 41 (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
Reproductive system and breast disorders			
Uterine Prolapse			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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			
Appendicitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 41 (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
Lung Abscess			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 41 (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 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (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	Adalimumab (CP)	Placebo --> 100 mg CNTO1959 (after CP)	5 mg CNTO1959 (after CP)
Total subjects affected by serious			

adverse events			
subjects affected / exposed	1 / 43 (2.33%)	0 / 39 (0.00%)	2 / 38 (5.26%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 43 (2.33%)	0 / 39 (0.00%)	0 / 38 (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
Cardiac disorders			
Atrial Flutter			
subjects affected / exposed	1 / 43 (2.33%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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			
Oesophagitis Haemorrhagic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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
Umbilical Hernia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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
Reproductive system and breast disorders			
Uterine Prolapse			

subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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
Lung Abscess			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (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	15 mg CNTO1959 (after CP)	50 mg CNTO1959 (after CP)	100 mg CNTO1959 (after CP)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Haematoma			

subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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			
Atrial Flutter			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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 / 41 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Oesophagitis Haemorrhagic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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
Umbilical Hernia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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
Reproductive system and breast disorders			
Uterine Prolapse			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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			
Appendicitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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
Lung Abscess			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (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	200 mg CNTO1959 (after CP)	Adalimumab (after CP)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 38 (0.00%)	1 / 39 (2.56%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial Flutter			

subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Oesophagitis Haemorrhagic			
subjects affected / exposed	0 / 38 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Uterine Prolapse			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo (CP)	5 mg CNTO1959 (CP)	15 mg CNTO1959 (CP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 42 (30.95%)	15 / 41 (36.59%)	10 / 41 (24.39%)
Injury, poisoning and procedural complications			
Muscle Strain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 42 (2.38%)	1 / 41 (2.44%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 42 (2.38%)	3 / 41 (7.32%)	4 / 41 (9.76%)
occurrences (all)	1	3	4
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	3 / 42 (7.14%)	1 / 41 (2.44%)	1 / 41 (2.44%)
occurrences (all)	3	1	1
Influenza Like Illness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Injection Site Erythema			
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 42 (2.38%)	1 / 41 (2.44%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	4 / 42 (9.52%)	1 / 41 (2.44%)	0 / 41 (0.00%)
occurrences (all)	4	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 42 (2.38%)	1 / 41 (2.44%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Back Pain			
subjects affected / exposed	0 / 42 (0.00%)	3 / 41 (7.32%)	1 / 41 (2.44%)
occurrences (all)	0	3	1
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 41 (2.44%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	0 / 41 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Nasopharyngitis			

subjects affected / exposed	1 / 42 (2.38%)	6 / 41 (14.63%)	4 / 41 (9.76%)
occurrences (all)	1	6	4
Sinusitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 42 (2.38%)	3 / 41 (7.32%)	0 / 41 (0.00%)
occurrences (all)	1	3	0

Non-serious adverse events	50 mg CNTO1959 (CP)	100 mg CNTO1959 (CP)	200 mg CNTO1959 (CP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 42 (23.81%)	7 / 42 (16.67%)	8 / 41 (19.51%)
Injury, poisoning and procedural complications			
Muscle Strain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 42 (7.14%)	1 / 42 (2.38%)	1 / 41 (2.44%)
occurrences (all)	4	1	1
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 42 (4.76%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 41 (2.44%)
occurrences (all)	0	1	6
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	3
Oropharyngeal Pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
Back Pain			
subjects affected / exposed	0 / 42 (0.00%)	2 / 42 (4.76%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 42 (2.38%)	2 / 41 (4.88%)
occurrences (all)	1	1	2
Sinusitis			
subjects affected / exposed	1 / 42 (2.38%)	2 / 42 (4.76%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	3 / 41 (7.32%)
occurrences (all)	2	0	3

Non-serious adverse events	Adalimumab (CP)	Placebo --> 100 mg CNTO1959 (after CP)	5 mg CNTO1959 (after CP)
Total subjects affected by non-serious adverse events			

subjects affected / exposed	10 / 43 (23.26%)	16 / 39 (41.03%)	12 / 38 (31.58%)
Injury, poisoning and procedural complications			
Muscle Strain			
subjects affected / exposed	1 / 43 (2.33%)	2 / 39 (5.13%)	0 / 38 (0.00%)
occurrences (all)	1	2	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 43 (0.00%)	1 / 39 (2.56%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 43 (0.00%)	1 / 39 (2.56%)	1 / 38 (2.63%)
occurrences (all)	0	1	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	5 / 43 (11.63%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	18	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 43 (4.65%)	3 / 39 (7.69%)	2 / 38 (5.26%)
occurrences (all)	2	4	2
Back Pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 39 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 43 (0.00%)	2 / 39 (5.13%)	1 / 38 (2.63%)
occurrences (all)	0	4	1
Influenza			
subjects affected / exposed	0 / 43 (0.00%)	1 / 39 (2.56%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 43 (4.65%)	4 / 39 (10.26%)	6 / 38 (15.79%)
occurrences (all)	2	4	8
Sinusitis			
subjects affected / exposed	0 / 43 (0.00%)	2 / 39 (5.13%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 43 (4.65%)	4 / 39 (10.26%)	4 / 38 (10.53%)
occurrences (all)	2	5	5

Non-serious adverse events	15 mg CNTO1959 (after CP)	50 mg CNTO1959 (after CP)	100 mg CNTO1959 (after CP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 41 (9.76%)	11 / 39 (28.21%)	16 / 40 (40.00%)
Injury, poisoning and procedural complications			
Muscle Strain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 41 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Nervous system disorders			
Headache			

subjects affected / exposed	0 / 41 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Oropharyngeal Pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Back Pain			
subjects affected / exposed	1 / 41 (2.44%)	1 / 39 (2.56%)	2 / 40 (5.00%)
occurrences (all)	1	1	2
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Influenza			

subjects affected / exposed	0 / 41 (0.00%)	0 / 39 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	1 / 41 (2.44%)	7 / 39 (17.95%)	4 / 40 (10.00%)
occurrences (all)	1	7	5
Sinusitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 39 (2.56%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 39 (0.00%)	3 / 40 (7.50%)
occurrences (all)	1	0	4

Non-serious adverse events	200 mg CNTO1959 (after CP)	Adalimumab (after CP)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 38 (31.58%)	13 / 39 (33.33%)	
Injury, poisoning and procedural complications			
Muscle Strain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 38 (2.63%)	1 / 39 (2.56%)	
occurrences (all)	1	1	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 38 (2.63%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 38 (2.63%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Influenza Like Illness			
subjects affected / exposed	0 / 38 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	2	
Injection Site Erythema			

subjects affected / exposed	0 / 38 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	12	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 38 (5.26%)	1 / 39 (2.56%)	
occurrences (all)	2	1	
Oropharyngeal Pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 39 (2.56%)	
occurrences (all)	1	1	
Back Pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 39 (2.56%)	
occurrences (all)	1	1	
Influenza			
subjects affected / exposed	1 / 38 (2.63%)	1 / 39 (2.56%)	
occurrences (all)	1	1	
Nasopharyngitis			
subjects affected / exposed	5 / 38 (13.16%)	6 / 39 (15.38%)	
occurrences (all)	11	7	
Sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 38 (5.26%)	3 / 39 (7.69%)	
occurrences (all)	2	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 September 2011	The first amendment was implemented before the study was initiated, and included the following changes: addition of an exclusion criterion regarding the use of anti-TNFα agents, clarification of the reference time point for receiving treatments targeted to IL -12, IL 17A, or IL 23 in inclusion/exclusion criteria, updating of exclusion criterion regarding time frame for receiving live vaccines, removal of interactive voice response system (IVRS) as a method of collecting unblinding information, clarification of the time frame for the observation for severe allergic reactions, and other minor editorial changes.
27 February 2012	The second amendment included the following changes: an inclusion criterion was updated to allow entry of participants willing to receive adalimumab injections by a care provider at home, the exclusion criterion requiring participants not to have a known history of human immunodeficiency virus (HIV) was updated to require documentation of a negative HIV test prior to enrollment. In addition, text was added to clarify the exact duration of sample storage, the Sponsor's name was changed from Centocor to Janssen Research & Development, and other minor editorial changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported