



Clinical trial results:

A multicenter extension trial of subcutaneously administered AIN457 in patients with moderate to severe chronic plaque-type psoriasis

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.novfor> complete trial results.

Summary

EudraCT number	2009-017234-51
Trial protocol	DE FR IS NO
Global end of trial date	18 October 2016

Results information

Result version number	v1 (current)
This version publication date	06 July 2018
First version publication date	06 July 2018

Trial information

Trial identification

Sponsor protocol code	CAIN457A2211E1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01132612
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,

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	18 October 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	18 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and tolerability of subcutaneously administered secukinumab in the treatment of moderate to severe chronic plaque-type psoriasis as assessed by vital signs, clinical laboratory variables, and adverse events (AEs) monitoring.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2010
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	France: 22
Country: Number of subjects enrolled	Germany: 74
Country: Number of subjects enrolled	Iceland: 16
Country: Number of subjects enrolled	Israel: 8
Country: Number of subjects enrolled	Japan: 37
Country: Number of subjects enrolled	Norway: 7
Country: Number of subjects enrolled	United States: 111
Worldwide total number of subjects	275
EEA total number of subjects	119

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)	262
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants continued their regimens as assigned in CAIN457A2211 (NCT00941031) and were enrolled into one of the following: fixed time interval regimen (FI), treatment at start of relapse regimen (SR) or open-label (OL). There were no more placebo treated patients at the end of the core. Therefore, there is no placebo arm in the extension.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Fixed-time interval regimen

Arm description:

Secukinumab 150 mg subcutaneous (sc) administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 150 mg subcutaneous (sc) administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter

Arm title	Treatment at start of relapse regimen
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Arm description:

Placebo administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter. If relapse, then switch to secukinumab 150 mg sc administered every 4 weeks

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

Dosage and administration details:

Placebo administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter. If relapse, then switch to secukinumab 150 mg sc administered every 4 weeks

Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457A
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter. If

relapse, then switch to secukinumab 150 mg sc administered every 4 weeks

Arm title	Open-label
Arm description: Secukinumab 150 mg sc administered every 4 weeks.	
Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	Ain457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Secukinumab 150 mg sc administered every 4 weeks	

Number of subjects in period 1	Fixed-time interval regimen	Treatment at start of relapse regimen	Open-label
Started	46	42	187
Completed	6	7	17
Not completed	40	35	170
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	5	8	19
Adverse event, non-fatal	5	2	15
Protocol deviation	-	-	3
Administrative problems	5	1	52
Lost to follow-up	2	2	7
Lack of efficacy	23	22	73

Baseline characteristics

Reporting groups

Reporting group title	Fixed-time interval regimen
Reporting group description: Secukinumab 150 mg subcutaneous (sc) administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter	
Reporting group title	Treatment at start of relapse regimen
Reporting group description: Placebo administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter. If relapse, then switch to secukinumab 150 mg sc administered every 4 weeks	
Reporting group title	Open-label
Reporting group description: Secukinumab 150 mg sc administered every 4 weeks.	

Reporting group values	Fixed-time interval regimen	Treatment at start of relapse regimen	Open-label
Number of subjects	46	42	187
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	44	42	176
From 65-84 years	2	0	11
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	43.0	39.9	45.0
standard deviation	± 13.71	± 12.12	± 11.78
Gender, Male/Female Units: Subjects			
Female	15	12	39
Male	31	30	148

Reporting group values	Total		
Number of subjects	275		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		

Adolescents (12-17 years)	0		
Adults (18-64 years)	262		
From 65-84 years	13		
85 years and over	0		
Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: Subjects			
Female	66		
Male	209		

End points

End points reporting groups

Reporting group title	Fixed-time interval regimen
Reporting group description: Secukinumab 150 mg subcutaneous (sc) administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter	
Reporting group title	Treatment at start of relapse regimen
Reporting group description: Placebo administered at Week 1 (baseline) of the extension study and every 12 weeks thereafter. If relapse, then switch to secukinumab 150 mg sc administered every 4 weeks	
Reporting group title	Open-label
Reporting group description: Secukinumab 150 mg sc administered every 4 weeks.	

Primary: Number of participants with Adverse Events, Serious Adverse Events and Deaths

End point title	Number of participants with Adverse Events, Serious Adverse Events and Deaths ^[1]
End point description: Safety was assessed by frequency of adverse events including serious adverse events.	
End point type	Primary
End point timeframe: up to week 351	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis does not apply to this end point.

End point values	Fixed-time interval regimen	Treatment at start of relapse regimen	Open-label	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	42	187	
Units: Participants				
Adverse events	44	41	180	
Serious adverse events	9	4	43	
Deaths	0	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with at least 50%, 75% or 90% improvement from baseline in Psoriasis Area and Severity Index (PASI) and IGA mod 2009 0 or 1 response

End point title	Number of participants with at least 50%, 75% or 90% improvement from baseline in Psoriasis Area and Severity Index (PASI) and IGA mod 2009 0 or 1 response
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End point description:

PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). The IGA scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe and 5 = very severe.

End point type	Secondary
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End point timeframe:

Extension weeks: 1, 25, 73 and 301 (too few data points were available to perform analysis at week 301)

End point values	Fixed-time interval regimen	Treatment at start of relapse regimen	Open-label	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	42	187	
Units: Number of participants				
Extension week 1, PASI 50 (n=46,40,174)	43	34	163	
Extension week 1, PASI 75 (n=46,40,174)	31	16	102	
Extension week 1, PASI 90 (n=46,40,174)	17	3	61	
Ext. week 1, IGA mod 2009 0 or 1 (n=44,38,168)	24	7	70	
Extension week 25, PASI 50 (n=35,33,159)	29	27	142	
Extension week 25, PASI 75 (n=35,33,159)	19	10	91	
Extension week 25, PASI 90 (n=35,33,159)	12	2	42	
Ext. week 25, IGA mod 2009 0 or 1 (n=35,33,159)	15	4	48	
Extension week 73, PASI 50 (n=19,19,114)	18	17	100	
Extension week 73, PASI 75 (n=19,19,114)	14	8	66	
Extension week 73, PASI 90 (n=19,19,114)	8	1	31	
Ext. week 73, IGA mod 2009 0 or 1 (n=19,19,114)	9	4	35	
Extension week 301, PASI 50 (n=0,0,3)	9999	9999	3	
Extension week 301, PASI 75 (n=0,0,3)	9999	9999	2	
Extension week 301, PASI 90 (n=0,0,3)	9999	9999	1	
Extension week 301, IGA mod 2009 0 or 1 (n=0,0,3)	9999	9999	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Long-term immunogenicity assessed by the number of participants developing anti secukinumab antibodies during the trial

End point title	Long-term immunogenicity assessed by the number of participants developing anti secukinumab antibodies during the trial
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End point description:

Describes the number of participants tested positive for anti-secukinumab antibodies. It refers to the number of participants who had no positive values at baseline but developed them only after start of secukinumab treatment.

End point type	Secondary
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End point timeframe:

up to week 351

End point values	Fixed-time interval regimen	Treatment at start of relapse regimen	Open-label	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	41	184	
Units: Participants	0	0	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	AIN457A Fixed interval
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Reporting group description:

AIN457A Fixed interval

Reporting group title	AIN457A open label
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Reporting group description:

AIN457A open label

Reporting group title	AIN457A Start of relapse
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Reporting group description:

AIN457A Start of relapse

Serious adverse events	AIN457A Fixed interval	AIN457A open label	AIN457A Start of relapse
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 46 (19.57%)	43 / 187 (22.99%)	4 / 42 (9.52%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 46 (0.00%)	2 / 187 (1.07%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colon cancer			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Malignant melanoma			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Asthma			
subjects affected / exposed	1 / 46 (2.17%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Depression			
subjects affected / exposed	0 / 46 (0.00%)	2 / 187 (1.07%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Fibrin D dimer increased			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Streptococcus test positive			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Injury, poisoning and procedural complications			
Laceration			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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

Meniscus injury			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Muscle injury			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Road traffic accident			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Tendon injury			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Upper limb fracture			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Angina pectoris			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Cardiac arrest			

subjects affected / exposed	0 / 46 (0.00%)	2 / 187 (1.07%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Coronary artery stenosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 187 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Facial paralysis			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Hemiparesis			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Hepatic encephalopathy			

subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Migraine			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Syncope			
subjects affected / exposed	1 / 46 (2.17%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Inguinal hernia			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intestinal ischaemia			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Intussusception			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Nausea			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Hepatobiliary disorders			
Hepatic cirrhosis			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Psoriasis			
subjects affected / exposed	0 / 46 (0.00%)	2 / 187 (1.07%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	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 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Bladder stenosis			

subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
End stage renal disease			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematuria			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Intervertebral disc disorder			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Osteoarthritis			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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			

Abscess bacterial			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Cellulitis			
subjects affected / exposed	0 / 46 (0.00%)	4 / 187 (2.14%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	2 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 46 (2.17%)	0 / 187 (0.00%)	0 / 42 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impetigo			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected dermal cyst			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Nail infection			

subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Osteomyelitis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Paronychia			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Staphylococcal abscess			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Urinary tract infection			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Diabetes mellitus			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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
Hyperkalaemia			
subjects affected / exposed	0 / 46 (0.00%)	1 / 187 (0.53%)	0 / 42 (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

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

Non-serious adverse events	AIN457A Fixed interval	AIN457A open label	AIN457A Start of relapse
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 46 (91.30%)	164 / 187 (87.70%)	35 / 42 (83.33%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 46 (2.17%)	12 / 187 (6.42%)	0 / 42 (0.00%)
occurrences (all)	1	19	0
C-reactive protein increased			
subjects affected / exposed	3 / 46 (6.52%)	6 / 187 (3.21%)	0 / 42 (0.00%)
occurrences (all)	3	6	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 46 (4.35%)	10 / 187 (5.35%)	2 / 42 (4.76%)
occurrences (all)	2	16	3
Ligament sprain			

subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1	10 / 187 (5.35%) 12	2 / 42 (4.76%) 2
Procedural pain subjects affected / exposed occurrences (all)	4 / 46 (8.70%) 4	6 / 187 (3.21%) 6	0 / 42 (0.00%) 0
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	4 / 46 (8.70%) 5	26 / 187 (13.90%) 33	6 / 42 (14.29%) 10
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	3 / 46 (6.52%) 3	4 / 187 (2.14%) 4	0 / 42 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	11 / 46 (23.91%) 16	29 / 187 (15.51%) 66	6 / 42 (14.29%) 6
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 2	12 / 187 (6.42%) 16	3 / 42 (7.14%) 6
Influenza like illness subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 2	12 / 187 (6.42%) 28	2 / 42 (4.76%) 5
Pyrexia subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 3	9 / 187 (4.81%) 12	4 / 42 (9.52%) 4
Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 4	11 / 187 (5.88%) 15	0 / 42 (0.00%) 0
Dental caries subjects affected / exposed occurrences (all)	3 / 46 (6.52%) 3	6 / 187 (3.21%) 8	1 / 42 (2.38%) 1
Diarrhoea subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 3	20 / 187 (10.70%) 26	2 / 42 (4.76%) 2

Nausea subjects affected / exposed occurrences (all)	3 / 46 (6.52%) 4	12 / 187 (6.42%) 12	3 / 42 (7.14%) 3
Toothache subjects affected / exposed occurrences (all)	4 / 46 (8.70%) 4	14 / 187 (7.49%) 19	1 / 42 (2.38%) 1
Vomiting subjects affected / exposed occurrences (all)	1 / 46 (2.17%) 1	13 / 187 (6.95%) 17	3 / 42 (7.14%) 4
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	2 / 46 (4.35%) 2	20 / 187 (10.70%) 26	4 / 42 (9.52%) 6
Oropharyngeal pain subjects affected / exposed occurrences (all)	5 / 46 (10.87%) 7	14 / 187 (7.49%) 26	3 / 42 (7.14%) 4
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all)	4 / 46 (8.70%) 6	6 / 187 (3.21%) 9	0 / 42 (0.00%) 0
Psoriasis subjects affected / exposed occurrences (all)	13 / 46 (28.26%) 32	59 / 187 (31.55%) 145	16 / 42 (38.10%) 41
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 46 (0.00%) 0	11 / 187 (5.88%) 13	0 / 42 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	9 / 46 (19.57%) 14	43 / 187 (22.99%) 66	6 / 42 (14.29%) 8
Arthritis subjects affected / exposed occurrences (all)	3 / 46 (6.52%) 6	6 / 187 (3.21%) 6	1 / 42 (2.38%) 1
Back pain			

subjects affected / exposed	5 / 46 (10.87%)	30 / 187 (16.04%)	7 / 42 (16.67%)
occurrences (all)	6	52	8
Musculoskeletal pain			
subjects affected / exposed	5 / 46 (10.87%)	15 / 187 (8.02%)	0 / 42 (0.00%)
occurrences (all)	7	20	0
Myalgia			
subjects affected / exposed	2 / 46 (4.35%)	8 / 187 (4.28%)	3 / 42 (7.14%)
occurrences (all)	4	8	4
Neck pain			
subjects affected / exposed	3 / 46 (6.52%)	6 / 187 (3.21%)	1 / 42 (2.38%)
occurrences (all)	4	8	1
Pain in extremity			
subjects affected / exposed	4 / 46 (8.70%)	11 / 187 (5.88%)	1 / 42 (2.38%)
occurrences (all)	8	12	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 46 (4.35%)	21 / 187 (11.23%)	1 / 42 (2.38%)
occurrences (all)	3	30	1
Conjunctivitis			
subjects affected / exposed	4 / 46 (8.70%)	4 / 187 (2.14%)	0 / 42 (0.00%)
occurrences (all)	5	10	0
Gastroenteritis viral			
subjects affected / exposed	1 / 46 (2.17%)	9 / 187 (4.81%)	4 / 42 (9.52%)
occurrences (all)	1	9	4
Influenza			
subjects affected / exposed	4 / 46 (8.70%)	14 / 187 (7.49%)	2 / 42 (4.76%)
occurrences (all)	5	17	2
Nasopharyngitis			
subjects affected / exposed	20 / 46 (43.48%)	91 / 187 (48.66%)	16 / 42 (38.10%)
occurrences (all)	58	260	30
Oral herpes			
subjects affected / exposed	1 / 46 (2.17%)	10 / 187 (5.35%)	1 / 42 (2.38%)
occurrences (all)	2	13	1
Pharyngitis streptococcal			
subjects affected / exposed	3 / 46 (6.52%)	4 / 187 (2.14%)	2 / 42 (4.76%)
occurrences (all)	4	4	2

Sinusitis			
subjects affected / exposed	9 / 46 (19.57%)	17 / 187 (9.09%)	3 / 42 (7.14%)
occurrences (all)	11	21	5
Tonsillitis			
subjects affected / exposed	1 / 46 (2.17%)	14 / 187 (7.49%)	0 / 42 (0.00%)
occurrences (all)	1	18	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 46 (6.52%)	28 / 187 (14.97%)	4 / 42 (9.52%)
occurrences (all)	4	60	5
Urinary tract infection			
subjects affected / exposed	3 / 46 (6.52%)	6 / 187 (3.21%)	4 / 42 (9.52%)
occurrences (all)	3	9	6
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 46 (2.17%)	14 / 187 (7.49%)	3 / 42 (7.14%)
occurrences (all)	3	20	3
Hypertriglyceridaemia			
subjects affected / exposed	0 / 46 (0.00%)	10 / 187 (5.35%)	1 / 42 (2.38%)
occurrences (all)	0	12	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 April 2010	<p>The purpose of the amendment was to correct an inconsistency in the study protocol title in the protocol synopsis section embedded in the study protocol. The PK collection number at Visit F12 was rectified for coherence. The global model patient information / informed consent was also revised to correct the inconsistency in the study protocol title.</p> <p>The changes described in this amended protocol, which occurred prior to study unblinding, were non-substantial and did not require IRB/IEC approval prior to implementation.</p>
09 May 2011	<p>The purpose of the amendment was to update the benefit-risk assessment for the treatment of plaque-type psoriasis with secukinumab after data from phase II study had become available. This assessment confirmed that this therapy was regarded as beneficial for the treated patients and therefore it was decided that the patients in study CAIN457A2211E1 should be offered the opportunity to continue receiving secukinumab for a longer period (prolongation of 3 years) than originally planned and in selected countries where the operational feasibility and practicality does exist. In addition, prolonging the treatment period allowed for gathering long-term efficacy and safety data.</p> <p>Additionally an interim analysis was introduced to support the submission of secukinumab for the treatment of moderate to severe chronic plaque-type psoriasis.</p>
27 June 2014	<p>The main purpose of this amendment was to provide continued treatment for patients in the trial for additional two years or until drug was commercially available in the market in the country of participation. This extension of the study allowed for safety, tolerability and efficacy data to be collected from the participating patients for a longer time period. Eligible patients were considered for participation in this extension of the study prolongation at given site, provided the amendment was approved at the time the patient completed the prolongation of CAIN457A22E1 (i.e. visit of Week 225). This amendment offered further extension of the study to all patients that have completed the Week 225 visit. The patients who continued, remained on the same treatment regimen they were taking in the extension prolongation part. The patients who did not continue beyond the Week 225 were moved to the non-treatment follow-up period.</p> <p>At the time of this amendment about 65 patients were on the trial. No patient was treated in the placebo arm.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.novfor> for complete trial results.

Notes:

