Clinical trial results:
A multicenter, randomized, double-blind, placebo-controlled, 52-weeks study to demonstrate the efficacy, safety and tolerability of subcutaneous secukinumab injections with 2 mL pre-filled syringes (300 mg) in adult subjects with moderate to severe plaque psoriasis – ALLURE

Summary

EudraCT number	2015-005170-38
Trial protocol	GB LV BE ES IS
Global end of trial date	08 June 2018

Results information

Result version number	v1 (current)
This version publication date	23 June 2019
First version publication date	23 June 2019

Trial information

Trial identification

Sponsor protocol code	CAIN457A2323

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02748863
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, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.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	05 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 June 2018
Global end of trial reached?	Yes
Global end of trial date	08 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to demonstrate the efficacy of secukinumab 300 mg when administered as 2 mL pre-filled syringes (PFSs) in patients with plaque-type psoriasis with respect to both PASI 75 and IGA mod 2011 0 or 1 response (co-primary endpoint) at Week 12, compared to placebo.

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	12 December 2016
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	Germany: 26
Country: Number of subjects enrolled	Spain: 27
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Iceland: 22
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Latvia: 27
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	Russian Federation: 24
Country: Number of subjects enrolled	United States: 45
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	Turkey: 4
Worldwide total number of subjects	214
EEA total number of subjects	126

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	200
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 251 patients were screened and 214 patients were randomized

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab 2 mL PFS

Arm description:

Secukinumab 300 mg in one 2 mL pre-filled syringe

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

Dosage and administration details:

2ML PFS

Arm title	Secukinumab 2 x 1 mL PFS

Arm description:

Secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg (current approved form)

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

Dosage and administration details:

2 x 1 mL PFS

Arm title	Placebo

Arm description:

Placebo, provided in a 2 mL pre-filled syringe Placebo, provided in a 1 mL pre-filled syringe

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

Dosage and administration details:

2ML PFS

Number of subjects in period 1	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo
Started	72	71	71
Completed	72	69	68
Not completed	0	2	3
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	-	1	-
Lack of efficacy	-	-	1

Period 2	
Period 2 title	Treatment Period 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms	
Are arms mutually exclusive?	No
Arm title	Secukinumab 2 mL PFS

Arm description:

Secukinumab 300 mg in one 2 mL pre-filled syringe

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intravenous use

Dosage and administration details:

300 mg in one 2 mL pre-filled syringe

Arm title	Secukinumab 2 x 1 mL PFS

Arm description:

Secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg (current approved form)

Arm type	Experimental
Investigational medicinal product name	secuk
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intrauterine use

Dosage and administration details:

Two 300 mg 1 mL pre-filled syringes

Arm title	Placebo

Arm description:	
Placebo, provided in a 2 mL pre-filled syringe Placebo, provided in a 1 mL pre-filled syringe	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placeo
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
2 ml PFS	
Arm title	Secukinumab 2 mL PFS following placebo
Arm description:	
Switched from placebo to secukinumab 300 mg, provided in one 2 mL pre-filled syringe	
Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intravenous use
Dosage and administration details:	
300 mg in one 2 mL pre-filled syringe	
Arm title	Secukinumab 2 x 1 mL PFS following placebo
Arm description:	
Switched from placebo to secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg	
Arm type	Experimental
Investigational medicinal product name	secuk
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intrauterine use
Dosage and administration details:	
Two 300 mg 1 mL pre-filled syringes	

Number of subjects in period 2	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo
Started	72	69	71
Completed	67	66	68
Not completed	5	3	3
Consent withdrawn by subject	-	-	2
Adverse event, non-fatal	3	2	-
Pregnancy	-	-	-
Lost to follow-up	2	-	-
Lack of efficacy	-	1	1

Number of subjects in period 2	Secukinumab 2 mL PFS following placebo	Secukinumab 2 x 1 mL PFS following placebo

Started	34	34
Completed	32	33
Not completed	2	1
Consent withdrawn by subject	-	-
Adverse event, non-fatal	-	-
Pregnancy	-	1
Lost to follow-up	2	-
Lack of efficacy	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Secukinumab 2 mL PFS
Reporting group description: Secukinumab 300 mg in one 2 mL pre-filled syringe	
Reporting group title	Secukinumab 2 x 1 mL PFS
Reporting group description: Secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg (current approved form)	
Reporting group title	Placebo
Reporting group description: Placebo, provided in a 2 mL pre-filled syringe Placebo, provided in a 1 mL pre-filled syringe	

Reporting group values	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo
Number of subjects	72	71	71
Age, Customized Units: Subjects			
>65 years	68	64	68
>=65 years	4	7	3
>=75 years	0	0	0
Age continuous Units: years			
arithmetic mean	43.0	46.2	41.4
standard deviation	± 13.87	± 13.90	± 12.88
Sex: Female, Male Units: Subjects			
Female	28	28	25
Male	44	43	46
Race/Ethnicity, Customized Units: Subjects			
Caucasian	64	66	64
Black	2	1	1
Asian	4	4	4
Pacific Islander	0	0	1
Other	2	0	1

Reporting group values	Total		
Number of subjects	214		
Age, Customized Units: Subjects			
>65 years	200		
>=65 years	14		
>=75 years	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		

Sex: Female, Male Units: Subjects			
Female	81		
Male	133		
Race/Ethnicity, Customized Units: Subjects			
Caucasian	194		
Black	4		
Asian	12		
Pacific Islander	1		
Other	3		

End points

End points reporting groups

Reporting group title	Secukinumab 2 mL PFS
Reporting group description: Secukinumab 300 mg in one 2 mL pre-filled syringe	
Reporting group title	Secukinumab 2 x 1 mL PFS
Reporting group description: Secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg (current approved form)	
Reporting group title	Placebo
Reporting group description: Placebo, provided in a 2 mL pre-filled syringe Placebo, provided in a 1 mL pre-filled syringe	
Reporting group title	Secukinumab 2 mL PFS
Reporting group description: Secukinumab 300 mg in one 2 mL pre-filled syringe	
Reporting group title	Secukinumab 2 x 1 mL PFS
Reporting group description: Secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg (current approved form)	
Reporting group title	Placebo
Reporting group description: Placebo, provided in a 2 mL pre-filled syringe Placebo, provided in a 1 mL pre-filled syringe	
Reporting group title	Secukinumab 2 mL PFS following placebo
Reporting group description: Switched from placebo to secukinumab 300 mg, provided in one 2 mL pre-filled syringe	
Reporting group title	Secukinumab 2 x 1 mL PFS following placebo
Reporting group description: Switched from placebo to secukinumab 300 mg provided in 2 pre-filled syringes of 1 mL/150 mg	

Primary: Participants with Psoriasis Area and Severity Index (PASI) 75 response after 12 weeks of treatment

End point title	Participants with Psoriasis Area and Severity Index (PASI) 75 response after 12 weeks of treatment
End point description: Number of participants who achieved ≥ 75% reduction in PASI compared to baseline 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).	
End point type	Primary
End point timeframe: 12 weeks	

End point values	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	71	
Units: participants	64	58	1	

Statistical analyses

Statistical analysis title	Severity (PASI)
Comparison groups	Secukinumab 2 mL PFS v Placebo
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	717.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	68
upper limit	7569.56

Statistical analysis title	PASI 75
Comparison groups	Secukinumab 2 x 1 mL PFS v Placebo
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	419.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.87
upper limit	4302.75

Primary: Participants with IGA mod 2011 0 or 1 after 12 weeks of treatment

End point title	Participants with IGA mod 2011 0 or 1 after 12 weeks of treatment

End point description:

The Investigator’s Global Assessment (IGA) mod 2011 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, and 4 = severe. Treatment success was defined as achievement of IGA mod 2001 score of 0 or 1. Number of participants who achieved IGA mod 2011 0 or 1 and improved by at least 2 points on the IGA scale compared to baseline

End point type	Primary
End point timeframe:	
12 weeks	

End point values	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	71	
Units: participants	55	49	1	

Statistical analyses

Statistical analysis title	IGA
Comparison groups	Secukinumab 2 mL PFS v Placebo
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	400.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.48
upper limit	3379.99

Secondary: Participants with PASI 90 after 12 weeks of treatment

End point title	Participants with PASI 90 after 12 weeks of treatment
End point description:	
Number of participants who achieved ≥ 90% and 100% reduction in PASI compared to baseline	
End point type	Secondary
End point timeframe:	
12 weeks	

End point values	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	71	
Units: participants	48	50	1	

Statistical analyses

Statistical analysis title	PASI
Comparison groups	Secukinumab 2 mL PFS v Placebo
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	168.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.2
upper limit	1337.22

Secondary: PASI 100 response after 12 weeks of treatment

End point title	PASI 100 response after 12 weeks of treatment
End point description:	
Participants who achieved 100% reduction in PASI compared to baseline	
End point type	Secondary
End point timeframe:	
12 weeks	

End point values	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	71	
Units: participants	28	26	0	

Statistical analyses

Statistical analysis title	PASI 100
Comparison groups	Secukinumab 2 mL PFS v Placebo

Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	t-test, 2-sided
Parameter estimate	Risk difference (RD)
Point estimate	38.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.41
upper limit	50.09

Statistical analysis title	PASI
Comparison groups	Secukinumab 2 x 1 mL PFS v Placebo
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	t-test, 2-sided
Parameter estimate	Risk difference (RD)
Point estimate	36.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.19
upper limit	47.76

Secondary: Number of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response

End point title	Number of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response
End point description:	
PASI response over time up to week 52: Number of participants who achieved ≥ 50%, 75%, 90% and 100% reduction in PASI and achieve IGA mod 2011 0 or 1 and improved by at least 2 points on the IGA scale compared to baseline	
End point type	Secondary
End point timeframe:	
up to week 52	

End point values	Secukinumab 2 mL PFS	Secukinumab 2 x 1 mL PFS	Placebo	Secukinumab 2 mL PFS following placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	72	71	71	34
Units: participants				
Week 1 IGA 0/1	1	0	0	0
Week 1 PASI 50	5	5	1	0
Week 1 PASI 75	0	2	0	0
Week 1 PASI 90	0	0	0	0
Week 1 PASI 100	0	0	0	0
Week 2 IGA 0/1	2	1	1	0
Week 2 PASI 50	18	28	1	1
Week 2 PASI 75	4	5	0	0
Week 2 PASI 90	0	1	0	0
Week 2 PASI 100	0	1	0	0
Week 3 IGA 0/1	6	11	1	0
Week 3 PASI 50	39	40	5	3
Week 3 PASI 75	14	17	0	0
Week 3 PASI 90	4	4	0	0
Week 3 PASI 100	0	1	0	0
Week 4 IGA 0/1	19	23	0	0
Week 4 PASI 50	53	52	6	5
Week 4 PASI 75	29	32	1	1
Week 4 PASI 90	10	13	0	0
Week 4 PASI 100	3	3	0	0
Week 8 IGA 0/1	43	41	0	0
Week 8 PASI 50	66	60	5	3
Week 8 PASI 75	53	51	0	0
Week 8 PASI 90	35	31	0	0
Week 8 PASI 100	8	11	0	0
Week 12 IGA 0/1	55	49	1	0
Week 12 PASI 50	67	61	5	2
Week 12 PASI 75	64	58	1	0
Week 12 PASI 90	48	50	1	0
Week 12 PASI 100	28	26	0	0
Week 16 IGA 0/1	57	52	0	14
Week 16 PASI 50	69	61	0	27
Week 16 PASI 75	65	60	0	17
Week 16 PASI 90	56	55	0	8
Week 16 PASI 100	37	31	0	5
Week 28 IGA 0/1	64	54	0	30
Week 28 PASI 50	71	66	0	33
Week 28 PASI 75	69	60	0	32
Week 28 PASI 90	62	56	0	26
Week 28 PASI 100	44	34	0	16
Week 40 IGA 0/1	60	55	0	28
Week 40 PASI 50	69	67	0	33
Week 40 PASI 75	66	63	0	31
Week 40 PASI 90	58	57	0	27
Week 40 PASI 100	40	37	0	20
Week 52 IGA 0/1	55	55	0	28

Week 52 PASI 50	67	67	0	31
Week 52 PASI 75	63	62	0	30
Week 52 PASI 90	54	58	0	25
Week 52 PASI 100	40	37	0	20

End point values	Secukinumab 2 x 1 mL PFS following placebo			
Subject group type	Reporting group			
Number of subjects analysed	34			
Units: participants				
Week 1 IGA 0/1	0			
Week 1 PASI 50	1			
Week 1 PASI 75	0			
Week 1 PASI 90	0			
Week 1 PASI 100	0			
Week 2 IGA 0/1	1			
Week 2 PASI 50	0			
Week 2 PASI 75	0			
Week 2 PASI 90	0			
Week 2 PASI 100	0			
Week 3 IGA 0/1	1			
Week 3 PASI 50	1			
Week 3 PASI 75	0			
Week 3 PASI 90	0			
Week 3 PASI 100	0			
Week 4 IGA 0/1	0			
Week 4 PASI 50	1			
Week 4 PASI 75	0			
Week 4 PASI 90	0			
Week 4 PASI 100	0			
Week 8 IGA 0/1	0			
Week 8 PASI 50	2			
Week 8 PASI 75	0			
Week 8 PASI 90	0			
Week 8 PASI 100	0			
Week 12 IGA 0/1	0			
Week 12 PASI 50	2			
Week 12 PASI 75	0			
Week 12 PASI 90	0			
Week 12 PASI 100	0			
Week 16 IGA 0/1	5			
Week 16 PASI 50	20			
Week 16 PASI 75	13			
Week 16 PASI 90	4			
Week 16 PASI 100	1			
Week 28 IGA 0/1	25			
Week 28 PASI 50	30			
Week 28 PASI 75	28			

Week 28 PASI 90	21			
Week 28 PASI 100	12			
Week 40 IGA 0/1	25			
Week 40 PASI 50	33			
Week 40 PASI 75	31			
Week 40 PASI 90	24			
Week 40 PASI 100	17			
Week 52 IGA 0/1	26			
Week 52 PASI 50	32			
Week 52 PASI 75	31			
Week 52 PASI 90	26			
Week 52 PASI 100	16			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
AEs and SAEs were collected for maximum duration of treatment and follow up for a participant per protocol for approximately 52 weeks	
Adverse event reporting additional description:	
All cause mortality (deaths) was collected for as long as participants could be contacted from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV) up to a maximum of 52 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	AIN457 300 mg (2mL PFS)
Reporting group description:	
Treatment period 1 secukinumab 300 mg (2mL PFS)	
Reporting group title	AIN457 300 mg (2x1mL PFS)
Reporting group description:	
Treatment period 1 secukinumab 300 mg (2x1mL PFS)	
Reporting group title	Placebo
Reporting group description:	
Treatment period 1 Placebo	
Reporting group title	Any AIN457 300 mg (2mL PFS)
Reporting group description:	
Any secukinumab 300 mg (2mL PFS)	
Reporting group title	Any AIN457 300 mg (2x1mL PFS)
Reporting group description:	
Any secukinumab 300 mg (2x1mL PFS)	
Reporting group title	Any AIN457 300 mg
Reporting group description:	
Any secukinumab 300 mg	

Serious adverse events	AIN457 300 mg (2mL PFS)	AIN457 300 mg (2x1mL PFS)	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	2 / 71 (2.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rib fracture			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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			
Myocardial infarction			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	0 / 71 (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
Crohn's disease			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Diarrhoea			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Gastritis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Pancreatitis acute			

subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Vomiting			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Haemothorax			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Hypoventilation			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Pleural effusion			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Sleep apnoea syndrome			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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			
Psoriatic arthropathy			

subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Diverticulitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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
Pharyngitis bacterial			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Any AIN457 300 mg (2mL PFS)	Any AIN457 300 mg (2x1mL PFS)	Any AIN457 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 106 (7.55%)	5 / 105 (4.76%)	13 / 211 (6.16%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 211 (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
Rib fracture			

subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	1 / 106 (0.94%)	1 / 105 (0.95%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Haemothorax			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoventilation			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Psoriatic arthropathy			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis bacterial			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	AIN457 300 mg (2mL PFS)	AIN457 300 mg (2x1mL PFS)	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 72 (45.83%)	39 / 71 (54.93%)	29 / 71 (40.85%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 72 (1.39%)	1 / 71 (1.41%)	2 / 71 (2.82%)
occurrences (all)	1	1	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	2 / 71 (2.82%)
occurrences (all)	0	1	2
Weight increased			
subjects affected / exposed	2 / 72 (2.78%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			

Ligament sprain			
subjects affected / exposed	1 / 72 (1.39%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	1	2	0
Limb injury			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	3 / 71 (4.23%)
occurrences (all)	0	1	3
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 72 (8.33%)	6 / 71 (8.45%)	3 / 71 (4.23%)
occurrences (all)	9	7	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 72 (2.78%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	2	0	2
Injection site bruising			
subjects affected / exposed	2 / 72 (2.78%)	1 / 71 (1.41%)	1 / 71 (1.41%)
occurrences (all)	2	1	1
Injection site erythema			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	2 / 72 (2.78%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	6	0	0
Injection site swelling			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	2 / 72 (2.78%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	2 / 72 (2.78%)	3 / 71 (4.23%)	0 / 71 (0.00%)
occurrences (all)	2	3	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	2 / 71 (2.82%)
occurrences (all)	0	2	2
Nausea			
subjects affected / exposed	2 / 72 (2.78%)	2 / 71 (2.82%)	1 / 71 (1.41%)
occurrences (all)	2	2	1
Toothache			
subjects affected / exposed	2 / 72 (2.78%)	0 / 71 (0.00%)	2 / 71 (2.82%)
occurrences (all)	3	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 72 (1.39%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal pain			
subjects affected / exposed	3 / 72 (4.17%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	3	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 72 (1.39%)	1 / 71 (1.41%)	2 / 71 (2.82%)
occurrences (all)	1	1	2
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	5 / 72 (6.94%)	3 / 71 (4.23%)	3 / 71 (4.23%)
occurrences (all)	6	3	4
Psoriasis			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
Back pain			
subjects affected / exposed	4 / 72 (5.56%)	3 / 71 (4.23%)	2 / 71 (2.82%)
occurrences (all)	5	3	2
Myalgia			

subjects affected / exposed	2 / 72 (2.78%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis			
subjects affected / exposed	1 / 72 (1.39%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Folliculitis			
subjects affected / exposed	1 / 72 (1.39%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	7 / 72 (9.72%)	8 / 71 (11.27%)	8 / 71 (11.27%)
occurrences (all)	8	8	8
Oral herpes			
subjects affected / exposed	3 / 72 (4.17%)	0 / 71 (0.00%)	2 / 71 (2.82%)
occurrences (all)	3	0	2
Pharyngitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	2 / 71 (2.82%)
occurrences (all)	0	0	2
Respiratory tract infection viral			
subjects affected / exposed	2 / 72 (2.78%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	2	0	1
Rhinitis			
subjects affected / exposed	1 / 72 (1.39%)	1 / 71 (1.41%)	1 / 71 (1.41%)
occurrences (all)	1	1	1
Sinusitis			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0

Tonsillitis			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 72 (1.39%)	1 / 71 (1.41%)	2 / 71 (2.82%)
occurrences (all)	1	1	2
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 72 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Any AIN457 300 mg (2mL PFS)	Any AIN457 300 mg (2x1mL PFS)	Any AIN457 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 106 (56.60%)	68 / 105 (64.76%)	128 / 211 (60.66%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 106 (1.89%)	2 / 105 (1.90%)	4 / 211 (1.90%)
occurrences (all)	2	2	4
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 106 (0.94%)	1 / 105 (0.95%)	2 / 211 (0.95%)
occurrences (all)	1	1	2
Weight increased			
subjects affected / exposed	3 / 106 (2.83%)	0 / 105 (0.00%)	3 / 211 (1.42%)
occurrences (all)	3	0	3
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 106 (0.94%)	3 / 105 (2.86%)	4 / 211 (1.90%)
occurrences (all)	1	3	4
Limb injury			
subjects affected / exposed	3 / 106 (2.83%)	0 / 105 (0.00%)	3 / 211 (1.42%)
occurrences (all)	3	0	3
Vascular disorders			

Hypertension			
subjects affected / exposed	3 / 106 (2.83%)	5 / 105 (4.76%)	8 / 211 (3.79%)
occurrences (all)	3	5	8
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 106 (9.43%)	8 / 105 (7.62%)	18 / 211 (8.53%)
occurrences (all)	25	10	35
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 106 (5.66%)	3 / 105 (2.86%)	9 / 211 (4.27%)
occurrences (all)	6	4	10
Injection site bruising			
subjects affected / exposed	2 / 106 (1.89%)	2 / 105 (1.90%)	4 / 211 (1.90%)
occurrences (all)	3	2	5
Injection site erythema			
subjects affected / exposed	3 / 106 (2.83%)	0 / 105 (0.00%)	3 / 211 (1.42%)
occurrences (all)	3	0	3
Injection site pruritus			
subjects affected / exposed	2 / 106 (1.89%)	0 / 105 (0.00%)	2 / 211 (0.95%)
occurrences (all)	6	0	6
Injection site swelling			
subjects affected / exposed	0 / 106 (0.00%)	2 / 105 (1.90%)	2 / 211 (0.95%)
occurrences (all)	0	2	2
Pyrexia			
subjects affected / exposed	2 / 106 (1.89%)	2 / 105 (1.90%)	4 / 211 (1.90%)
occurrences (all)	3	2	5
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 106 (5.66%)	6 / 105 (5.71%)	12 / 211 (5.69%)
occurrences (all)	6	6	12
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 106 (1.89%)	2 / 105 (1.90%)	4 / 211 (1.90%)
occurrences (all)	2	2	4
Nausea			
subjects affected / exposed	3 / 106 (2.83%)	3 / 105 (2.86%)	6 / 211 (2.84%)
occurrences (all)	3	4	7

Toothache			
subjects affected / exposed	3 / 106 (2.83%)	1 / 105 (0.95%)	4 / 211 (1.90%)
occurrences (all)	4	1	5
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 106 (3.77%)	3 / 105 (2.86%)	7 / 211 (3.32%)
occurrences (all)	4	3	7
Oropharyngeal pain			
subjects affected / exposed	4 / 106 (3.77%)	1 / 105 (0.95%)	5 / 211 (2.37%)
occurrences (all)	5	1	6
Rhinorrhoea			
subjects affected / exposed	2 / 106 (1.89%)	2 / 105 (1.90%)	4 / 211 (1.90%)
occurrences (all)	3	2	5
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	10 / 106 (9.43%)	4 / 105 (3.81%)	14 / 211 (6.64%)
occurrences (all)	13	4	17
Psoriasis			
subjects affected / exposed	0 / 106 (0.00%)	3 / 105 (2.86%)	3 / 211 (1.42%)
occurrences (all)	0	4	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 106 (2.83%)	3 / 105 (2.86%)	6 / 211 (2.84%)
occurrences (all)	4	3	7
Back pain			
subjects affected / exposed	6 / 106 (5.66%)	4 / 105 (3.81%)	10 / 211 (4.74%)
occurrences (all)	8	4	12
Myalgia			
subjects affected / exposed	3 / 106 (2.83%)	1 / 105 (0.95%)	4 / 211 (1.90%)
occurrences (all)	3	2	5
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 106 (0.94%)	2 / 105 (1.90%)	3 / 211 (1.42%)
occurrences (all)	1	3	4
Conjunctivitis			

subjects affected / exposed	3 / 106 (2.83%)	2 / 105 (1.90%)	5 / 211 (2.37%)
occurrences (all)	4	2	6
Folliculitis			
subjects affected / exposed	2 / 106 (1.89%)	4 / 105 (3.81%)	6 / 211 (2.84%)
occurrences (all)	2	4	6
Hordeolum			
subjects affected / exposed	0 / 106 (0.00%)	3 / 105 (2.86%)	3 / 211 (1.42%)
occurrences (all)	0	3	3
Influenza			
subjects affected / exposed	2 / 106 (1.89%)	8 / 105 (7.62%)	10 / 211 (4.74%)
occurrences (all)	2	8	10
Nasopharyngitis			
subjects affected / exposed	13 / 106 (12.26%)	17 / 105 (16.19%)	30 / 211 (14.22%)
occurrences (all)	17	19	36
Oral herpes			
subjects affected / exposed	3 / 106 (2.83%)	3 / 105 (2.86%)	6 / 211 (2.84%)
occurrences (all)	4	3	7
Pharyngitis			
subjects affected / exposed	5 / 106 (4.72%)	1 / 105 (0.95%)	6 / 211 (2.84%)
occurrences (all)	5	1	6
Respiratory tract infection viral			
subjects affected / exposed	2 / 106 (1.89%)	5 / 105 (4.76%)	7 / 211 (3.32%)
occurrences (all)	6	6	12
Rhinitis			
subjects affected / exposed	4 / 106 (3.77%)	5 / 105 (4.76%)	9 / 211 (4.27%)
occurrences (all)	5	5	10
Sinusitis			
subjects affected / exposed	1 / 106 (0.94%)	2 / 105 (1.90%)	3 / 211 (1.42%)
occurrences (all)	1	2	3
Tonsillitis			
subjects affected / exposed	2 / 106 (1.89%)	2 / 105 (1.90%)	4 / 211 (1.90%)
occurrences (all)	2	2	4
Upper respiratory tract infection			
subjects affected / exposed	5 / 106 (4.72%)	5 / 105 (4.76%)	10 / 211 (4.74%)
occurrences (all)	6	8	14
Vulvovaginal candidiasis			

subjects affected / exposed occurrences (all)	0 / 106 (0.00%) 0	2 / 105 (1.90%) 2	2 / 211 (0.95%) 2
Metabolism and nutrition disorders Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 106 (0.00%) 0	2 / 105 (1.90%) 2	2 / 211 (0.95%) 2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

"Other pre-specified outcomes" such as assessment of the subject usability and assessment of Dermatology Life Quality Index (DLQI) scores are exploratory in nature and are not reported in these results

Notes: