Clinical trial results:
A Phase II, randomized, double-blind, placebo-controlled, multiple-dose study to evaluate the safety, tolerability, and efficacy of CIM331 in atopic dermatitis patients who are inadequately controlled by or intolerant to topical therapy.

Summary

EudraCT number	2013-002470-46
Trial protocol	GB DE
Global end of trial date	06 June 2016

Results information

Result version number	v1 (current)
This version publication date	30 June 2017
First version publication date	30 June 2017

Trial information

Trial identification

Sponsor protocol code	CIM003JG

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01986933
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Chugai Pharma Europe Ltd.
Sponsor organisation address	Mulliner House, Flanders Road, London, United Kingdom, W4 1NN
Public contact	Clinical trials information, Chugai Pharmaceutical Co., Ltd., +81 332730934, clinical-trials@chugai-pharm.co.jp
Scientific contact	Clinical trials information, Chugai Pharmaceutical Co., Ltd., +81 332730934, clinical-trials@chugai-pharm.co.jp

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	09 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2015
Global end of trial reached?	Yes
Global end of trial date	06 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the dose response profile of CIM331 in the treatment of pruritus as defined by the percent improvement in pruritus from baseline to Week 12, assessed by patients using the pruritus VAS (Part A).

Protection of trial subjects:

This study was conducted in full conformance with the ICH E6 guideline for GCP and the principles of the Declaration of Helsinki, or the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the individual.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 December 2013
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	Poland: 66
Country: Number of subjects enrolled	United Kingdom: 7
Country: Number of subjects enrolled	Germany: 53
Country: Number of subjects enrolled	United States: 59
Country: Number of subjects enrolled	Japan: 79
Worldwide total number of subjects	264
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)	264
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 57 study sites in 5 countries. A total of 397 subjects were screened between 25 Nov 2013 and 30 Dec 2014. 264 subjects were randomized and treated. 114 subjects were screen failures and 19 subjects were run-in failures due to exclusion and inclusion criteria not met.

Pre-assignment

Screening details:

Randomization was stratified by region (US, Europe and Japan). Assignment to arms was done centrally in 1:1:1:1:1 ratio for Nemolizumab (0.1mg/kg Q4W, 0.5mg/kg Q4W, 2.0mg/kg Q4W, 2.0mg/kg Q8W) and Placebo.

Period 1

Period 1 title	12-week placebo-controlled period (Pt A)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

In order to maintain the blind, Nemolizumab and the placebo formulation were of identical volume and provided in identical containers.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo: subcutaneous injections every 4 weeks on Day 1, Week 4 and Week 8

Arm type	Placebo
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (0.1 mg/kg) q4w

Arm description:

Nemolizumab (0.1 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks

Arm type	Experimental
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (0.5 mg/kg) q4w

Arm description:

Nemolizumab (0.5 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks

Arm type	Experimental

Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (2.0 mg/kg) q4w

Arm description:

Nemolizumab (2.0 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks

Arm type	Experimental
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (2.0 mg/kg) q8w

Arm description:

Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections Dose on Day 1 and at Week 8, placebo at Week 4.

Arm type	Experimental
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Number of subjects in period 1	Placebo	Nemolizumab (0.1 mg/kg) q4w	Nemolizumab (0.5 mg/kg) q4w
Started	53	53	54
Completed	44	44	45
Not completed	9	9	9
Consent withdrawn by subject	5	2	6
Withdrawal by subject due to lack of efficacy	-	-	-
Adverse event, non-fatal	1	5	2
Lost to follow-up	-	1	-
Lack of efficacy	3	1	1

Number of subjects in period 1	Nemolizumab (2.0 mg/kg) q4w	Nemolizumab (2.0 mg/kg) q8w
Started	52	52
Completed	45	38
Not completed	7	14

Consent withdrawn by subject	2	7
Withdrawal by subject due to lack of efficacy	-	2
Adverse event, non-fatal	2	4
Lost to follow-up	1	-
Lack of efficacy	2	1

Period 2

Period 2 title	64wks Active(PtA)+Active Treatment(PtB)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Blinding implementation details:

In order to maintain the blind, Nemolizumab and the placebo formulation were of identical volume and provided in identical containers.

Arms

Are arms mutually exclusive?	Yes
Arm title	Nemolizumab (0.1 mg/kg) q4w

Arm description:

CIM331 (0.1 mg/kg) was given subcutaneously every 4 weeks for 64 weeks

Arm type	Experimental
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (0.5 mg/kg) q4w

Arm description:

CIM331 (0.5 mg/kg) given subcutaneously every 4 weeks for 64 weeks.

Arm type	Experimental
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (2.0 mg/kg) q4w

Arm description:

CIM331 (2.0 mg/kg) given subcutaneously every 4 weeks for 64 weeks.

Arm type	Experimental

Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Arm title	Nemolizumab (2.0 mg/kg) q8w

Arm description:

Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections every 4 weeks for 12 weeks. Patients in this dosing group received placebo at Week 12, Nemolizumab at Week 16, and then alternating doses of placebo and Nemolizumab.

Arm type	Experimental
Investigational medicinal product name	Nemolizumab
Investigational medicinal product code	CIM331
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous injection in non-lesional abdomen at 20 µL/kg.

Number of subjects in period 2[1]	Nemolizumab (0.1 mg/kg) q4w	Nemolizumab (0.5 mg/kg) q4w	Nemolizumab (2.0 mg/kg) q4w
Started	41	38	39
Completed	31	28	30
Not completed	10	10	9
Consent withdrawn by subject	4	7	6
Physician decision	-	1	1
Withdrawal by subject due to lack of efficacy	-	-	-
Adverse event, non-fatal	2	-	1
Patient return PIC due to skin worsening	-	-	1
Pregnancy	-	-	-
Lost to follow-up	-	-	-
Lack of efficacy	3	2	-
Met Withdrawal Criteria	1	-	-

Number of subjects in period 2[1]	Nemolizumab (2.0 mg/kg) q8w
Started	35
Completed	19
Not completed	16
Consent withdrawn by subject	6
Physician decision	-

Withdrawal by subject due to lack of efficacy	1
Adverse event, non-fatal	3
Patient return PIC due to skin worsening	-
Pregnancy	1
Lost to follow-up	1
Lack of efficacy	4
Met Withdrawal Criteria	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: It was optional for patients to participate in the part B of the study, therefore some patients decided to decline and not participate in part B.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo: subcutaneous injections every 4 weeks on Day 1, Week 4 and Week 8	
Reporting group title	Nemolizumab (0.1 mg/kg) q4w
Reporting group description:	
Nemolizumab (0.1 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks	
Reporting group title	Nemolizumab (0.5 mg/kg) q4w
Reporting group description:	
Nemolizumab (0.5 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks	
Reporting group title	Nemolizumab (2.0 mg/kg) q4w
Reporting group description:	
Nemolizumab (2.0 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks	
Reporting group title	Nemolizumab (2.0 mg/kg) q8w
Reporting group description:	
Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections Dose on Day 1 and at Week 8, placebo at Week 4.	

Reporting group values	Placebo	Nemolizumab (0.1 mg/kg) q4w	Nemolizumab (0.5 mg/kg) q4w
Number of subjects	53	53	54
Age categorical			
Data is reported for the 264 treatred subjects included in the analyses.			
Units: Subjects			
Adults (18-64 years)	53	53	54
Age continuous			
Data is reported for the 264 treatred subjects included in the analyses.			
Units: years			
arithmetic mean	37	33.5	33.7
standard deviation	± 13.1	± 10.3	± 11.7
Gender categorical			
Data is reported for the 264 treated subjects included in the analyses.			
Units: Subjects			
Female	28	25	32
Male	25	28	22

Reporting group values	Nemolizumab (2.0 mg/kg) q4w	Nemolizumab (2.0 mg/kg) q8w	Total
Number of subjects	52	52	264
Age categorical			
Data is reported for the 264 treatred subjects included in the analyses.			
Units: Subjects			
Adults (18-64 years)	52	52	264
Age continuous			
Data is reported for the 264 treatred subjects included in the analyses.			
Units: years			
arithmetic mean	34.4	35.8	
standard deviation	± 11.9	± 13.6	-

Gender categorical			
Data is reported for the 264 treated subjects included in the analyses.			
Units: Subjects			
Female	21	23	129
Male	31	29	135

Subject analysis sets

Subject analysis set title	Intent to treat
Subject analysis set type	Intention-to-treat

Subject analysis set description:

ITT population will include all patients who receive at least one dose of double-blind study drug. Patients who receive study drug different from that to which they are randomized will be included in the group to which they are randomized.

Reporting group values	Intent to treat		
Number of subjects	264		
Age categorical			
Data is reported for the 264 treatred subjects included in the analyses.			
Units: Subjects			
Adults (18-64 years)	264		
Age continuous			
Data is reported for the 264 treatred subjects included in the analyses.			
Units: years			
arithmetic mean	34.9		
standard deviation	± 12.1		
Gender categorical			
Data is reported for the 264 treated subjects included in the analyses.			
Units: Subjects			
Female	129		
Male	135		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo: subcutaneous injections every 4 weeks on Day 1, Week 4 and Week 8	
Reporting group title	Nemolizumab (0.1 mg/kg) q4w
Reporting group description:	
Nemolizumab (0.1 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks	
Reporting group title	Nemolizumab (0.5 mg/kg) q4w
Reporting group description:	
Nemolizumab (0.5 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks	
Reporting group title	Nemolizumab (2.0 mg/kg) q4w
Reporting group description:	
Nemolizumab (2.0 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks	
Reporting group title	Nemolizumab (2.0 mg/kg) q8w
Reporting group description:	
Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections Dose on Day 1 and at Week 8, placebo at Week 4.	
Reporting group title	Nemolizumab (0.1 mg/kg) q4w
Reporting group description:	
CIM331 (0.1 mg/kg) was given subcutaneously every 4 weeks for 64 weeks	
Reporting group title	Nemolizumab (0.5 mg/kg) q4w
Reporting group description:	
CIM331 (0.5 mg/kg) given subcutaneously every 4 weeks for 64 weeks.	
Reporting group title	Nemolizumab (2.0 mg/kg) q4w
Reporting group description:	
CIM331 (2.0 mg/kg) given subcutaneously every 4 weeks for 64 weeks.	
Reporting group title	Nemolizumab (2.0 mg/kg) q8w
Reporting group description:	
Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections every 4 weeks for 12 weeks. Patients in this dosing group received placebo at Week 12, Nemolizumab at Week 16, and then alternating doses of placebo and Nemolizumab.	
Subject analysis set title	Intent to treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
ITT population will include all patients who receive at least one dose of double-blind study drug. Patients who receive study drug different from that to which they are randomized will be included in the group to which they are randomized.	

Primary: The percent improvement in pruritus from baseline to Week 12, assessed by patients using the pruritus visual analogue scale (VAS)

End point title	The percent improvement in pruritus from baseline to Week 12, assessed by patients using the pruritus visual analogue scale (VAS)[1]
End point description:	
Pruritus intensity in the last 24 hours, from 0 (no itch) to 10 (worst imaginable itch).	
End point type	Primary
End point timeframe:	
Baseline and week 12	

Notes:

[1] - 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: Statistical analysis was not performed on the other arm that were not reported.

End point values	Placebo	Nemolizumab (0.1 mg/kg) q4w	Nemolizumab (0.5 mg/kg) q4w	Nemolizumab (2.0 mg/kg) q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	45	47
Units: percent				
least squares mean (confidence interval 95%)	-20.07 (-29.94 to -10.21)	-41.46 (-51.21 to -31.71)	-61.24 (-71.13 to -51.35)	-60.46 (-69.98 to -50.95)

Statistical analyses

Statistical analysis title	Difference in % change

Statistical analysis description:

The primary analysis of the percent improvement VAS from baseline in pruritus VAS to Week 12 will be the pairwise comparison of each CIM331 Q4W dose against placebo.

Comparison groups	Placebo v Nemolizumab (0.1 mg/kg) q4w
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0027
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-21.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.25
upper limit	-7.53

Statistical analysis title	Difference in % change

Statistical analysis description:

The primary analysis of the percent improvement VAS from baseline in pruritus VAS to Week 12 will be the pairwise comparison of each CIM331 Q4W dose against placebo.

Comparison groups	Placebo v Nemolizumab (0.5 mg/kg) q4w
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [2]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-41.16

Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.17
upper limit	-27.15

Notes:

[2] - Since a hierarchical decision procedure can be regarded as a closed testing procedure, no inflation of the alpha level due to multiple comparisons exists, and the global 1-sided significance alpha level of 0.025 is maintained.

Statistical analysis title	Difference in % change

Statistical analysis description:

The primary analysis of the percent improvement VAS from baseline in pruritus VAS to Week 12 will be the pairwise comparison of each CIM331 Q4W dose against placebo.

Comparison groups	Placebo v Nemolizumab (2.0 mg/kg) q4w
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-40.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.11
upper limit	-26.67

Notes:

[3] - Since a hierarchical decision procedure can be regarded as a closed testing procedure, no inflation of the alpha level due to multiple comparisons exists, and the global 1-sided significance alpha level of 0.025 is maintained.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Period 1 : 12-week placebo-controlled period (Part A)
Period 2 : 64wks Active (Part A) + Active Treatment (Part B) (Part A+B)

Adverse event reporting additional description:

The Investigator is responsible for ensuring that all adverse events are recorded on the Adverse Event eCRF and reported to the Sponsor. For each adverse event recorded on the Adverse Event eCRF, the Investigator will make an assessment of seriousness, severity, and causality.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	Placebo (Part A)

Reporting group description:

Placebo: subcutaneous injections every 4 weeks on Day 1, Week 4 and Week 8

Reporting group title	Nemolizumab (0.1 mg/kg) q4w (Part A)

Reporting group description:

Nemolizumab (0.1 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks

Reporting group title	Nemolizumab (0.5 mg/kg) q4w (Part A)

Reporting group description:

Nemolizumab (0.5 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks

Reporting group title	Nemolizumab (2.0 mg/kg) q4w (Part A)

Reporting group description:

Nemolizumab (2.0 mg/kg) q4w: subcutaneous injections every 4 weeks for 12 weeks

Reporting group title	Nemolizumab (2.0 mg/kg) q8w (Part A)

Reporting group description:

Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections Dose on Day 1 and at Week 8, placebo at Week 4.

Reporting group title	Nemolizumab (0.1 mg/kg) q4w (Part A + B)

Reporting group description:

CIM331 (0.1 mg/kg) was given subcutaneously every 4 weeks for 64 weeks

Reporting group title	Nemolizumab (0.5 mg/kg) q4w (Part A + B)

Reporting group description:

CIM331 (0.5 mg/kg) given subcutaneously every 4 weeks for 64 weeks.

Reporting group title	Nemolizumab (2.0 mg/kg) q4w (Part A + B)

Reporting group description:

CIM331 (2.0 mg/kg) given subcutaneously every 4 weeks for 64 weeks.

Reporting group title	Nemolizumab (2.0 mg/kg) q8w (Part A + B)

Reporting group description:

Nemolizumab (2.0 mg/kg) q8w: subcutaneous injections every 4 weeks for 12 weeks. Patients in this dosing group received placebo at Week 12, Nemolizumab at Week 16, and then alternating doses of placebo and Nemolizumab."

Serious adverse events	Placebo (Part A)	Nemolizumab (0.1 mg/kg) q4w (Part A)	Nemolizumab (0.5 mg/kg) q4w (Part A)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 53 (1.89%)	1 / 53 (1.89%)	0 / 54 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Upper limb fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Joint dislocation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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 fibrillation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Coronary artery stenosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
Parkinson's disease			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Grand mal convulsion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Blood and lymphatic system disorders			
Lymphadenopathy			

subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	1 / 53 (1.89%)	0 / 53 (0.00%)	0 / 54 (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
Cataract			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Hepatobiliary disorders			
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Urticaria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Rash			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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			
Pyoderma			

subjects affected / exposed	0 / 53 (0.00%)	1 / 53 (1.89%)	0 / 54 (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
Skin infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Herpes zoster			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Dermatitis exfoliative			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Herpes simplex			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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
Pyelonephritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (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	Nemolizumab (2.0 mg/kg) q4w (Part A)	Nemolizumab (2.0 mg/kg) q8w (Part A)	Nemolizumab (0.1 mg/kg) q4w (Part A + B)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 52 (5.77%)	5 / 52 (9.62%)	3 / 53 (5.66%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Upper limb fracture			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Joint dislocation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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 fibrillation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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			
Parkinson's disease			
subjects affected / exposed	0 / 52 (0.00%)	1 / 52 (1.92%)	0 / 53 (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
Grand mal convulsion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 52 (1.92%)	0 / 52 (0.00%)	0 / 53 (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
Eye disorders			
Retinal detachment			

subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Cataract			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Hepatobiliary disorders			
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	2 / 52 (3.85%)	1 / 52 (1.92%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Rash			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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			
Pyoderma			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 52 (0.00%)	0 / 53 (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

Herpes zoster			
subjects affected / exposed	0 / 52 (0.00%)	1 / 52 (1.92%)	0 / 53 (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
Dermatitis exfoliative			
subjects affected / exposed	0 / 52 (0.00%)	1 / 52 (1.92%)	0 / 53 (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
Herpes simplex			
subjects affected / exposed	0 / 52 (0.00%)	1 / 52 (1.92%)	0 / 53 (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
Infection			
subjects affected / exposed	0 / 52 (0.00%)	2 / 52 (3.85%)	0 / 53 (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
Pyelonephritis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	0 / 53 (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	Nemolizumab (0.5 mg/kg) q4w (Part A + B)	Nemolizumab (2.0 mg/kg) q4w (Part A + B)	Nemolizumab (2.0 mg/kg) q8w (Part A + B)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 54 (5.56%)	4 / 52 (7.69%)	9 / 52 (17.31%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Upper limb fracture			
subjects affected / exposed	0 / 54 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	0 / 54 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Parkinson's disease			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			

subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 54 (1.85%)	2 / 52 (3.85%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 54 (1.85%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	1 / 54 (1.85%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pyoderma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 54 (0.00%)	1 / 52 (1.92%)	0 / 52 (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
Herpes zoster			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dermatitis exfoliative			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	2 / 52 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo (Part A)	Nemolizumab (0.1 mg/kg) q4w (Part A)	Nemolizumab (0.5 mg/kg) q4w (Part A)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 53 (67.92%)	38 / 53 (71.70%)	36 / 54 (66.67%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 53 (5.66%)	2 / 53 (3.77%)	2 / 54 (3.70%)
occurrences (all)	3	2	2
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 53 (0.00%)	3 / 53 (5.66%)	2 / 54 (3.70%)
occurrences (all)	0	5	3
Dizziness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Oedema peripheral			
subjects affected / exposed	0 / 53 (0.00%)	2 / 53 (3.77%)	3 / 54 (5.56%)
occurrences (all)	0	3	3
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	3 / 53 (5.66%)	2 / 53 (3.77%)	1 / 54 (1.85%)
occurrences (all)	3	2	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	7 / 53 (13.21%)	11 / 53 (20.75%)	10 / 54 (18.52%)
occurrences (all)	8	12	11
Urticaria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 53 (15.09%)	9 / 53 (16.98%)	6 / 54 (11.11%)
occurrences (all)	8	12	8
Upper respiratory tract infection			
subjects affected / exposed	6 / 53 (11.32%)	4 / 53 (7.55%)	1 / 54 (1.85%)
occurrences (all)	7	5	1
Folliculitis			
subjects affected / exposed	3 / 53 (5.66%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	3	0	0
Impetigo			

subjects affected / exposed	0 / 53 (0.00%)	4 / 53 (7.55%)	0 / 54 (0.00%)
occurrences (all)	0	4	0
Influenza			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 53 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Nemolizumab (2.0 mg/kg) q4w (Part A)	Nemolizumab (2.0 mg/kg) q8w (Part A)	Nemolizumab (0.1 mg/kg) q4w (Part A + B)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 52 (76.92%)	37 / 52 (71.15%)	47 / 53 (88.68%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	4 / 52 (7.69%)	3 / 52 (5.77%)	5 / 53 (9.43%)
occurrences (all)	4	3	6
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 52 (5.77%)	1 / 52 (1.92%)	3 / 53 (5.66%)
occurrences (all)	3	4	6
Dizziness			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	3 / 53 (5.66%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
Oedema peripheral			

subjects affected / exposed	5 / 52 (9.62%)	2 / 52 (3.85%)	2 / 53 (3.77%)
occurrences (all)	6	3	3
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 52 (1.92%)	1 / 52 (1.92%)	3 / 53 (5.66%)
occurrences (all)	1	1	3
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	2 / 53 (3.77%)
occurrences (all)	0	0	2
Asthma			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	3 / 53 (5.66%)
occurrences (all)	0	0	3
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	9 / 52 (17.31%)	9 / 52 (17.31%)	15 / 53 (28.30%)
occurrences (all)	11	10	20
Urticaria			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 52 (9.62%)	7 / 52 (13.46%)	15 / 53 (28.30%)
occurrences (all)	7	11	33
Upper respiratory tract infection			
subjects affected / exposed	4 / 52 (7.69%)	5 / 52 (9.62%)	6 / 53 (11.32%)
occurrences (all)	4	5	8
Folliculitis			
subjects affected / exposed	0 / 52 (0.00%)	1 / 52 (1.92%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Impetigo			

subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	6 / 53 (11.32%)
occurrences (all)	0	0	7
Influenza			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	5 / 53 (9.43%)
occurrences (all)	0	0	5
Pharyngitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	3 / 53 (5.66%)
occurrences (all)	0	0	3
Cystitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1

Non-serious adverse events	Nemolizumab (0.5 mg/kg) q4w (Part A + B)	Nemolizumab (2.0 mg/kg) q4w (Part A + B)	Nemolizumab (2.0 mg/kg) q8w (Part A + B)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	46 / 54 (85.19%)	52 / 52 (100.00%)	43 / 52 (82.69%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 54 (5.56%)	9 / 52 (17.31%)	6 / 52 (11.54%)
occurrences (all)	7	14	6
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 54 (11.11%)	5 / 52 (9.62%)	2 / 52 (3.85%)
occurrences (all)	10	5	3
Dizziness			
subjects affected / exposed	0 / 54 (0.00%)	0 / 52 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Oedema peripheral			

subjects affected / exposed	3 / 54 (5.56%)	6 / 52 (11.54%)	2 / 52 (3.85%)
occurrences (all)	3	8	3
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 54 (1.85%)	1 / 52 (1.92%)	2 / 52 (3.85%)
occurrences (all)	1	1	3
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 54 (5.56%)	1 / 52 (1.92%)	1 / 52 (1.92%)
occurrences (all)	3	2	1
Asthma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	12 / 54 (22.22%)	12 / 52 (23.08%)	9 / 52 (17.31%)
occurrences (all)	15	14	11
Urticaria			
subjects affected / exposed	3 / 54 (5.56%)	1 / 52 (1.92%)	1 / 52 (1.92%)
occurrences (all)	5	3	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 54 (3.70%)	3 / 52 (5.77%)	2 / 52 (3.85%)
occurrences (all)	2	5	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	14 / 54 (25.93%)	15 / 52 (28.85%)	12 / 52 (23.08%)
occurrences (all)	31	25	21
Upper respiratory tract infection			
subjects affected / exposed	3 / 54 (5.56%)	5 / 52 (9.62%)	5 / 52 (9.62%)
occurrences (all)	8	9	6
Folliculitis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 52 (1.92%)	3 / 52 (5.77%)
occurrences (all)	0	1	3
Impetigo			

subjects affected / exposed	3 / 54 (5.56%)	0 / 52 (0.00%)	3 / 52 (5.77%)
occurrences (all)	3	0	3
Influenza			
subjects affected / exposed	1 / 54 (1.85%)	2 / 52 (3.85%)	0 / 52 (0.00%)
occurrences (all)	1	2	0
Pharyngitis			
subjects affected / exposed	3 / 54 (5.56%)	3 / 52 (5.77%)	1 / 52 (1.92%)
occurrences (all)	3	3	1
Bronchitis			
subjects affected / exposed	2 / 54 (3.70%)	2 / 52 (3.85%)	0 / 52 (0.00%)
occurrences (all)	2	2	0
Cystitis			
subjects affected / exposed	3 / 54 (5.56%)	1 / 52 (1.92%)	1 / 52 (1.92%)
occurrences (all)	3	1	1
Sinusitis			
subjects affected / exposed	3 / 54 (5.56%)	1 / 52 (1.92%)	1 / 52 (1.92%)
occurrences (all)	3	1	1

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

None reported