Clinical trial results:
A Phase 2 Multi-Center, Open-Label, Follow-Up Study to Assess The Long-Term Safety and Efficacy of CDP6038 Administered Subcutaneously to Subjects With Active Rheumatoid Arthritis Who completed Study RA0056

Summary

EudraCT number	2010-022224-77
Trial protocol	GB BE
Global end of trial date	05 August 2013

Results information

Result version number	v1 (current)
This version publication date	23 March 2022
First version publication date	23 March 2022

Trial information

Trial identification

Sponsor protocol code	RA0057

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	11 October 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2013
Global end of trial reached?	Yes
Global end of trial date	05 August 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the long-term safety of CDP6038 dosed at 120 milligrams (mg) once every 2 weeks (q2w) while treating the signs and symptoms of active rheumatoid arthritis in participants who have previously failed TNFα blocker therapy.

Protection of trial subjects:

During the conduct of the study all subjects were closely monitored.

Background therapy:

Not applicable

Evidence for comparator: -

Actual start date of recruitment	07 March 2011
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	Belgium: 3
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	United States: 183
Worldwide total number of subjects	190
EEA total number of subjects	3

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)	147
From 65 to 84 years	43

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The present study was an open-label extension to study RA0056 (NCT01242488). Subjects completing the 12-week treatment period of study RA0056 had the opportunity to participate in this study. First subject enrolled: 07 March 2011. Early termination: 05 Aug 2013.

Pre-assignment

Screening details:

198 subjects completed the parent study RA0056 (NCT01242488); 190 subjects were enrolled in study RA0057. The study was a single treatment study and all subjects received CDP6038 (olokizumab) 120 mg sc q2w, however, some results are also presented according to the previously assigned treatment arms of the parent study RA0056.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	RA0056 CDP6038 (Olokizumab) 120 mg q2w

Arm description:

CDP6038 (olokizumab) 120 mg administered every 2 weeks (q2w) sc in Study RA0056, and maintained at same dose (i.e. 120 mg q2w sc) at start of study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 120 mg olokizumab q2w at prespecified time points.

Arm title	RA0056 CDP6038 (Olokizumab) 120 mg q4w

Arm description:

CDP6038 (olokizumab) 120 mg administered every 4 weeks (q4w) sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 120 mg olokizumab q4w at prespecified time points.

Arm title	RA0056 CDP6038 (Olokizumab) 240 mg q2w

Arm description:

CDP6038 (olokizumab) 240 mg administered q2w sc in study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental

Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 240 mg olokizumab q2w at prespecified time points.

Arm title	RA0056 CDP6038 (Olokizumab) 240 mg q4w

Arm description:

CDP6038 (olokizumab) 240 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 240 mg olokizumab q4w at prespecified time points.

Arm title	RA0056 CDP6038 (Olokizumab) 60 mg q2w

Arm description:

CDP6038 (olokizumab) 60 mg administered q2w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 60 mg olokizumab q2w at prespecified time points.

Arm title	RA0056 CDP6038 (Olokizumab) 60 mg q4w

Arm description:

CDP6038 (olokizumab) 60 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 60 mg olokizumab q4w at prespecified time points.

Arm title	RA0056 Placebo

Arm description:

Placebo (sodium chloride, 0.9%) was administered q2w or q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Placebo

Investigational medicinal product name	Olokizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo matched to olokizumab at prespecified time points.

Arm title	RA0056 Tocilizumab 8 mg/kg q4w

Arm description:

Tocilizumab 8 mg/kg administered q4w iv in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Arm type	Experimental
Investigational medicinal product name	Tocilizumab
Investigational medicinal product code	CDP6038
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 8 mg tocilizumab q4w at prespecified time points.

Number of subjects in period 1	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w
Started	20	20	21
Completed	4	12	8
Not completed	16	8	13
Patient decision due to transport	-	-	-
Methotrexate discontinued	-	-	-
Failure to comply with visits	-	-	-
Required restricted steroid injections	-	-	-
Investigator discretion	-	-	-
Consent withdrawn by subject	4	2	2
Ongoing missed appointments	-	-	-
Adverse event, non-fatal	3	1	4
Study termination	8	1	5
Continued elevated liver enzymes	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	1
Lack of efficacy	1	4	1
Protocol deviation	-	-	-

Number of subjects in period 1	RA0056 CDP6038 (Olokizumab) 240 mg q4w	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w
Started	20	17	16

Completed	7	7	5
Not completed	13	10	11
Patient decision due to transport	-	-	-
Methotrexate discontinued	1	-	-
Failure to comply with visits	-	-	-
Required restricted steroid injections	-	-	-
Investigator discretion	-	-	-
Consent withdrawn by subject	1	1	1
Ongoing missed appointments	-	-	-
Adverse event, non-fatal	3	1	6
Study termination	4	4	4
Continued elevated liver enzymes	1	-	-
Unspecified	-	-	-
Lost to follow-up	1	2	-
Lack of efficacy	1	1	-
Protocol deviation	1	1	-

Number of subjects in period 1	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Started	40	36
Completed	9	15
Not completed	31	21
Patient decision due to transport	-	1
Methotrexate discontinued	-	-
Failure to comply with visits	-	1
Required restricted steroid injections	1	-
Investigator discretion	1	-
Consent withdrawn by subject	2	1
Ongoing missed appointments	1	-
Adverse event, non-fatal	11	3
Study termination	8	10
Continued elevated liver enzymes	-	-
Unspecified	1	-
Lost to follow-up	4	2
Lack of efficacy	2	3
Protocol deviation	-	-

Baseline characteristics

Reporting groups	
Reporting group title	RA0056 CDP6038 (Olokizumab) 120 mg q2w
Reporting group description:	
CDP6038 (olokizumab) 120 mg administered every 2 weeks (q2w) sc in Study RA0056, and maintained at same dose (i.e. 120 mg q2w sc) at start of study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 120 mg q4w
Reporting group description:	
CDP6038 (olokizumab) 120 mg administered every 4 weeks (q4w) sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 240 mg q2w
Reporting group description:	
CDP6038 (olokizumab) 240 mg administered q2w sc in study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Reporting group description:	
CDP6038 (olokizumab) 240 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 60 mg q2w
Reporting group description:	
CDP6038 (olokizumab) 60 mg administered q2w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 60 mg q4w
Reporting group description:	
CDP6038 (olokizumab) 60 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 Placebo
Reporting group description:	
Placebo (sodium chloride, 0.9%) was administered q2w or q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 Tocilizumab 8 mg/kg q4w
Reporting group description:	
Tocilizumab 8 mg/kg administered q4w iv in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	

Reporting group values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w
Number of subjects	20	20	21
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	17	16	17
>=65 years	3	4	4
Age continuous Units: years			
arithmetic mean	53.8	54.5	56.1
standard deviation	± 10.99	± 11.9	± 12.3
Gender, Male/Female Units: participants			
Female	17	17	19

Male	3	3	2

Reporting group values	RA0056 CDP6038 (Olokizumab) 240 mg q4w	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w
Number of subjects	20	17	16
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	14	13	14
>=65 years	6	4	2
Age continuous Units: years			
arithmetic mean	55.0	57.9	54.0
standard deviation	± 12.7	± 10.0	± 12.1
Gender, Male/Female Units: participants			
Female	16	14	14
Male	4	3	2

Reporting group values	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w	Total
Number of subjects	40	36	190
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	27	29	147
>=65 years	13	7	43
Age continuous Units: years			
arithmetic mean	58.9	36.8	
standard deviation	± 12.5	± 10.3	-
Gender, Male/Female Units: participants			
Female	33	31	161
Male	7	5	29

End points

End points reporting groups

Reporting group title	RA0056 CDP6038 (Olokizumab) 120 mg q2w
Reporting group description:	
CDP6038 (olokizumab) 120 mg administered every 2 weeks (q2w) sc in Study RA0056, and maintained at same dose (i.e. 120 mg q2w sc) at start of study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 120 mg q4w
Reporting group description:	
CDP6038 (olokizumab) 120 mg administered every 4 weeks (q4w) sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 240 mg q2w
Reporting group description:	
CDP6038 (olokizumab) 240 mg administered q2w sc in study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Reporting group description:	
CDP6038 (olokizumab) 240 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 60 mg q2w
Reporting group description:	
CDP6038 (olokizumab) 60 mg administered q2w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 CDP6038 (Olokizumab) 60 mg q4w
Reporting group description:	
CDP6038 (olokizumab) 60 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 Placebo
Reporting group description:	
Placebo (sodium chloride, 0.9%) was administered q2w or q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Reporting group title	RA0056 Tocilizumab 8 mg/kg q4w
Reporting group description:	
Tocilizumab 8 mg/kg administered q4w iv in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.	
Subject analysis set title	RA0056 CDP6038 (olokizumab) Combined
Subject analysis set type	Full analysis
Subject analysis set description:	
All doses of CDP6038 (olokizumab) (60 mg, 120 mg and 240 mg in Study RA0056) were pooled together as one combined treatment group. All subjects switched to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056).	

Primary: Number of subjects with treatment-emergent adverse events (TEAEs)

End point title	Number of subjects with treatment-emergent adverse events (TEAEs)[1]
End point description:	
Reported TEAEs included adverse events that started or worsened after the first dose of CDP6038 (olokizumab) in Study RA0057 and within 30 days after the last dose. Safety Population included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) in Study RA0057.	
End point type	Primary
End point timeframe:	
From Baseline (Week 0 of Study RA0057) until 30 days after the last dose (maximum up to 780 days)	

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: Only descriptive analyses was planned to be reported for this endpoint.

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: participants	17	20	19	18

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: participants	15	15	39	35

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in the Disease Activity Score-28-joint count (C-reactive protein) (DAS28[CRP]) to Week 12 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in the Disease Activity Score-28-joint count (C-reactive protein) (DAS28[CRP]) to Week 12 of Study RA0057

End point description:

DAS28(CRP) was calculated using tender/painful joint count (TJC) and swollen joint count (SJC) from 28 joints, Patient's Global Assessment of Disease Activity (PtGADA)-Visual Analog Scale (VAS) and CRP using formula:DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on same 2-point scale (0=absent; 1=present). • PtGADA: 100mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP calculated in mg/L. The 28 joints: shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), proximal interphalangeal (PIP) joints of hands; and knees. Scores on DAS28(CRP): 0 to 10 (higher scores = more disease activity). A negative change in score= an improvement in disease activity. Full analysis set: all enrolled subjects who received at least 1 dose of CDP6038 and had at least 1 efficacy assessment in RA0057. Number of Participants Analyzed =participants evaluable for this assessment.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 12 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	19	15
Units: units on a scale				
arithmetic mean (standard deviation)	-2.2809 (± 1.45737)	-2.2485 (± 1.39384)	-2.5123 (± 1.39667)	-2.2230 (± 1.17572)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	32	29
Units: units on a scale				
arithmetic mean (standard deviation)	-1.6957 (± 0.67335)	-2.1735 (± 1.56606)	-2.3727 (± 1.41421)	-2.4710 (± 1.43947)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	94			
Units: units on a scale				
arithmetic mean (standard deviation)	-2.2020 (± 1.30149)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in DAS28(CRP) to Week 24 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in DAS28(CRP) to Week 24 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, PtGADA-VAS and CRP according to formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and PIP joints of hands; and knees. Scores on DAS28(CRP) range from 0 to approximately 10, where higher scores =more disease activity. A negative change in DAS28(CRP) score indicates an improvement in disease activity. FAS included all enrolled subjects who received at least 1 injection of CDP6038 and had at least 1 efficacy measurement in RA0057. When baseline and actual mean scores were not available, change from baseline was not calculated. Number of Participants analyzed (N)=participants who were evaluable for assessment.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 24 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	19	10
Units: units on a scale				
arithmetic mean (standard deviation)	-2.6441 (± 1.46566)	1.46566 (± 1.17637)	-2.5811 (± 1.40191)	-2.5999 (± 1.16812)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	31	29
Units: units on a scale				
arithmetic mean (standard deviation)	-1.7189 (± 0.87218)	-2.4221 (± 1.37341)	-2.1484 (± 1.34676)	-2.7624 (± 1.47841)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	83			
Units: units on a scale				
arithmetic mean (standard deviation)	-2.4624 (± 1.28049)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in DAS28(CRP) to Week 48 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in DAS28(CRP) to Week 48 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, PtGADA-VAS and CRP according to formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value

calculated in mg/L. The 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and PIP joints of hands; and knees. Scores on DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A negative change in DAS28(CRP) score indicates an improvement in disease activity. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057. When baseline and actual mean scores were not available, change from baseline was not calculated. N =participants who were evaluable for assessment.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	12	13	10
Units: units on a scale				
arithmetic mean (standard deviation)	-2.3257 (± 1.07427)	-2.2498 (± 1.66580)	-2.5277 (± 1.56763)	-2.7050 (± 0.96160)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	20	22
Units: units on a scale				
arithmetic mean (standard deviation)	-2.3824 (± 0.79065)	-2.1501 (± 0.64141)	-2.2403 (± 1.47765)	-2.7611 (± 1.31329)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: units on a scale				
arithmetic mean (standard deviation)	-2.3919 (± 1.17675)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in DAS28(CRP) to

Week 96 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in DAS28(CRP) to Week 96 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, PtGADA-VAS and CRP according to formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and PIP joints of hands; and knees. Scores on DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A negative change in DAS28(CRP) score indicates an improvement in disease activity. Analysis population was FAS. When baseline and actual mean scores were not available, change from baseline was not calculated. Here, N signifies participants who were evaluable for assessment. 99999 signifies that standard deviation (S.D.) could not be calculated as there was only 1 evaluable participant.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	3	2
Units: units on a scale				
arithmetic mean (standard deviation)	-3.2427 (± 1.74642)	-3.5767 (± 99999)	-2.5985 (± 2.16200)	-3.0999 (± 0.02877)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	2	5
Units: units on a scale				
arithmetic mean (standard deviation)	-1.7516 (± 2.03992)	-2.6451 (± 0.96108)	-3.3173 (± 3.23508)	-3.7982 (± 1.23889)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: units on a scale				
arithmetic mean (standard deviation)	-2.7032 (± 1.50391)			

Statistical analyses

No statistical analyses for this end point

Secondary: The American College of Rheumatology (ACR) 20% (ACR20) improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 12 of Study RA0057

End point title	The American College of Rheumatology (ACR) 20% (ACR20) improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 12 of Study RA0057

End point description:

ACR20 =at least 20% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, Physician's Global Assessment of Disease Activity (PhGADA)-VAS, Patient's Assessment of Arthritis Pain (PAAP)-VAS, Health Assessment Questionnaire-Disability Index (HAQ-DI) and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present).•PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms).•PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. Analysis population was FAS.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 12 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	40.0	50.0	76.2	35.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	58.8	50.0	47.5	52.8

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	51.8			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR20 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 24 of Study RA0057

End point title	The ACR20 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 24 of Study RA0057

End point description:

ACR20 represents at least 20% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 24 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	40.0	50.0	66.7	30.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	47.1	62.5	42.5	63.9

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	49.1			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR20 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 48 of Study RA0057

End point title	The ACR20 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 48 of Study RA0057

End point description:

ACR20 represents at least 20% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	40.0	30.0	42.9	35.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	47.1	43.8	25.0	50.0

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	39.5			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR20 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 96 of Study RA0057

End point title	The ACR20 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 96 of Study RA0057

End point description:

ACR20 represents at least 20% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	15.0	5.0	9.5	5.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	11.8	12.5	2.5	13.9

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	9.6			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR 50% (ACR50) improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 12 of Study RA0057

End point title	The ACR 50% (ACR50) improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 12 of Study RA0057

End point description:

ACR50 represents at least 50% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 12 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	25.0	15.0	33.3	15.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	17.6	18.8	27.5	38.9

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	21.1			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR50 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 24 of Study RA0057

End point title	The ACR50 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 24 of Study RA0057

End point description:

ACR50 represents at least 50% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities

(20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 24 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	20.0	20.0	33.3	15.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	11.8	43.8	25.0	41.7

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	23.7			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR50 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 48 of Study RA0057

End point title	The ACR50 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 48 of Study RA0057

End point description:

ACR50 represents at least 50% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)

+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	10.0	15.0	28.6	20.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	35.3	31.3	15.0	33.3

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	22.8			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR50 improvement criteria response rate from Baseline (Week 0 of

Study RA0056) to Week 96 of Study RA0057

End point title	The ACR50 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 96 of Study RA0057

End point description:

ACR50 represents at least 50% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	10.0	5.0	4.8	0.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	11.8	6.3	2.5	8.3

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	6.1			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR 70% (ACR70) improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 12 of Study RA0057

End point title	The ACR 70% (ACR70) improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 12 of Study RA0057

End point description:

ACR70 represents at least 70% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 12 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	10.0	5.0	19.0	5.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	0.0	18.8	15.0	13.9

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				

number (not applicable)	9.6			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR70 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 24 of Study RA0057

End point title	The ACR70 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 24 of Study RA0057

End point description:

ACR70 represents at least 70% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 24 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	10.0	15.0	19.0	5.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	0.0	12.5	10.0	25.0

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	10.5			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR70 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 48 of Study RA0057

End point title	The ACR70 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 48 of Study RA0057

End point description:

ACR70 represents at least 70% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	5.0	5.0	23.8	10.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	11.8	6.3	10.0	13.9

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	10.5			

Statistical analyses

No statistical analyses for this end point

Secondary: The ACR70 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 96 of Study RA0057

End point title	The ACR70 improvement criteria response rate from Baseline (Week 0 of Study RA0056) to Week 96 of Study RA0057

End point description:

ACR70 represents at least 70% improvement from Baseline for each of TJC (68 joints)+ SJC (66 joints)+ at least 3 components of 5 for:PtGADA-VAS, PhGADA-VAS, PAAP-VAS, HAQ-DI and CRP. Assessments: •TJC and SJC: same 2-point scale (0=absent;1=present). •PtGADA: 100 mm VAS (0=very good, no symptoms;100=very poor, severe symptoms). •PhGADA: 100 mm VAS (0=very good, asymptomatic, no limitation of normal activities;100=very poor, very severe symptoms which were intolerable, inability to carry out all normal activities). •PAAP: 100 mm VAS (0=no pain;100=most severe pain). •HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), its score (0-3) computed from item scores, with lower scores indicates less disability. •CRP in mg/L. Missing values were considered as non-responding status. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) up to Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of responders				
number (not applicable)	5.0	0.0	4.8	0.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of responders				
number (not applicable)	5.9	0.0	2.5	5.6

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: Percentage of responders				
number (not applicable)	2.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) <2.6 at Week 12 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) <2.6 at Week 12 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score less than 2.6 implies remission. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 12 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	25.0	30.0	38.1	25.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	0	18.8	25.0	25.0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) <2.6 at Week 24 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) <2.6 at Week 24 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score less than 2.6 implies remission. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 24 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	25.0	35.0	33.3	25.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	17.6	12.5	20.0	33.3

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) <2.6 at Week 48 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) <2.6 at Week 48 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score less than 2.6 implies remission. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	20.0	30.0	23.8	20.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	29.4	12.5	15.0	22.2

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) <2.6 at Week 96 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) <2.6 at Week 96 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score less than 2.6 implies remission. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	10.0	5.0	9.5	5.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	11.8	0	2.5	8.3

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) ≤3.2 at Week 12 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) ≤3.2 at Week 12 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score less than or equal to (<=) 3.2 implies low disease activity. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 12 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	35.6	40.0	52.4	30.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	17.6	25.0	35.0	44.4

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) ≤3.2 at Week 24 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) ≤3.2 at Week 24 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score <=3.2 implies low disease activity. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition

had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 24 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	35.0	40.0	38.1	30.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	23.5	37.5	35.0	50.0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) ≤3.2 at Week 48 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) ≤3.2 at Week 48 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score <=3.2 implies low disease activity. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	25.0	45.0	23.8	25.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	29.4	18.8	22.5	47.2

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with DAS28(CRP) ≤3.2 at Week 96 of Study RA0057

End point title	Percentage of subjects with DAS28(CRP) ≤3.2 at Week 96 of Study RA0057

End point description:

DAS28(CRP) was calculated using the TJC and SJC from 28 joints, the PtGADA-VAS, and CRP according to the formula: DAS28(CRP)=0.56 * (TJC)^1/2 + 0.28 * (SJC)^1/2 + 0.36 * ln(CRP[mg/L]+1) + 0.014 * PtGADA + 0.96 Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 100 mm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • CRP value calculated in mg/L. The 28 joints included the shoulders, elbows, wrists; metacarpophalangeal (MCP), thumb interphalangeal (IP), and proximal interphalangeal (PIP) joints of the hands; and the knees. Scores on the DAS28(CRP) range from 0 to approximately 10, where higher scores indicate more disease activity. A DAS28(CRP) score <=3.2 implies low disease activity. FAS included all enrolled subjects who received at least 1 injection of CDP6038 (olokizumab) and in addition had at least 1 efficacy measurement in Study RA0057.

End point type	Secondary

End point timeframe:

Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	20
Units: Percentage of subjects				
number (not applicable)	15.0	5.0	9.5	5.0

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	16	40	36
Units: Percentage of subjects				
number (not applicable)	11.8	0	2.5	11.1

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in the Clinical Disease Activity Index (CDAI) to Week 48 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in the Clinical Disease Activity Index (CDAI) to Week 48 of Study RA0057

End point description:

CDAI was calculated using the TJC (28 joints), SJC (28 joints), PtGADA-VAS and PhGADA-VAS, according to following formula: SJC + TJC + PtGADA + PhGADA Assessments: • TJC and SJC: assessed on same 2-point scale (0=absent; 1=present). • PtGADA: 10 cm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • PhGADA: 10 cm VAS (0=very good, asymptomatic and no limitation of normal activities; 100=very poor, very severe symptoms which were intolerable and inability to carry out all normal activities). The 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and proximal PIP joints of hands; and knees. Total score range is from 0-100, with the high scores representing high disease activity. A negative change in CDAI score indicates an improvement in disease activity. Analysis population was FAS. When baseline and actual mean scores were not available, change from baseline was not calculated. Number of participants analyzed =participants who were evaluable for assessment.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	13	14	10
Units: units on a scale				
arithmetic mean (standard deviation)	-80.1000 (± 53.28425)	-65.3373 (± 63.72098)	-94.3335 (± 61.48562)	-80.8077 (± 57.91606)

End point values	RA0056 CDP6038 (Olokizumab)	RA0056 CDP6038 (Olokizumab)	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w

	60 mg q2w	60 mg q4w		
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	20	23
Units: units on a scale				
arithmetic mean (standard deviation)	-79.9231 (± 30.09849)	-84.8378 (± 33.77586)	-74.3315 (± 53.99274)	-83.4950 (± 42.48396)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	69			
Units: units on a scale				
arithmetic mean (standard deviation)	-80.9650 (± 51.40554)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in the CDAI to Week 96 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in the CDAI to Week 96 of Study RA0057

End point description:

CDAI was calculated using TJC (28 joints), SJC (28 joints), PtGADA-VAS and PhGADA-VAS, as per formula: SJC + TJC + PtGADA + PhGADA Assessments: • TJC and SJC: assessed on same 2-point scale (0=absent; 1=present). • PtGADA: 10 cm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • PhGADA: 10 cm VAS (0=very good, asymptomatic and no limitation of normal activities; 100=very poor, very severe symptoms which were intolerable and inability to carry out all normal activities). 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and proximal PIP joints of hands; and knees. Total score range is from 0-100, high scores=high disease activity. A negative change in CDAI score indicates an improvement in disease activity. Analysis population was FAS. When baseline and actual mean scores were not available, change from baseline was not calculated. N=participants who were evaluable for assessment. 99999=S.D. could not be calculated as there was only 1 evaluable participant.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	3	2
Units: units on a scale				
arithmetic mean (standard deviation)	-108.0000 (±	-118.0000 (±	-89.0000 (±	-74.3846 (±

66.77574)	99999)	55.97321)	4.78657)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	2	5
Units: units on a scale				
arithmetic mean (standard deviation)	-74.0000 (± 55.74944)	-90.5000 (± 13.43503)	-104.5000 (± 126.57211)	-107.4000 (± 51.52960)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: units on a scale				
arithmetic mean (standard deviation)	-90.0550 (± 3.51706)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in the Simplified Disease Activity Index (SDAI) to Week 48 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in the Simplified Disease Activity Index (SDAI) to Week 48 of Study RA0057

End point description:

SDAI =TJC (28 joints), SJC (28 joints), PtGADA-VAS, PhGADA-VAS and CRP (in milligrams per decilitre [mg/dL]), as per the formula: SJC + TJC + PtGADA + PhGADA + CRP (mg/dL) Assessments: • TJC and SJC: assessed on the same 2-point scale (0=absent; 1=present). • PtGADA: 10 cm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • PhGADA: 10 cm VAS (0=very good, asymptomatic and no limitation of normal activities; 100=very poor, very severe symptoms which were intolerable and inability to carry out all normal activities). • CRP range was from 0 to 10 mg/dL. 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and proximal PIP joints of hands; and knees. SDAI score ranges from 0 to 86, higher scores=worse disease. A negative change in SDAI score indicates an improvement in disease activity. Analysis population was FAS. When baseline and actual mean scores were not available, change from baseline was not calculated. N=participants who were evaluable for the assessment.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of Study RA0056) and Week 48 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	13	13	10
Units: units on a scale				
arithmetic mean (standard deviation)	-92.1000 (± 62.22799)	-75.8757 (± 74.37825)	-104.6668 (± 80.47988)	-92.4077 (± 55.42723)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	20	23
Units: units on a scale				
arithmetic mean (standard deviation)	-87.7564 (± 28.41084)	-112.5378 (± 52.99896)	-87.5815 (± 59.26016)	-107.4080 (± 60.17362)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	68			
Units: units on a scale				
arithmetic mean (standard deviation)	-93.6851 (± 61.14304)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline (Week 0 of Study RA0056) in the SDAI to Week 96 of Study RA0057

End point title	Change from Baseline (Week 0 of Study RA0056) in the SDAI to Week 96 of Study RA0057

End point description:

SDAI was calculated using TJC (28 joints),SJC (28 joints), PtGADA-VAS, PhGADA-VAS and CRP (mg/dL), as per formula: SJC + TJC + PtGADA + PhGADA + CRP (mg/dL) Assessments:• TJC and SJC: assessed on same 2-point scale (0=absent; 1=present).• PtGADA: 10 cm VAS (0=very good, no symptoms; 100=very poor, severe symptoms). • PhGADA: 10 cm VAS (0=very good, asymptomatic and no limitation of normal activities; 100=very poor, very severe symptoms which were intolerable and inability to carry out all normal activities).• CRP range=0 to 10 mg/dL. 28 joints included shoulders, elbows, wrists; MCP, thumb IP, and proximal PIP joints of hands; and knees. SDAI score range=0 to 86, higher scores=worse disease. A negative change in SDAI score=improvement in disease activity. Analysis population was FAS. When baseline and actual mean scores were not available, change from baseline was not calculated. N=participants evaluable for assessment. 99999=S.D. was not calculated due to 1 evaluable participant.

End point type	Secondary

End point timeframe:
Baseline (Week 0 of Study RA0056) and Week 96 (Study RA0057)

End point values	RA0056 CDP6038 (Olokizumab) 120 mg q2w	RA0056 CDP6038 (Olokizumab) 120 mg q4w	RA0056 CDP6038 (Olokizumab) 240 mg q2w	RA0056 CDP6038 (Olokizumab) 240 mg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	3	2
Units: units on a scale				
arithmetic mean (standard deviation)	-111.0000 (± 68.78953)	-125.0000 (± 99999)	-90.3333 (± 56.04760)	-91.8846 (± 29.53531)

End point values	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (Olokizumab) 60 mg q4w	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	2	5
Units: units on a scale				
arithmetic mean (standard deviation)	-75.3333 (± 56.09219)	-147.5000 (± 77.07464)	-128.0000 (± 147.07821)	-143.4000 (± 80.28574)

End point values	RA0056 CDP6038 (olokizumab) Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: units on a scale				
arithmetic mean (standard deviation)	-102.4121 (± 52.99390)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline (Week 0 of Study RA0057) until 30 days after the last dose (maximum up to 780 days)

Adverse event reporting additional description:

Reported TEAEs included adverse events that started or worsened after the first dose of CDP6038 (olokizumab) in Study RA0057 and within 30 days after the last dose.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	RA0056 CDP6038 (Olokizumab) 60 mg q2w

Reporting group description:

CDP6038 (olokizumab) 60 mg administered q2w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Reporting group title	RA0056 CDP6038 (olokizumab) 60 mg q4w

Reporting group description:

CDP6038 (olokizumab) 60 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Reporting group title	RA0056 CDP6038 (olokizumab) 120 mg q2w

Reporting group description:

CDP6038 (olokizumab) 120 mg administered q2w sc in Study RA0056, and maintained at same dose (i.e. 120 mg q2w sc) at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Reporting group title	RA0056 CDP6038 (olokizumab) 120 mg q4w

Reporting group description:

CDP6038 (olokizumab) 120 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Reporting group title	RA0056 CDP6038 (olokizumab) 240 mg q2w

Reporting group description:

CDP6038 (olokizumab) 240 mg administered q2w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056).

Reporting group title	RA0056 CDP6038 (olokizumab) 240 mg q4w

Reporting group description:

CDP6038 (olokizumab) 240 mg administered q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Reporting group title	RA0056 Placebo

Reporting group description:

Placebo (sodium chloride, 0.9%) was administered q2w or q4w sc in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Reporting group title	RA0056 Tocilizumab 8 mg/kg q4w

Reporting group description:

Tocilizumab 8 mg/kg administered q4w iv in Study RA0056, followed by switch to CDP6038 (olokizumab) 120 mg q2w sc at start of Study RA0057 (Week 12 of RA0056) for 48 weeks.

Serious adverse events	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (olokizumab) 60 mg q4w	RA0056 CDP6038 (olokizumab) 120 mg q2w
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 17 (29.41%)	3 / 16 (18.75%)	3 / 20 (15.00%)

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)			
Bladder cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Basal cell carcinoma			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (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
B-cell lymphoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Basosquamous carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Hypertension			

subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Femoral artery occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Deep vein thrombosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (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
Surgical and medical procedures			
Cholecystectomy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (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
Spinal fusion surgery			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Chest discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Unevaluable event			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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

Multi-organ failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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			
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Pulmonary infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (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
Emphysema			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (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
Pulmonary fibrosis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (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
Laryngospasm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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 suicidal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Anxiety disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Depression			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Hip fracture			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (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
Road traffic accident			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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 disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Angina pectoris			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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			
Transient ischaemic attack			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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			

Gastric perforation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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			
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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			
Cervical spinal stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Arthralgia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (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
Musculoskeletal pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (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
Back pain			

subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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			
Cellulitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Appendicitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Gangrene			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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 acute			

subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Diabetic foot infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (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 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Incision site cellulitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (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
Furuncle			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Necrotising fasciitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (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	RA0056 CDP6038 (olokizumab) 120 mg q4w	RA0056 CDP6038 (olokizumab) 240 mg q2w	RA0056 CDP6038 (olokizumab) 240 mg q4w

Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 20 (30.00%)	6 / 21 (28.57%)	7 / 20 (35.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
B-cell lymphoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Basosquamous carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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

Hypertension			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Surgical and medical procedures			
Cholecystectomy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Spinal fusion surgery			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unevaluable event			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Multi-organ failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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			
Pulmonary embolism			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (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
Pulmonary infarction			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (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	0 / 20 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Emphysema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Pulmonary fibrosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Laryngospasm			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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 suicidal			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Anxiety disorder			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (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 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (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
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Hip fracture			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Road traffic accident			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Bradycardia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (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 disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Angina pectoris			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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			
Transient ischaemic attack			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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			

Gastric perforation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (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
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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			
Cervical spinal stenosis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Back pain			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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			
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Staphylococcal infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Localised infection			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Appendicitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Gangrene			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Subcutaneous abscess			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (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
Diverticulitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			

subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (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 foot infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Incision site cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Furuncle			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Necrotising fasciitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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
Sepsis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (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	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w	

Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 40 (35.00%)	4 / 36 (11.11%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basosquamous carcinoma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hypertension			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery occlusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Cholecystectomy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fusion surgery			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unevaluable event			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Multi-organ failure			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary infarction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary fibrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Depression suicidal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			

subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Gastric perforation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Cervical spinal stenosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			

subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			

subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Sepsis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	

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

Non-serious adverse events	RA0056 CDP6038 (Olokizumab) 60 mg q2w	RA0056 CDP6038 (olokizumab) 60 mg q4w	RA0056 CDP6038 (olokizumab) 120 mg q2w
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 17 (88.24%)	15 / 16 (93.75%)	16 / 20 (80.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	3 / 20 (15.00%)
occurrences (all)	0	2	4
Deep vein thrombosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Injection site reaction			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
Oedema peripheral			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	2
Injection site erythema			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	9	2	0
Injection site bruising			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Injection site pain			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	16	0

Injection site induration			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Injection site rash			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site haematoma			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Respiratory tract congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	3
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Cough			

subjects affected / exposed	1 / 17 (5.88%)	4 / 16 (25.00%)	0 / 20 (0.00%)
occurrences (all)	1	6	0
Rhinorrhoea			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 17 (5.88%)	3 / 16 (18.75%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
Sinus congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Laryngeal mass			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Blood pressure increased			

subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Lipids increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood cholesterol increased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Liver function test abnormal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood pressure diastolic increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood pressure systolic increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haematocrit decreased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Haemoglobin decreased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Mammogram abnormal			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Red cell distribution width increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	2 / 17 (11.76%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	4	1	0
Limb injury			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Muscle strain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Wound			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Upper limb fracture			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Meniscus injury			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	5
Carpal tunnel syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	1 / 20 (5.00%)
occurrences (all)	0	6	1
Leukopenia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	0 / 20 (0.00%)
occurrences (all)	0	6	0
Anaemia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Macrocytosis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Monocytopenia			

subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Vertigo			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Eye pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
Flatulence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hiatus hernia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	5 / 20 (25.00%)
occurrences (all)	1	1	5
Ecchymosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Skin ulcer			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Onychomadesis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Rash erythematous			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pyuria			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 17 (17.65%)	1 / 16 (6.25%)	1 / 20 (5.00%)
occurrences (all)	3	2	6
Muscle spasms			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	1 / 20 (5.00%)
occurrences (all)	1	1	2
Musculoskeletal pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	2
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	4
Rheumatoid arthritis			
subjects affected / exposed	1 / 17 (5.88%)	3 / 16 (18.75%)	3 / 20 (15.00%)
occurrences (all)	1	3	3
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bursitis			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Fibromyalgia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Sacroiliitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Tendon calcification			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Rheumatoid nodule			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	1 / 17 (5.88%)	3 / 16 (18.75%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
Cellulitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Ear infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Influenza			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	2 / 17 (11.76%)	2 / 16 (12.50%)	1 / 20 (5.00%)
occurrences (all)	2	2	3
Oral herpes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Otitis media			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Sinusitis			
subjects affected / exposed	1 / 17 (5.88%)	2 / 16 (12.50%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
Upper respiratory tract infection			
subjects affected / exposed	4 / 17 (23.53%)	3 / 16 (18.75%)	3 / 20 (15.00%)
occurrences (all)	6	3	3
Urinary tract infection			
subjects affected / exposed	2 / 17 (11.76%)	3 / 16 (18.75%)	2 / 20 (10.00%)
occurrences (all)	3	5	2
Gastroenteritis viral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	2 / 17 (11.76%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Vaginitis bacterial			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Staphylococcal abscess			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Hyperlipidaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hypokalaemia			

subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 16 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	RA0056 CDP6038 (olokizumab) 120 mg q4w	RA0056 CDP6038 (olokizumab) 240 mg q2w	RA0056 CDP6038 (olokizumab) 240 mg q4w
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	18 / 21 (85.71%)	17 / 20 (85.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 20 (5.00%)	3 / 21 (14.29%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
Deep vein thrombosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	2 / 20 (10.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
Oedema peripheral			
subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Injection site erythema			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injection site pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	11
Injection site induration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 20 (10.00%)	2 / 21 (9.52%)	2 / 20 (10.00%)
occurrences (all)	2	2	2
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	2 / 20 (10.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	3	0	2
Nasal congestion			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Respiratory tract congestion			

subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Wheezing			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	4 / 20 (20.00%)	3 / 21 (14.29%)	2 / 20 (10.00%)
occurrences (all)	6	3	2
Rhinorrhoea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Sinus congestion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Laryngeal mass			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Blood pressure increased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Lipids increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	2 / 20 (10.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Liver function test abnormal			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Platelet count decreased			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood pressure diastolic increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mammogram abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Red cell distribution width increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	3 / 20 (15.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Contusion			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Limb injury			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Muscle strain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Excoriation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	2 / 20 (10.00%)
occurrences (all)	0	1	5
Wound			

subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Cartilage injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 20 (30.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	7	2	1
Carpal tunnel syndrome			
subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Sciatica			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 20 (5.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	2	2	0
Leukopenia			

subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Anaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Macrocytosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Ear pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 20 (5.00%)	3 / 21 (14.29%)	1 / 20 (5.00%)
occurrences (all)	1	4	1
Flatulence			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 20 (15.00%)	3 / 21 (14.29%)	1 / 20 (5.00%)
occurrences (all)	3	3	1
Constipation			
subjects affected / exposed	2 / 20 (10.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Haemorrhoids			
subjects affected / exposed	2 / 20 (10.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	1 / 20 (5.00%)	3 / 21 (14.29%)	1 / 20 (5.00%)
occurrences (all)	2	4	5
Abdominal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Periodontal disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 20 (5.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Ecchymosis			
subjects affected / exposed	2 / 20 (10.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Erythema			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Blister			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Onychomadesis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pyuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	3 / 20 (15.00%)
occurrences (all)	0	2	5
Muscle spasms			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			

subjects affected / exposed	2 / 20 (10.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
Rheumatoid arthritis			
subjects affected / exposed	2 / 20 (10.00%)	1 / 21 (4.76%)	3 / 20 (15.00%)
occurrences (all)	3	2	3
Back pain			
subjects affected / exposed	5 / 20 (25.00%)	2 / 21 (9.52%)	2 / 20 (10.00%)
occurrences (all)	5	2	2
Bursitis			
subjects affected / exposed	2 / 20 (10.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
Joint swelling			
subjects affected / exposed	1 / 20 (5.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Osteoarthritis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Fibromyalgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sacroiliitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tendon calcification			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rheumatoid nodule			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 20 (10.00%)	3 / 21 (14.29%)	3 / 20 (15.00%)
occurrences (all)	2	3	4
Cellulitis			
subjects affected / exposed	2 / 20 (10.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	4	1	0
Ear infection			
subjects affected / exposed	2 / 20 (10.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Herpes zoster			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	6 / 20 (30.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	10	0	1
Oral herpes			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	3	1	0
Otitis media			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	3 / 20 (15.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	3	0	2

Upper respiratory tract infection			
subjects affected / exposed	3 / 20 (15.00%)	9 / 21 (42.86%)	2 / 20 (10.00%)
occurrences (all)	3	12	2
Urinary tract infection			
subjects affected / exposed	1 / 20 (5.00%)	6 / 21 (28.57%)	2 / 20 (10.00%)
occurrences (all)	3	24	2
Gastroenteritis viral			
subjects affected / exposed	1 / 20 (5.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Pharyngitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	2 / 20 (10.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Fungal infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Skin infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Staphylococcal infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vaginitis bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Staphylococcal abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Hypokalaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	2 / 20 (10.00%)
occurrences (all)	0	1	2

Non-serious adverse events	RA0056 Placebo	RA0056 Tocilizumab 8 mg/kg q4w	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 40 (90.00%)	35 / 36 (97.22%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 40 (5.00%)	5 / 36 (13.89%)	
occurrences (all)	2	5	
Deep vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 40 (10.00%)	2 / 36 (5.56%)	
occurrences (all)	4	2	
Injection site reaction			
subjects affected / exposed	6 / 40 (15.00%)	8 / 36 (22.22%)	
occurrences (all)	8	14	
Oedema peripheral			

subjects affected / exposed	3 / 40 (7.50%)	2 / 36 (5.56%)	
occurrences (all)	3	3	
Injection site erythema			
subjects affected / exposed	2 / 40 (5.00%)	2 / 36 (5.56%)	
occurrences (all)	4	2	
Injection site bruising			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Injection site pain			
subjects affected / exposed	3 / 40 (7.50%)	3 / 36 (8.33%)	
occurrences (all)	18	21	
Injection site induration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Injection site rash			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Vessel puncture site haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Pain			
subjects affected / exposed	0 / 40 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Respiratory, thoracic and mediastinal disorders			

Epistaxis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Nasal congestion			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Respiratory tract congestion			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	3	
Wheezing			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	6 / 40 (15.00%)	5 / 36 (13.89%)	
occurrences (all)	7	8	
Rhinorrhoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	1 / 40 (2.50%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Sinus congestion			
subjects affected / exposed	0 / 40 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Laryngeal mass			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Psychiatric disorders			
Depression			
subjects affected / exposed	4 / 40 (10.00%)	1 / 36 (2.78%)	
occurrences (all)	4	1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	5	1	
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	5	1	
Blood pressure increased			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	8	
Lipids increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood cholesterol increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Liver function test abnormal			
subjects affected / exposed	3 / 40 (7.50%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Platelet count decreased			
subjects affected / exposed	2 / 40 (5.00%)	2 / 36 (5.56%)	
occurrences (all)	4	2	
Low density lipoprotein increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood pressure diastolic increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood pressure systolic increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			

subjects affected / exposed	3 / 40 (7.50%)	0 / 36 (0.00%)	
occurrences (all)	5	0	
Blood triglycerides increased			
subjects affected / exposed	1 / 40 (2.50%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Haematocrit decreased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Haemoglobin decreased			
subjects affected / exposed	2 / 40 (5.00%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Mammogram abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Red cell distribution width increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	2	2	
Contusion			
subjects affected / exposed	2 / 40 (5.00%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Limb injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Muscle strain			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	3	
Excoriation			
subjects affected / exposed	2 / 40 (5.00%)	2 / 36 (5.56%)	
occurrences (all)	2	4	
Fall			

subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Wound			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Cartilage injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Upper limb fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Meniscus injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 40 (2.50%)	4 / 36 (11.11%)	
occurrences (all)	1	8	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Sciatica			
subjects affected / exposed	1 / 40 (2.50%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Hypoaesthesia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Neutropenia			

subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Anaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Macrocytosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Monocytopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Ear pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Eye pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	7 / 40 (17.50%)	4 / 36 (11.11%)	
occurrences (all)	8	4	
Flatulence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	3 / 40 (7.50%)	1 / 36 (2.78%)	
occurrences (all)	3	4	
Constipation			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Haemorrhoids			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	5 / 40 (12.50%)	2 / 36 (5.56%)	
occurrences (all)	5	2	
Abdominal pain			
subjects affected / exposed	2 / 40 (5.00%)	3 / 36 (8.33%)	
occurrences (all)	2	3	
Periodontal disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hiatus hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	1 / 40 (2.50%)	3 / 36 (8.33%)	
occurrences (all)	1	5	
Ecchymosis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 40 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Blister			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Skin ulcer			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Onychomadesis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rash erythematous			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Ingrowing nail			
subjects affected / exposed	3 / 40 (7.50%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Renal and urinary disorders			
Pyuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nephrolithiasis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 40 (12.50%)	6 / 36 (16.67%)	
occurrences (all)	5	10	
Muscle spasms			

subjects affected / exposed	2 / 40 (5.00%)	2 / 36 (5.56%)	
occurrences (all)	3	3	
Musculoskeletal pain			
subjects affected / exposed	2 / 40 (5.00%)	2 / 36 (5.56%)	
occurrences (all)	3	3	
Pain in extremity			
subjects affected / exposed	4 / 40 (10.00%)	3 / 36 (8.33%)	
occurrences (all)	4	5	
Rheumatoid arthritis			
subjects affected / exposed	3 / 40 (7.50%)	4 / 36 (11.11%)	
occurrences (all)	3	5	
Back pain			
subjects affected / exposed	7 / 40 (17.50%)	4 / 36 (11.11%)	
occurrences (all)	7	4	
Bursitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Joint swelling			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Osteoarthritis			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Fibromyalgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Sacroiliitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Tendon calcification			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rheumatoid nodule			

subjects affected / exposed	1 / 40 (2.50%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Spinal osteoarthritis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Myalgia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	3	
Bone pain			
subjects affected / exposed	0 / 40 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 40 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Infections and infestations			
Bronchitis			
subjects affected / exposed	5 / 40 (12.50%)	3 / 36 (8.33%)	
occurrences (all)	7	4	
Cellulitis			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	3	
Ear infection			
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Herpes zoster			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	3 / 40 (7.50%)	2 / 36 (5.56%)	
occurrences (all)	3	2	
Nasopharyngitis			
subjects affected / exposed	3 / 40 (7.50%)	3 / 36 (8.33%)	
occurrences (all)	3	5	
Oral herpes			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	1	2	

Otitis media				
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)		
occurrences (all)	1	0		
Sinusitis				
subjects affected / exposed	4 / 40 (10.00%)	6 / 36 (16.67%)		
occurrences (all)	4	7		
Upper respiratory tract infection				
subjects affected / exposed	7 / 40 (17.50%)	5 / 36 (13.89%)		
occurrences (all)	10	9		
Urinary tract infection				
subjects affected / exposed	5 / 40 (12.50%)	5 / 36 (13.89%)		
occurrences (all)	12	11		
Gastroenteritis viral				
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)		
occurrences (all)	2	3		
Pharyngitis				
subjects affected / exposed	2 / 40 (5.00%)	1 / 36 (2.78%)		
occurrences (all)	2	1		
Pneumonia				
subjects affected / exposed	2 / 40 (5.00%)	0 / 36 (0.00%)		
occurrences (all)	2	0		
Fungal infection				
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)		
occurrences (all)	1	0		
Skin infection				
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Staphylococcal infection				
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)		
occurrences (all)	1	3		
Respiratory tract infection				
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)		
occurrences (all)	0	1		
Vaginitis bacterial				
subjects affected / exposed	1 / 40 (2.50%)	0 / 36 (0.00%)		
occurrences (all)	1	0		

Staphylococcal abscess			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	1 / 40 (2.50%)	2 / 36 (5.56%)	
occurrences (all)	2	2	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	3 / 40 (7.50%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Hyperlipidaemia			
subjects affected / exposed	3 / 40 (7.50%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Hypokalaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Hypoglycaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 November 2010	Amendment 1 dated 30 November 2010 implemented the following changes: • Clarification that subjects were not monitored and observed in the clinic for at least 30 minutes post olokizumab administration • The stable MTX dose range was changed from 15 to 25 mg/week to 12.5 to 25 mg/week • The TB testing was performed using either the PPD test or Elispot (or QuantiFERON-TB GOLD if the Elispot test was not available) • Change in inclusion criteria to clarify that female subjects of childbearing potential must agree to use at least 2 forms of adequate contraception during the study and for 6 months (24 weeks) after their last dose of olokizumab • Clarification that all additional withdrawal and dose modifications based on laboratory abnormalities • All sc injections of olokizumab were to be administered by qualified study personnel and not just study nurses and the study facility must have had adequate arrangements in order to manage anaphylactic reactions • Addition that there was a potential interaction of olokizumab with hepatic cytochrome P450 enzymes so that close attention was to be paid to the effectiveness or toxicity of the subjects' coadministered medication(s) known to be metabolized/eliminated by cytochrome P450 enzymes and/or sodium/taurocholate cotransporting polypeptide and dose adjustments made as needed • Clarification that the subjects could be in the sitting (instead of supine) position when vital signs were measured.
12 May 2011	Amendment 2 dated 12 May 2011 implemented the following changes: • Added information updates on clinical Studies RA0010 and RA0074 in the Introduction • Clarification in withdrawal criteria that if a subject developed three or more noninvasive nonmelanoma skin cancers, or any other malignancy, since the start of Study RA0056, he/she should be withdrawn from the study • Removal of the assessment of the Epstein-Barr Virus (EBV) viral load from the laboratory assessments at Visit 7 and Visit 25 and the Early Discontinuation Visit • Removal of the assessment of complements C3 and C4 from the laboratory hematology assessments; with footnotes specifying that the ESR was to be analyzed by the site and subjects should arrive at the study center in a fasted state for the blood draw for Apo B, Apo A-1, Lp(a) • Correction in equation used for the determination of DAS28 (CRP) • Addition of CSP code for the analysis of PK analysis samples • Clarification that the study facility must have adequate arrangements to manage anaphylactic reactions • Clarification that the CXR taken at Week 48 and every 72 weeks thereafter until study completion should be a plain posteroanterior CXR • Addition of a reference that the newly added RA-related events may be anticipated for subjects with RA as per the FDA's Final Rule for Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans, 21 C.F.R. Parts 312 and 320, 2011.

15 September 2011	Amendment 3 dated 15 September 2011 implemented the following changes: • Clarification to allow MTX dose reductions/adjustments, but not dose increases, during the study and addition of the requirement for subjects to take folate supplementation during the study to minimize MTX toxicity • Clarification that exclusion of subjects with evidence of active or latent TB should be based on the Investigators' medical judgement. • Clarification on minimum permissible timeframe between olokizumab doses to be 11 days • Clarification to allow concomitant medication dose reductions after Week 12 in subjects who have achieved a significant reduction in RA clinical disease activity based on the Investigator's medical judgment • Clarification to allow intra-articular injection of hyaluronic acid after Week 12 • Clarification of those study visits where the subjects were required to attend in a fasted state • Update of the section on anticipated AEs for implementation of the FDA final rule • The CSP Section 11.6.5.1.2 regarding TB detection simplified.

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.

The clinical trial was terminated early as a result of a strategic UCB decision to out-license the study drug for further development. As a result, only small numbers of subjects were still in the study past the Week 48 time point.

Notes: