



Clinical trial results:

A Multi-Centre, Randomized, Double-Blind, Placebo-Controlled, Dose-Finding and Proof of Concept Study, to Assess the Efficacy, Safety and Tolerability, Pharmacokinetics and Pharmacodynamics of Namilumab/MT203 at 4 Different Subcutaneous Doses – together with an Open-Label, Dose-Escalated Extension to Assess Safety and Efficacy of One Year Treatment - in Subjects with Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2013-002806-30
Trial protocol	DE LV DK PL
Global end of trial date	23 February 2016

Results information

Result version number	v1 (current)
This version publication date	11 March 2017
First version publication date	11 March 2017

Trial information

Trial identification

Sponsor protocol code	M1-1188_203
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	U1111-1146-1219

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	61 Aldwych, London, WC2B 4AE, United Kingdom,
Public contact	Program Manager, Takeda Development Centre Europe Ltd., + 18778253327, clinicaltrialregistry@tpna.com
Scientific contact	Program Manager, Takeda Development Centre Europe Ltd., +1 8778253327, clinicaltrialregistry@tpna.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	02 December 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To establish proof of efficacy of namilumab in moderate to severe plaque psoriasis, as measured by the proportion of subjects achieving a reduction in Psoriasis Area and Severity Index (PASI) scores greater than or equal to (\geq) 75 percent (%) from Baseline (hereafter referred to as PASI75) response rate at Week 12.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 56
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Latvia: 17
Country: Number of subjects enrolled	Poland: 46
Worldwide total number of subjects	122
EEA total number of subjects	66

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)	121
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled into the double-blind treatment evaluation at 17 investigative sites in Canada, Denmark, Germany, Latvia, and Poland. Only those sites in Denmark, Latvia and Poland participated in the extension period which included open-label treatment with study medication.

Pre-assignment

Screening details:

Participants with diagnosis of moderate to severe plaque psoriasis without clinically significant lung/respiratory disorders were screened for enrollment into the study. To fulfill screening requirements, chest X-ray was carried out prior to Baseline visit which included assignment to the double-blind study treatment and first dosing with study drug.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Double-Blind Period: Placebo

Arm description:

Namilumab-matching placebo solution (2 separate injections) subcutaneously on Day 1, followed by namilumab-matching placebo, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Arm type	Placebo
Investigational medicinal product name	Namilumab placebo-matching injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Namilumab-matching placebo solution (2 separate injections) subcutaneously on Day 1, followed by namilumab-matching placebo, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Arm title	Double-Blind Period: Namilumab 20 mg
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Arm description:

Namilumab 40 milligram (mg) injection (2 separate injections of 20 mg) subcutaneously on Day 1, followed by namilumab 20 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

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

Dosage and administration details:

Namilumab 40 milligram (mg) injection (2 separate injections of 20 mg) subcutaneously on Day 1, followed by namilumab 20 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Arm title	Double-Blind Period: Namilumab 50 mg
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Arm description:

Namilumab 100 mg injection (2 separate injections of 50 mg) subcutaneously on Day 1, followed by namilumab 50 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

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

Dosage and administration details:

Namilumab 100 mg injection (2 separate injections of 50 mg) subcutaneously on Day 1, followed by namilumab 50 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Arm title	Double-Blind Period: Namilumab 80 mg
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Arm description:

Namilumab 160 mg injection (2 separate injections of 80 mg), subcutaneously on Day 1, followed by namilumab 80 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

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

Dosage and administration details:

Namilumab 160 mg injection (2 separate injections of 80 mg) subcutaneously on Day 1, followed by namilumab 80 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Arm title	Double-Blind Period: Namilumab 150 mg
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Arm description:

Namilumab 300 mg injection (2 separate injections of 150 mg) subcutaneously on Day 1, followed by namilumab 150 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

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

Dosage and administration details:

Namilumab 300 mg injection (2 separate injections of 150 mg) subcutaneously on Day 1, followed by namilumab 150 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Number of subjects in period 1	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg
Started	24	24	24
Completed	17	16	20
Not completed	7	8	4
Consent withdrawn by subject	2	4	3

Adverse event, non-fatal	-	-	-
Other	1	2	-
Pregnancy	-	-	-
Lost to follow-up	1	1	1
Lack of efficacy	3	1	-

Number of subjects in period 1	Double-Blind Period: Namilumab 80 mg	Double-Blind Period: Namilumab 150 mg
Started	25	25
Completed	18	18
Not completed	7	7
Consent withdrawn by subject	2	3
Adverse event, non-fatal	-	1
Other	-	-
Pregnancy	-	1
Lost to follow-up	2	-
Lack of efficacy	3	2

Period 2

Period 2 title	Open-Label Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Open-Label Period: Namilumab 80 mg

Arm description:

Namilumab 80 mg, single injection, subcutaneously every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.

Arm type	Experimental
Investigational medicinal product name	Namilumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion, Solution for injection, Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Namilumab 80 mg, injection, subcutaneously, every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.

Arm title	Open-Label Period: Namilumab 150 mg
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Arm description:

Namilumab 150 mg, single injection, subcutaneously from Week 8 and then every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.

Arm type	Experimental
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Investigational medicinal product name	Namilumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion, Solution for injection, Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Namilumab 150 mg, single injection, subcutaneously from Week 8 and then every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.

Number of subjects in period 2 ^[1]	Open-Label Period: Namilumab 80 mg	Open-Label Period: Namilumab 150 mg
Started	12	48
Completed	0	0
Not completed	12	48
Consent withdrawn by subject	1	3
Study Termination	10	39
Lost to follow-up	1	1
Lack of efficacy	-	5

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants were enrolled into the double-blind treatment evaluation at 17 investigative sites in Canada, Denmark, Germany, Latvia, and Poland. Only those sites in Denmark, Latvia and Poland participated in the extension period which included open-label treatment with study medication.

Baseline characteristics

Reporting groups

Reporting group title	Double-Blind Period: Placebo
Reporting group description: Namilumab-matching placebo solution (2 separate injections) subcutaneously on Day 1, followed by namilumab-matching placebo, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 20 mg
Reporting group description: Namilumab 40 milligram (mg) injection (2 separate injections of 20 mg) subcutaneously on Day 1, followed by namilumab 20 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 50 mg
Reporting group description: Namilumab 100 mg injection (2 separate injections of 50 mg) subcutaneously on Day 1, followed by namilumab 50 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 80 mg
Reporting group description: Namilumab 160 mg injection (2 separate injections of 80 mg), subcutaneously on Day 1, followed by namilumab 80 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 150 mg
Reporting group description: Namilumab 300 mg injection (2 separate injections of 150 mg) subcutaneously on Day 1, followed by namilumab 150 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	

Reporting group values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg
Number of subjects	24	24	24
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	24	24
From 65-84 years	1	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	40.8	41.1	42.3
standard deviation	± 15.2	± 11.28	± 10.92
Gender, Male/Female Units: subjects			
Female	9	4	5
Male	15	20	19

Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino	10	10	12
Unknown or Not Reported	14	14	12
Race/Ethnicity, Customized Units: Subjects			
Asian	2	1	2
Black or African American	0	0	1
Native Hawaiian or Other Pacific Islander	0	1	0
White	22	22	21
Smoking Classification Units: Subjects			
Never Smoked	7	11	9
Current Smoker	8	5	9
Ex-Smoker	9	8	6
Region of Enrollment Units: Subjects			
Canada	10	10	12
Denmark	0	1	0
Germany	0	0	0
Latvia	5	5	2
Poland	9	8	10
Study Specific Characteristic Height Units: centimeter			
arithmetic mean	172.3	176.1	176.5
standard deviation	± 10.83	± 7.73	± 7.81
Study Specific Characteristic Weight Units: kilogram			
arithmetic mean	87.46	88.26	97.84
standard deviation	± 22.864	± 22.033	± 33.643
Study Specific Characteristic Body Mass Index Units: kilogram per square meter (kg/m^2)			
arithmetic mean	29.16	28.25	31.26
standard deviation	± 6.112	± 5.936	± 9.532

Reporting group values	Double-Blind Period: Namilumab 80 mg	Double-Blind Period: Namilumab 150 mg	Total
Number of subjects	25	25	122
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	25	25	121
From 65-84 years	0	0	1
85 years and over	0	0	0

Age Continuous Units: years arithmetic mean standard deviation	39 ± 12.04	39.8 ± 9.62	-
Gender, Male/Female Units: subjects			
Female	7	13	38
Male	18	12	84
Race/Ethnicity, Customized Units: Subjects			
Not Hispanic or Latino	12	12	56
Unknown or Not Reported	13	13	66
Race/Ethnicity, Customized Units: Subjects			
Asian	2	4	11
Black or African American	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	1
White	23	21	109
Smoking Classification Units: Subjects			
Never Smoked	13	12	52
Current Smoker	7	5	34
Ex-Smoker	5	8	36
Region of Enrollment Units: Subjects			
Canada	12	12	56
Denmark	0	1	2
Germany	0	1	1
Latvia	3	2	17
Poland	10	9	46
Study Specific Characteristic Height Units: centimeter arithmetic mean standard deviation	176.8 ± 8.59	168.1 ± 10.28	-
Study Specific Characteristic Weight Units: kilogram arithmetic mean standard deviation	95.5 ± 25.056	82.32 ± 24.634	-
Study Specific Characteristic Body Mass Index Units: kilogram per square meter (kg/m^2) arithmetic mean standard deviation	30.53 ± 7.641	29.01 ± 8.093	-

End points

End points reporting groups

Reporting group title	Double-Blind Period: Placebo
Reporting group description: Namilumab-matching placebo solution (2 separate injections) subcutaneously on Day 1, followed by namilumab-matching placebo, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 20 mg
Reporting group description: Namilumab 40 milligram (mg) injection (2 separate injections of 20 mg) subcutaneously on Day 1, followed by namilumab 20 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 50 mg
Reporting group description: Namilumab 100 mg injection (2 separate injections of 50 mg) subcutaneously on Day 1, followed by namilumab 50 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 80 mg
Reporting group description: Namilumab 160 mg injection (2 separate injections of 80 mg), subcutaneously on Day 1, followed by namilumab 80 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Double-Blind Period: Namilumab 150 mg
Reporting group description: Namilumab 300 mg injection (2 separate injections of 150 mg) subcutaneously on Day 1, followed by namilumab 150 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.	
Reporting group title	Open-Label Period: Namilumab 80 mg
Reporting group description: Namilumab 80 mg, single injection, subcutaneously every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.	
Reporting group title	Open-Label Period: Namilumab 150 mg
Reporting group description: Namilumab 150 mg, single injection, subcutaneously from Week 8 and then every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.	

Primary: Percentage of Subjects Achieving 75 Percent Reduction From Baseline Psoriasis Area and Severity Index (PASI) Score (PASI75 Response) at Week 12

End point title	Percentage of Subjects Achieving 75 Percent Reduction From Baseline Psoriasis Area and Severity Index (PASI) Score (PASI75 Response) at Week 12
End point description: PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. Body was divided into 4 sections: head(h), trunk(t), upper(u) and lower(l) extremities. Percent body surface area(A) involved was estimated: 0=No involvement to 6=90–100 percent(%). Severity was estimated by clinical signs: erythema(E), induration(I), and desquamation(D); scale: 0=no symptoms to 4=very marked. Final PASI = $0.1(Eh+Ih+Dh)Ah+0.3(Et+It+Dt)At+0.2(Eu+Iu+Du)Au+0.4(El+Il+Dl)Al$ where head: 0.1, upper extremities(arms): 0.2, trunk: 0.3, lower extremities(legs): 0.4 (corresponding to 10%, 20%, 30% and 40% of body surface area, respectively); total possible score range: 0=no disease to 72=maximal disease. Full analysis set(FAS) where baseline and Week 12 assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.	
End point type	Primary

End point timeframe:

Week 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	21	22	19
Units: percentage of subjects				
number (not applicable)	8.7	9.5	0	5.3

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage of subjects				
number (not applicable)	0			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
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Statistical analysis description:

Cochran-Mantel-Haenszel (CMH) P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.925
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.008
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.162
upper limit	0.179

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
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Statistical analysis description:

CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.162
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.087
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.202
upper limit	0.028

Statistical analysis title

Week 12: Namilumab Placebo vs 80 mg

Statistical analysis description:

CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.671
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.034
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.187
upper limit	0.118

Statistical analysis title

Week 12: Namilumab Placebo vs 150 mg

Statistical analysis description:

CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
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Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.182
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.087
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.202
upper limit	0.028

Secondary: Percentage of Subjects Achieving 75 Percent Reduction From Baseline PASI Score (PASI75 Response) at Weeks 2, 4, 6, and 10

End point title	Percentage of Subjects Achieving 75 Percent Reduction From Baseline PASI Score (PASI75 Response) at Weeks 2, 4, 6, and 10
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End point description:

PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. Body was divided into 4 sections: head(h), trunk(t), upper(u) and lower(l) extremities. Percent body surface area(A) involved was estimated: 0=No involvement to 6=90–100 percent(%). Severity was estimated by clinical signs: erythema(E), induration(I), and desquamation(D); scale: 0=no symptoms to 4=very marked. Final PASI=0.1(Eh+Ih+Dh)Ah+0.3(Et+It+Dt)At+0.2(Eu+Iu+Du)Au+0.4(El+Il+Dl)Al where head:0.1, upper extremities(arms):0.2, trunk:0.3, lower extremities(legs):0.4 (corresponding to 10%, 20%, 30% and 40% of body surface area, respectively); total possible score range: 0=no disease to 72=maximal disease. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
End point timeframe:	
Weeks 2, 4, 6 and 10	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0	0	0	0
Week 4 (n= 24, 24, 23, 24, 24)	0	0	4.3	0
Week 6 (n= 23, 23, 24, 24, 23)	4.3	8.7	4.2	4.2
Week 10 (n= 22, 22, 24, 24, 22)	9.1	4.5	0	4.2

End point values	Double-Blind Period:			
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	Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0			
Week 4 (n= 24, 24, 23, 24, 24)	0			
Week 6 (n= 23, 23, 24, 24, 23)	0			
Week 10 (n= 22, 22, 24, 24, 22)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Score at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in PASI Score at Weeks 2, 4, 6, 10, and 12
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End point description:

PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. Body was divided into 4 sections: head(h), trunk(t), upper(u) and lower(l) extremities. Percent body surface area(A) involved was estimated: 0=No involvement to 6=90–100 percent(%). Severity was estimated by clinical signs: erythema(E), induration(I), and desquamation(D); scale: 0=no symptoms to 4=very marked. Final PASI=0.1(Eh+Ih+Dh)Ah+0.3(Et+It+Dt)At+0.2(Eu+Iu+Du)Au+0.4(El+Il+Dl)Al where head:0.1, upper extremities(arms):0.2, trunk:0.3, lower extremities(legs):0.4 (corresponding to 10%, 20%, 30% and 40% of body surface area, respectively); total possible score range: 0=no disease to 72=maximal disease. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 2, 4, 6, 10, and 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	18.6 (± 1.65)	19.1 (± 1.57)	20.9 (± 1.62)	17.4 (± 1.57)
Change at Week 2 (n=24, 24, 24, 25, 25)	-2.2 (± 0.7)	-1.7 (± 0.67)	-1.2 (± 0.69)	-2.1 (± 0.67)
Change at Week 4 (n=24, 24, 23, 24, 24)	-3.6 (± 0.92)	-2.8 (± 0.9)	-1.9 (± 0.92)	-2.4 (± 0.9)
Change at Week 6 (n=23, 23, 24, 24, 23)	-5.1 (± 1.13)	-3.6 (± 1.1)	-1.4 (± 1.11)	-2.4 (± 1.1)
Change at Week 10 (n=22, 22, 24, 24, 22)	-6.4 (± 1.3)	-4.6 (± 1.29)	-3.2 (± 1.28)	-3.2 (± 1.27)
Change at Week 12 (n=23, 21, 22, 19, 20)	-6.3 (± 1.27)	-4.9 (± 1.26)	-4.4 (± 1.25)	-3.3 (± 1.26)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	17.3 (± 1.52)			
Change at Week 2 (n=24, 24, 24, 25, 25)	-1.4 (± 0.65)			
Change at Week 4 (n=24, 24, 23, 24, 24)	-2.2 (± 0.89)			
Change at Week 6 (n=23, 23, 24, 24, 23)	-2.4 (± 1.1)			
Change at Week 10 (n=22, 22, 24, 24, 22)	-3 (± 1.28)			
Change at Week 12 (n=23, 21, 22, 19, 20)	-3.4 (± 1.26)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.435
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	4.9
Variability estimate	Standard error of the mean
Dispersion value	1.75

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.279
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	5.4
Variability estimate	Standard error of the mean
Dispersion value	1.74

Statistical analysis title

Week 12: Namilumab Placebo vs 80 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.085
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	6.5
Variability estimate	Standard error of the mean
Dispersion value	1.74

Statistical analysis title

Week 12: Namilumab Placebo vs 150 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a

covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	6.3
Variability estimate	Standard error of the mean
Dispersion value	1.76

Secondary: Percentage of Subjects Achieving 50 Percent Reduction From Baseline PASI Score (PASI50 Response) at Weeks 2, 4, 6, 10 and 12

End point title	Percentage of Subjects Achieving 50 Percent Reduction From Baseline PASI Score (PASI50 Response) at Weeks 2, 4, 6, 10 and 12
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End point description:

PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. Body was divided into 4 sections: head(h), trunk(t), upper(u) and lower(l) extremities. Percent body surface area(A) involved was estimated: 0=No involvement to 6=90–100 percent(%). Severity was estimated by clinical signs: erythema(E), induration(I), and desquamation(D); scale: 0=no symptoms to 4=very marked. Final PASI=0.1(Eh+Ih+Dh)Ah+0.3(Et+It+Dt)At+0.2(Eu+Iu+Du)Au+0.4(El+Il+Dl)Al where head:0.1, upper extremities(arms):0.2, trunk:0.3, lower extremities(legs):0.4 (corresponding to 10%, 20%, 30% and 40% of body surface area, respectively); total possible score range: 0=no disease to 72=maximal disease. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
End point timeframe:	
Weeks 2, 4, 6, 10 and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	4.2	0	0	0
Week 4 (n= 24, 24, 23, 24, 24)	8.3	4.2	8.7	4.2
Week 6 (n= 23, 23, 24, 24, 23)	13	13	8.3	4.2
Week 10 (n= 22, 22, 24, 24, 22)	22.7	18.2	12.5	8.3

Week 12 (n= 23, 21, 22, 19, 20)	21.7	19	18.2	10.5
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End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0			
Week 4 (n= 24, 24, 23, 24, 24)	0			
Week 6 (n= 23, 23, 24, 24, 23)	4.3			
Week 10 (n= 22, 22, 24, 24, 22)	9.1			
Week 12 (n= 23, 21, 22, 19, 20)	20			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description: CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.827
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.027
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.265
upper limit	0.211

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description: CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.768
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.036
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.269
upper limit	0.198

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.338
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.112
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	0.106

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.017

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.261
upper limit	0.226

Secondary: Percentage of Subjects Achieving 90 Percent Reduction From Baseline PASI Score (PASI90 Response) at Weeks 2, 4, 6, 10 and 12

End point title	Percentage of Subjects Achieving 90 Percent Reduction From Baseline PASI Score (PASI90 Response) at Weeks 2, 4, 6, 10 and 12
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End point description:

PASI is an assessment of psoriasis lesion severity and affected body area combined into single score. Body was divided into 4 sections: head(h), trunk(t), upper(u) and lower(l) extremities. Percent body surface area(A) involved was estimated: 0=No involvement to 6=90–100 percent(%). Severity was estimated by clinical signs: erythema(E), induration(I), and desquamation(D); scale: 0=no symptoms to 4=very marked. Final PASI=0.1(Eh+Ih+Dh)Ah+0.3(Et+It+Dt)At+0.2(Eu+Iu+Du)Au+0.4(El+Il+Dl)Al where head:0.1, upper extremities(arms):0.2, trunk:0.3, lower extremities(legs):0.4 (corresponding to 10%, 20%, 30% and 40% of body surface area, respectively); total possible score range: 0=no disease to 72=maximal disease. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 6, 10 and 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0	0	0	0
Week 4 (n= 24, 24, 23, 24, 24)	0	0	0	0
Week 6 (n= 23, 23, 24, 24, 23)	0	4.3	0	0
Week 10 (n= 22, 22, 24, 24, 22)	0	4.5	0	0
Week 12 (n= 23, 21, 22, 19, 20)	0	4.8	0	0

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0			

Week 4 (n= 24, 24, 23, 24, 24)	0			
Week 6 (n= 23, 23, 24, 24, 23)	0			
Week 10 (n= 22, 22, 24, 24, 22)	0			
Week 12 (n= 23, 21, 22, 19, 20)	0			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and responder status controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.295
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.048
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.043
upper limit	0.139

Secondary: Percentage of Subjects Achieving Greater Than or Equal to (\geq) 2 Point Improvement From Baseline in Static Physicians Global Assessment (sPGA) Score at Weeks 2, 4, 6, 10 and 12

End point title	Percentage of Subjects Achieving Greater Than or Equal to (\geq) 2 Point Improvement From Baseline in Static Physicians Global Assessment (sPGA) Score at Weeks 2, 4, 6, 10 and 12
End point description:	
sPGA for psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, plaque elevation and skin scaling across all psoriatic lesions. sPGA of psoriasis scale ranges from 0 (clear) to 5 (very severe). Subjects who had ≥ 2 point improvement are reported. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.	
End point type	Secondary
End point timeframe:	
Weeks 2, 4, 6, 10 and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0	0	0	0
Week 4 (n= 24, 24, 23, 24, 24)	0	4.2	4.3	0
Week 6 (n= 23, 23, 24, 24, 23)	0	13	4.2	0
Week 10 (n= 22, 22, 24, 24, 22)	13.6	4.5	4.2	0
Week 12 (n= 23, 21, 22, 19, 20)	13	14.3	9.1	0

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0			
Week 4 (n= 24, 24, 23, 24, 24)	0			
Week 6 (n= 23, 23, 24, 24, 23)	0			
Week 10 (n= 22, 22, 24, 24, 22)	4.5			
Week 12 (n= 23, 21, 22, 19, 20)	5			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and sPGA response category controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.906
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.012
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.191
upper limit	0.216

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description: CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and sPGA response category controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.677
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.222
upper limit	0.143

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
Statistical analysis description: CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and sPGA response category controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.107
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.268
upper limit	0.007

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
Statistical analysis description: CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and sPGA response category controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.371
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.248
upper limit	0.087

Secondary: Percentage of Subjects Achieving a sPGA Response of Clear (0) or Almost Clear (1) at Weeks 2, 4, 6, 10 and 12

End point title	Percentage of Subjects Achieving a sPGA Response of Clear (0) or Almost Clear (1) at Weeks 2, 4, 6, 10 and 12
End point description:	<p>sPGA for psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, plaque elevation and skin scaling across all psoriatic lesions. sPGA of psoriasis scale ranges from 0 (clear) to 5 (very severe). 'Clear' and 'Almost clear' included all subjects who had scored a 0 or 1. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.</p>
End point type	Secondary
End point timeframe:	
Weeks 2, 4, 6, 10 and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0	0	0	0
Week 4 (n= 24, 24, 23, 24, 24)	0	0	0	0
Week 6 (n= 23, 23, 24, 24, 23)	0	4.3	0	0
Week 10 (n= 22, 22, 24, 24, 22)	0	4.5	0	0
Week 12 (n= 23, 21, 22, 19, 20)	0	9.5	0	0

End point values	Double-Blind Period: Namilumab 150 mg			
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Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of subjects				
number (not applicable)				
Week 2 (n= 24, 24, 24, 25, 25)	0			
Week 4 (n= 24, 24, 23, 24, 24)	0			
Week 6 (n= 23, 23, 24, 24, 23)	0			
Week 10 (n= 22, 22, 24, 24, 22)	0			
Week 12 (n= 23, 21, 22, 19, 20)	0			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description: CMH P-values are from a CMH Chi-Square test using a 2*2 contingency table of treatment and sPGA response category controlling for visit. Risk difference (namilumab - placebo) and corresponding 95% confidence interval were reported.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.134
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.095
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.221

Secondary: Change From Baseline in sPGA Score at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in sPGA Score at Weeks 2, 4, 6, 10, and 12
End point description: sPGA for psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, plaque elevation and skin scaling across all psoriatic lesions. sPGA of psoriasis scale ranges from 0 (clear) to 5 (very severe). FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.	
End point type	Secondary
End point timeframe: Baseline, Weeks 2, 4, 6, 10, and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	3.5 (± 0.11)	3.5 (± 0.11)	3.6 (± 0.11)	3.3 (± 0.11)
Change at Week 2 (n=24, 24, 24, 25, 25)	-0.1 (± 0.08)	-0.1 (± 0.08)	-0.2 (± 0.08)	-0.1 (± 0.08)
Change at Week 4 (n=24, 24, 23, 24, 24)	-0.1 (± 0.1)	-0.3 (± 0.1)	-0.2 (± 0.1)	-0.2 (± 0.1)
Change at Week 6 (n=23, 23, 24, 24, 23)	-0.3 (± 0.12)	-0.5 (± 0.12)	-0.3 (± 0.12)	-0.2 (± 0.12)
Change at Week 10 (n=22, 22, 24, 24, 22)	-0.4 (± 0.12)	-0.5 (± 0.12)	-0.4 (± 0.12)	-0.3 (± 0.12)
Change at Week 12 (n=23, 21, 22, 19, 20)	-0.4 (± 0.13)	-0.6 (± 0.13)	-0.6 (± 0.13)	-0.4 (± 0.13)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	3.6 (± 0.1)			
Change at Week 2 (n=24, 24, 24, 25, 25)	-0.1 (± 0.08)			
Change at Week 4 (n=24, 24, 23, 24, 24)	-0.3 (± 0.09)			
Change at Week 6 (n=23, 23, 24, 24, 23)	-0.2 (± 0.12)			
Change at Week 10 (n=22, 22, 24, 24, 22)	-0.5 (± 0.12)			
Change at Week 12 (n=23, 21, 22, 19, 20)	-0.5 (± 0.13)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an analysis of variance (ANOVA) model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.258
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	0.18

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.365
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	0.18

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
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Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.757
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.4
Variability estimate	Standard error of the mean
Dispersion value	0.18

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.825
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	0.18

Secondary: Change From Baseline in Affected Body Surface Area (BSA) at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in Affected Body Surface Area (BSA) at Weeks 2, 4, 6, 10, and 12
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End point description:

Assessment of BSA with psoriasis was performed by means of the palm method, where the palm of the subject's hand represented 1% of BSA. The affected areas were then calculated by their size compared to the subject's palm. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 2, 4, 6, 10, and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: percentage of total body surface area				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	23.09 (± 3.674)	24.39 (± 3.485)	26.16 (± 3.596)	22.35 (± 3.497)
Change at Week 2 (n=24, 24, 24, 25, 25)	-0.59 (± 0.624)	-0.22 (± 0.591)	0.21 (± 0.61)	-0.35 (± 0.594)
Change at Week 4 (n=24, 24, 23, 24, 24)	-0.86 (± 0.945)	-1.02 (± 0.923)	-0.24 (± 0.94)	-0.09 (± 0.923)
Change at Week 6 (n=23, 23, 24, 24, 23)	-1.78 (± 1.366)	-3.65 (± 1.351)	0.43 (± 1.349)	0.36 (± 1.34)
Change at Week 10 (n=22, 22, 24, 24, 22)	-3.24 (± 1.551)	-4.55 (± 1.542)	-0.63 (± 1.522)	0.45 (± 1.513)
Change at Week 12 (n=23, 21, 22, 19, 20)	-3.29 (± 1.537)	-3.48 (± 1.553)	-1.7 (± 1.527)	0.35 (± 1.559)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of total body surface area				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	21.84 (± 3.385)			
Change at Week 2 (n=24, 24, 24, 25, 25)	-0.26 (± 0.576)			
Change at Week 4 (n=24, 24, 23, 24, 24)	0.25 (± 0.911)			
Change at Week 6 (n=23, 23, 24, 24, 23)	0.12 (± 1.343)			
Change at Week 10 (n=22, 22, 24, 24, 22)	-0.51 (± 1.535)			
Change at Week 12 (n=23, 21, 22, 19, 20)	-0.51 (± 1.56)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.931
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.48
upper limit	4.1
Variability estimate	Standard error of the mean
Dispersion value	2.163

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.459
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.65
upper limit	5.84
Variability estimate	Standard error of the mean
Dispersion value	2.143

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.094
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	3.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	7.93
Variability estimate	Standard error of the mean
Dispersion value	2.161

Statistical analysis title

Week 12: Namilumab Placebo vs 150 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.203
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	2.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.52
upper limit	7.09
Variability estimate	Standard error of the mean
Dispersion value	2.173

Secondary: Change From Baseline in Visual Analogue Scale (VAS) Itching Score at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in Visual Analogue Scale (VAS) Itching Score at Weeks 2, 4, 6, 10, and 12
End point description:	
Assessments were performed using a portable electronic device, which was kept and used by the subject throughout the duration of the study. Subjects were asked to indicate their level of itching by marking a horizontal line with "No itch" at the left extreme and "Worst itch imaginable" at the right extreme (scale ranging from 0 - 10, but not shown on the line). Each assessment was intended to capture the severity of itching experienced during the previous 24 hours. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.	
End point type	Secondary
End point timeframe:	
Baseline, Weeks 2, 4, 6, 10, and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=23, 23, 24, 25, 25)	5.35 (± 0.633)	5.28 (± 0.6)	5.67 (± 0.61)	6.08 (± 0.593)
Change at Week 2 (n=23, 23, 23, 25, 24)	-1.34 (± 0.441)	-1.15 (± 0.418)	-1.92 (± 0.427)	-1.42 (± 0.417)
Change at Week 4 (n=23, 23, 23, 23, 24)	-1.38 (± 0.501)	-1.46 (± 0.48)	-2.1 (± 0.486)	-1.66 (± 0.477)
Change at Week 6 (n=22, 22, 24, 22, 23)	-1.08 (± 0.502)	-1.54 (± 0.482)	-2.01 (± 0.485)	-1.57 (± 0.479)
Change at Week 10 (n=21, 21, 24, 22, 21)	-1.12 (± 0.515)	-1.47 (± 0.497)	-2 (± 0.496)	-1.51 (± 0.492)
Change at Week 12 (n=22, 20, 22, 17, 20)	-0.95 (± 0.523)	-1.49 (± 0.508)	-2.11 (± 0.504)	-1.54 (± 0.508)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=23, 23, 24, 25, 25)	5 (± 0.575)			
Change at Week 2 (n=23, 23, 23, 25, 24)	-1.36 (± 0.402)			
Change at Week 4 (n=23, 23, 23, 23, 24)	-1.48 (± 0.462)			
Change at Week 6 (n=22, 22, 24, 22, 23)	-1.33 (± 0.464)			
Change at Week 10 (n=21, 21, 24, 22, 21)	-1.68 (± 0.481)			
Change at Week 12 (n=22, 20, 22, 17, 20)	-2.11 (± 0.494)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description: Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.448
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.92
upper limit	0.86
Variability estimate	Standard error of the mean
Dispersion value	0.7

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description: Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.099
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.53
upper limit	0.22
Variability estimate	Standard error of the mean
Dispersion value	0.692

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.396
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.96
upper limit	0.78
Variability estimate	Standard error of the mean
Dispersion value	0.69

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. LS mean difference (namilumab - placebo) and corresponding 95% confidence interval were reported. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.102
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.54
upper limit	0.23
Variability estimate	Standard error of the mean
Dispersion value	0.697

Secondary: Change From Baseline in VAS Joint Pain Score at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in VAS Joint Pain Score at Weeks 2, 4, 6, 10, and 12
End point description:	
Assessments were performed using a portable electronic device, which was kept and used by the subject throughout the duration of the study. Subjects were asked to indicate their severity of joint pain by marking a horizontal line with "No pain" at the left extreme and "Worst pain imaginable" at the right extreme (scale ranging from 0 - 10, but not shown on the line). Each assessment was intended to capture the severity of pain experienced during the previous 24 hours. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.	
End point type	Secondary
End point timeframe:	
Baseline, Weeks 2, 4, 6, 10, and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=23, 23, 24, 25, 25)	1.55 (± 0.618)	3.45 (± 0.585)	3.52 (± 0.595)	3.14 (± 0.579)
Change at Week 2 (n=23, 23, 23, 25, 24)	-0.25 (± 0.334)	-0.89 (± 0.316)	-0.81 (± 0.323)	-0.68 (± 0.311)
Change at Week 4 (n=23, 23, 23, 23, 24)	-0.28 (± 0.378)	-1.06 (± 0.362)	-0.91 (± 0.366)	-0.89 (± 0.356)
Change at Week 6 (n=22, 21, 24, 22, 23)	-0.04 (± 0.405)	-0.84 (± 0.39)	-0.9 (± 0.391)	-0.63 (± 0.384)
Change at Week 10 (n=21, 21, 24, 22, 21)	-0.08 (± 0.417)	-0.6 (± 0.402)	-0.77 (± 0.401)	-0.56 (± 0.396)
Change at Week 12 (n=22, 20, 22, 17, 20)	0.51 (± 0.458)	-0.54 (± 0.449)	-0.75 (± 0.444)	-0.47 (± 0.452)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			

Units: units on a scale				
least squares mean (standard error)				
Baseline (n=23, 23, 24, 25, 25)	2.13 (\pm 0.56)			
Change at Week 2 (n=23, 23, 23, 25, 24)	-0.3 (\pm 0.301)			
Change at Week 4 (n=23, 23, 23, 23, 24)	-0.47 (\pm 0.346)			
Change at Week 6 (n=22, 21, 24, 22, 23)	-0.47 (\pm 0.374)			
Change at Week 10 (n=21, 21, 24, 22, 21)	-0.56 (\pm 0.387)			
Change at Week 12 (n=22, 20, 22, 17, 20)	-0.72 (\pm 0.436)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description: Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.099
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.29
upper limit	-0.2
Variability estimate	Standard error of the mean
Dispersion value	0.626

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description: Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.49
upper limit	-0.03
Variability estimate	Standard error of the mean
Dispersion value	0.619

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.118
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.21
upper limit	0.25
Variability estimate	Standard error of the mean
Dispersion value	0.62

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
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Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.44
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.616

Secondary: Change From Baseline in VAS Morning Stiffness Score at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in VAS Morning Stiffness Score at Weeks 2, 4, 6, 10, and 12
End point description:	Assessments were performed using a portable electronic device, which was kept and used by the subject throughout the duration of the study. Subjects were asked to indicate their level of morning stiffness by marking a horizontal line with "No stiffness" at the left extreme and "Very severe stiffness" at the right extreme (scale ranging from 0 - 10, but not shown on the line). Each assessment was intended to capture the severity of stiffness experienced by the subject since waking on that particular day. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.
End point type	Secondary
End point timeframe:	Baseline, Weeks 2, 4, 6, 10, and 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=23, 23, 24, 25, 25)	1.73 (± 0.592)	3.32 (± 0.561)	3.33 (± 0.571)	2.77 (± 0.555)
Change at Week 2 (n=23, 23, 23, 25, 24)	-0.22 (± 0.276)	-0.87 (± 0.266)	-0.91 (± 0.271)	-0.67 (± 0.259)
Change at Week 4 (n=23, 23, 23, 23, 24)	-0.31 (± 0.316)	-0.95 (± 0.307)	-0.97 (± 0.31)	-0.8 (± 0.3)
Change at Week 6 (n=22, 21, 24, 22, 23)	-0.27 (± 0.351)	-0.84 (± 0.343)	-0.97 (± 0.342)	-0.61 (± 0.335)
Change at Week 10 (n=21, 21, 24, 22, 21)	-0.38 (± 0.372)	-0.74 (± 0.364)	-0.94 (± 0.362)	-0.46 (± 0.356)
Change at Week 12 (n=22, 20, 22, 17, 20)	-0.16 (± 0.368)	-0.79 (± 0.363)	-1.02 (± 0.359)	-0.43 (± 0.361)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=23, 23, 24, 25, 25)	2.32 (\pm 0.537)			
Change at Week 2 (n=23, 23, 23, 25, 24)	-0.32 (\pm 0.25)			
Change at Week 4 (n=23, 23, 23, 23, 24)	-0.26 (\pm 0.291)			
Change at Week 6 (n=22, 21, 24, 22, 23)	-0.21 (\pm 0.327)			
Change at Week 10 (n=21, 21, 24, 22, 21)	-0.24 (\pm 0.349)			
Change at Week 12 (n=22, 20, 22, 17, 20)	-0.24 (\pm 0.35)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.211
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.63
upper limit	0.36
Variability estimate	Standard error of the mean
Dispersion value	0.503

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.087
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.85
upper limit	0.13
Variability estimate	Standard error of the mean
Dispersion value	0.497

Statistical analysis title

Week 12: Namilumab Placebo vs 80 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.58
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.26
upper limit	0.71
Variability estimate	Standard error of the mean
Dispersion value	0.494

Statistical analysis title

Week 12: Namilumab Placebo vs 150 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a

covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.873
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.06
upper limit	0.9
Variability estimate	Standard error of the mean
Dispersion value	0.496

Secondary: Change From Baseline in Duration of Morning Stiffness at Weeks 2, 4, 6, 10, and 12

End point title	Change From Baseline in Duration of Morning Stiffness at Weeks 2, 4, 6, 10, and 12
End point description:	Assessments were performed using a portable electronic device, which was kept and used by the subject throughout the duration of the study. Duration of stiffness was elicited in response to a standard question included in the portable device. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.
End point type	Secondary
End point timeframe:	Baseline, Weeks 2, 4, 6, 10, and 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	17	18
Units: minutes				
least squares mean (standard error)				
Baseline (n=13, 17, 17, 18, 18)	6.6 (± 5.65)	14.2 (± 4.49)	18.2 (± 4.84)	16.6 (± 4.58)
Change at Week 2 (n=13, 16, 17, 17, 17)	1.2 (± 3.33)	-1.7 (± 2.67)	0.1 (± 2.85)	-5.3 (± 2.73)
Change at Week 4 (n=13, 16, 16, 16, 17)	-0.9 (± 3.49)	-3 (± 2.8)	2.4 (± 3.01)	-2.8 (± 2.88)
Change at Week 6 (n=13, 13, 17, 14, 16)	-0.6 (± 4.06)	-2.4 (± 3.39)	4.1 (± 3.5)	-2 (± 3.44)
Change at Week 10 (n=11, 15, 17, 15, 13)	-0.9 (± 4.3)	-2.3 (± 3.58)	5.2 (± 3.71)	-2 (± 3.64)

Change at Week 12 (n=13, 14, 16, 12, 12)	-1.4 (\pm 5.12)	-3 (\pm 4.35)	6.5 (\pm 4.44)	-0.6 (\pm 4.42)
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End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: minutes				
least squares mean (standard error)				
Baseline (n=13, 17, 17, 18, 18)	12.4 (\pm 4.91)			
Change at Week 2 (n=13, 16, 17, 17, 17)	-0.2 (\pm 2.88)			
Change at Week 4 (n=13, 16, 16, 16, 17)	1 (\pm 3.03)			
Change at Week 6 (n=13, 13, 17, 14, 16)	1.8 (\pm 3.55)			
Change at Week 10 (n=11, 15, 17, 15, 13)	1.3 (\pm 3.77)			
Change at Week 12 (n=13, 14, 16, 12, 12)	3 (\pm 4.56)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.803
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	11.8
Variability estimate	Standard error of the mean
Dispersion value	6.7

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.248
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	7.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	21.4
Variability estimate	Standard error of the mean
Dispersion value	6.73

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.914
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.7
upper limit	14.2
Variability estimate	Standard error of the mean
Dispersion value	6.67

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site, treatment, visit and interaction between visit and treatment as fixed effects, baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.523
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.2
upper limit	17.9
Variability estimate	Standard error of the mean
Dispersion value	6.74

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 12

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 12
End point description:	
<p>The DLQI is a 10-point rating scale for determining the impact of dermatological conditions on the subject's quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). Maximum total score is 30, where 0-1 represents "No effect at all on subject's life" and 21-30 "Extremely large effect on subject's life" - higher scores indicating poorer quality of life. FAS where baseline and Week 12 assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.</p>	
End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	21	22	19
Units: units on a scale				
least squares mean (standard error)				
Baseline	13.8 (± 1.95)	12.2 (± 1.85)	10.3 (± 1.83)	13.9 (± 1.95)
Change at Week 12	-0.7 (± 1.06)	-0.7 (± 1.01)	-1.9 (± 1.01)	-2.1 (± 1.06)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: units on a scale				
least squares mean (standard error)				
Baseline	11.4 (± 1.89)			
Change at Week 12	-2.8 (± 1.03)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from an Analysis of covariance (ANCOVA) model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.978
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	2.8
Variability estimate	Standard error of the mean
Dispersion value	1.37

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description:	
Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.389
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	1.5
Variability estimate	Standard error of the mean
Dispersion value	1.36

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.316
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	1.4
Variability estimate	Standard error of the mean
Dispersion value	1.39

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.142
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-2.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	0.7
Variability estimate	Standard error of the mean
Dispersion value	1.41

Secondary: Change From Baseline in Short Form 36 Health Survey (SF-36) at Week 12

End point title	Change From Baseline in Short Form 36 Health Survey (SF-36) at Week 12
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End point description:

SF-36 is a standardized survey evaluating 8 aspects of functional health and well-being: physical and social functioning, physical and emotional role limitations, bodily pain, general health, vitality, mental health. These 8 aspects are summarized as physical and mental health summary scores. The score range for the physical and mental health scores is 0-100 (100=highest level of functioning). FAS where baseline and Week 12 assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	22	19
Units: units on a scale				
least squares mean (standard error)				
Physical Health Summary Score: Baseline	52.9 (± 2.08)	46.6 (± 1.97)	49 (± 1.92)	52.8 (± 2.04)
Physical Health Summary Score: Change at Week 12	-0.5 (± 1.31)	-2.6 (± 1.24)	-0.8 (± 1.19)	0.9 (± 1.28)
Mental Health Summary Score: Baseline	43.7 (± 2.67)	42.9 (± 2.53)	42.8 (± 2.46)	42.3 (± 2.61)
Mental Health Summary Score: Change at Week 12	0.9 (± 1.78)	2.8 (± 1.69)	1.5 (± 1.64)	1.5 (± 1.75)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: units on a scale				
least squares mean (standard error)				

Physical Health Summary Score: Baseline	50.7 (\pm 2.05)			
Physical Health Summary Score: Change at Week 12	0.4 (\pm 1.27)			
Mental Health Summary Score: Baseline	46 (\pm 2.63)			
Mental Health Summary Score: Change at Week 12	1.6 (\pm 1.76)			

Statistical analyses

Statistical analysis title	Physical Health Summary Score: Placebo vs 20 mg
Statistical analysis description:	
Physical Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.229
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	1.4
Variability estimate	Standard error of the mean
Dispersion value	1.73

Statistical analysis title	Physical Health Summary Score: Placebo vs 50 mg
Statistical analysis description:	
Physical Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.863
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	3
Variability estimate	Standard error of the mean
Dispersion value	1.65

Statistical analysis title	Physical Health Summary Score: Placebo vs 80 mg
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Statistical analysis description:

Physical Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.403
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	4.7
Variability estimate	Standard error of the mean
Dispersion value	1.67

Statistical analysis title	Physical Health Summary Score: Placebo vs 150 mg
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Statistical analysis description:

Physical Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.597
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	4.4
Variability estimate	Standard error of the mean
Dispersion value	1.74

Statistical analysis title	Mental Health Summary Score: Placebo vs 20 mg
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Statistical analysis description:

Mental Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.416
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	6.5
Variability estimate	Standard error of the mean
Dispersion value	2.32

Statistical analysis title	Mental Health Summary Score: Placebo vs 50 mg
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Statistical analysis description:

Mental Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	5.1
Variability estimate	Standard error of the mean
Dispersion value	2.24

Statistical analysis title	Mental Health Summary Score: Placebo vs 80 mg
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Statistical analysis description:

Mental Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.798
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	5.2
Variability estimate	Standard error of the mean
Dispersion value	2.31

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Mental Health Summary Score: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.767
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	5.5
Variability estimate	Standard error of the mean
Dispersion value	2.4

Secondary: Change From Baseline in EuroQoL Health Questionnaire (EQ-5D)- Index Score at Week 12

End point title	Change From Baseline in EuroQoL Health Questionnaire (EQ-5D)- Index Score at Week 12
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End point description:

EQ-5D-Index score is a generic, multidimensional, health-related, quality-of-life instrument. The profile allows subjects to rate their health state in 5 health domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The score ranges from -0.594 to 1.000. The higher score indicates a better health state perceived by the subject. FAS where baseline and Week 12 assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	22	19
Units: units on a scale				
least squares mean (standard error)				
Baseline	0.86 (± 0.041)	0.8 (± 0.038)	0.84 (± 0.038)	0.81 (± 0.04)
Change at Week 12	-0.02 (± 0.033)	-0.04 (± 0.031)	-0.04 (± 0.03)	0.01 (± 0.033)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: units on a scale				
least squares mean (standard error)				
Baseline	0.87 (± 0.04)			
Change at Week 12	0.01 (± 0.033)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
Statistical analysis description: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.57
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.06
Variability estimate	Standard error of the mean
Dispersion value	0.043

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
Statistical analysis description: Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.	
Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.619
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.06

Variability estimate	Standard error of the mean
Dispersion value	0.042

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.597
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	0.11
Variability estimate	Standard error of the mean
Dispersion value	0.043

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.509
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	0.12
Variability estimate	Standard error of the mean
Dispersion value	0.044

Secondary: Change From Baseline in EQ-5D-VAS Score at Week 12

End point title	Change From Baseline in EQ-5D-VAS Score at Week 12
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End point description:

EQ-5D-VAS is a subject rated questionnaire to assess health-related quality of life in terms of a single index value. The VAS component rates current health state on a scale from 0 mm ("Worst imaginable health state") to 100 mm ("Best imaginable health state"); higher scores indicate a better health state. FAS where baseline and Week 12 assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline assessment of PASI in the double-blind period.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	20	17
Units: millimeter (mm)				
least squares mean (standard error)				
Baseline	76.8 (± 5.77)	58.9 (± 5.13)	67.2 (± 5.09)	75.3 (± 5.42)
Change at Week 12	0.5 (± 3.99)	-0.5 (± 3.67)	5.3 (± 3.51)	-1.4 (± 3.74)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: millimeter (mm)				
least squares mean (standard error)				
Baseline	74.3 (± 5.47)			
Change at Week 12	-1.9 (± 3.77)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
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Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.845
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	9.6
Variability estimate	Standard error of the mean
Dispersion value	5.32

Statistical analysis title	Week 12: Namilumab Placebo vs 50 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.323
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	14.4
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Week 12: Namilumab Placebo vs 80 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
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Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.697
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	7.8
Variability estimate	Standard error of the mean
Dispersion value	4.89

Statistical analysis title	Week 12: Namilumab Placebo vs 150 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from an ANCOVA model with main effect of study site and treatment with baseline value as a covariate. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.633
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	7.7
Variability estimate	Standard error of the mean
Dispersion value	5.1

Secondary: Mean Change From Baseline in Nail Psoriasis Severity Index (NAPSI) Score at Weeks 2, 4, 6, 10, and 12

End point title	Mean Change From Baseline in Nail Psoriasis Severity Index (NAPSI) Score at Weeks 2, 4, 6, 10, and 12
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End point description:

The NAPSI quantifies severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix (pitting, leukonychia, red spots on lunula, crumbling) and nail bed (onycholysis, splinter hemorrhages, subungual hyperkeratosis, oil drop [salmon patch dyschromia]). Each finger nail divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). The total NAPSI score equals the sum of scores for all of the finger nails evaluated and ranges from 0 to 80. Higher scores = more severe psoriasis. FAS where baseline and specified post-baseline assessment were available. FAS included all randomized and treated subjects who had at least one valid post-baseline

assessment of PASI in the double-blind period.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 2, 4, 6, 10, and 12	

End point values	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg	Double-Blind Period: Namilumab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	25
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	14.5 (± 3.56)	9.6 (± 3.37)	15.6 (± 3.48)	12 (± 3.39)
Change at Week 2 (n=24, 24, 24, 25, 25)	-0.8 (± 0.53)	0.1 (± 0.5)	0.8 (± 0.52)	0.4 (± 0.5)
Change at Week 4 (n=24, 24, 23, 24, 24)	-1.5 (± 0.77)	0 (± 0.75)	1.4 (± 0.77)	0.6 (± 0.75)
Change at Week 6 (n=23, 23, 24, 24, 23)	-1.5 (± 0.99)	-0.2 (± 0.98)	1.2 (± 0.98)	2.3 (± 0.97)
Change at Week 10 (n=22, 22, 24, 24, 21)	-2.4 (± 1.03)	-0.6 (± 1.02)	0.8 (± 1.01)	2 (± 1)
Change at Week 12 (n=23, 21, 22, 19, 20)	-1.5 (± 1.17)	-0.5 (± 1.18)	0.9 (± 1.16)	2.5 (± 1.17)

End point values	Double-Blind Period: Namilumab 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: units on a scale				
least squares mean (standard error)				
Baseline (n=24, 24, 24, 25, 25)	12.5 (± 3.28)			
Change at Week 2 (n=24, 24, 24, 25, 25)	0.1 (± 0.48)			
Change at Week 4 (n=24, 24, 23, 24, 24)	0.1 (± 0.74)			
Change at Week 6 (n=23, 23, 24, 24, 23)	-0.7 (± 0.97)			
Change at Week 10 (n=22, 22, 24, 24, 21)	0.6 (± 1.02)			
Change at Week 12 (n=23, 21, 22, 19, 20)	1 (± 1.18)			

Statistical analyses

Statistical analysis title	Week 12: Namilumab Placebo vs 20 mg
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Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site,treatment,visit and interaction between visit and treatment as fixed effects,baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 20 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.537
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	4.3
Variability estimate	Standard error of the mean
Dispersion value	1.64

Statistical analysis title

Week 12: Namilumab Placebo vs 50 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site,treatment,visit and interaction between visit and treatment as fixed effects,baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 50 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.142
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	5.6
Variability estimate	Standard error of the mean
Dispersion value	1.62

Statistical analysis title

Week 12: Namilumab Placebo vs 80 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site,treatment,visit and interaction between visit and treatment as fixed effects,baseline value as a

covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 80 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.015
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	7.3
Variability estimate	Standard error of the mean
Dispersion value	1.63

Statistical analysis title

Week 12: Namilumab Placebo vs 150 mg

Statistical analysis description:

Post-baseline least squares means and p-values were from a MMRM model with main effect of study site,treatment,visit and interaction between visit and treatment as fixed effects,baseline value as a covariate with an unstructured covariance structure. Baseline least squares means and p-values were obtained using an ANOVA model with terms for treatment and study site.

Comparison groups	Double-Blind Period: Placebo v Double-Blind Period: Namilumab 150 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.121
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	5.8
Variability estimate	Standard error of the mean
Dispersion value	1.64

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events are adverse events that started after the first dose of double-blind study drug and no more than 14 days (or 30 days for a serious adverse event) after the last dose of double-blind study drug.

Adverse event reporting additional description:

At each clinic visit the investigator was required to document any occurrence of adverse events - including at specified visits abnormal laboratory, ECG and lung function test findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	Double-Blind Period: Placebo
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Reporting group description:

Namimumab-matching placebo solution (2 separate injections) subcutaneously on Day 1, followed by namimumab-matching placebo, single injection subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Reporting group title	Double-Blind Period: Namimumab 20 mg
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Reporting group description:

Namimumab 40 milligram (mg) injection (2 separate injections of 20 mg), subcutaneously on Day 1, followed by namimumab 20 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Reporting group title	Double-Blind Period: Namimumab 50 mg
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Reporting group description:

Namimumab 100 mg injection (2 separate injections of 50 mg), subcutaneously on Day 1, followed by namimumab 50 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Reporting group title	Double-Blind Period: Namimumab 80 mg
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Reporting group description:

Namimumab 160 mg injection (2 separate injections of 80 mg), subcutaneously on Day 1, followed by namimumab 80 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Reporting group title	Double-Blind Period: Namimumab 150 mg
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Reporting group description:

Namimumab 300 mg injection (2 separate injections of 150 mg), subcutaneously on Day 1, followed by namimumab 150 mg, single injection, subcutaneously at Weeks 2, 6 and 10 during the double-blind period.

Reporting group title	Open-Label Period: Namimumab 80 mg
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Reporting group description:

Namimumab 80 mg, single injection, subcutaneously, every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.

Reporting group title	Open-Label Period: Namimumab 150 mg
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Reporting group description:

Namimumab 150 mg, single injection, subcutaneously from Week 8 and then every 4 weeks for 52 weeks during the open-label period on the basis of treatment response.

Reporting group title	Follow-up Period: Placebo
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Reporting group description:

Subjects who received namimumab-matching placebo injections during the double-blind treatment were to be followed-up for 18 weeks after the last dose of study drug - whether administered in the double-blind period or open-label extension period.

Reporting group title	Follow-up Period: Namimumab 20 mg
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Reporting group description:

Subjects who received nabilumab 20 mg injections during the double-blind treatment were to be followed-up for 18 weeks after the last dose of study drug - whether administered in the double-blind period or open-label extension period.

Reporting group title	Follow-up Period: Nabilumab 50 mg
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Reporting group description:

Subjects who received nabilumab 50 mg injections during the double-blind treatment were to be followed-up after the last dose of study drug - whether administered in the double-blind period or open-label extension period.

Reporting group title	Follow-up Period: Nabilumab 80 mg
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Reporting group description:

Subjects who received nabilumab 80 mg injections during the double-blind treatment were to be followed-up for 18 weeks after the last dose of study drug - whether administered in the double-blind period or open-label extension period.

Reporting group title	Follow-up: Nabilumab 150 mg
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Reporting group description:

Subjects who received nabilumab 150 mg injections during the double-blind treatment were to be followed-up for 18 weeks after the last dose of study drug - whether administered in the double-blind period or open-label extension period.

Serious adverse events	Double-Blind Period: Placebo	Double-Blind Period: Nabilumab 20 mg	Double-Blind Period: Nabilumab 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	0 / 24 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	0 / 24 (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

Serious adverse events	Double-Blind Period: Nabilumab 80 mg	Double-Blind Period: Nabilumab 150 mg	Open-Label Period: Nabilumab 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 12 (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	Open-Label Period: Nabilumab 150 mg	Follow-up Period: Placebo	Follow-up Period: Nabilumab 20 mg
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Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 24 (0.00%)	0 / 24 (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	Follow-up Period: Namilumab 50 mg	Follow-up Period: Namilumab 80 mg	Follow-up: Namilumab 150 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Double-Blind Period: Placebo	Double-Blind Period: Namilumab 20 mg	Double-Blind Period: Namilumab 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 24 (20.83%)	0 / 24 (0.00%)	2 / 24 (8.33%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Wound			

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 3 2 / 24 (8.33%) 2	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0	1 / 24 (4.17%) 2 1 / 24 (4.17%) 1
Metabolism and nutrition disorders Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0

Non-serious adverse events	Double-Blind Period: Namilumab 80 mg	Double-Blind Period: Namilumab 150 mg	Open-Label Period: Namilumab 80 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 25 (12.00%)	2 / 25 (8.00%)	1 / 12 (8.33%)
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1
Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all) Wound subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0 0 / 25 (0.00%) 0	0 / 25 (0.00%) 0 0 / 25 (0.00%) 0	1 / 12 (8.33%) 1 1 / 12 (8.33%) 1
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	1 / 25 (4.00%) 1	0 / 12 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 25 (4.00%) 1	1 / 12 (8.33%) 1
Metabolism and nutrition disorders Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1

Non-serious adverse events	Open-Label Period: Namilumab 150 mg	Follow-up Period: Placebo	Follow-up Period: Namilumab 20 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	2 / 48 (4.17%)	1 / 24 (4.17%)	0 / 24 (0.00%)
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all) Wound subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0 0 / 48 (0.00%) 0	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 48 (4.17%) 3 0 / 48 (0.00%) 0	0 / 24 (0.00%) 0 1 / 24 (4.17%) 1	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0
Metabolism and nutrition disorders			

Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
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Non-serious adverse events	Follow-up Period: Namilumab 50 mg	Follow-up Period: Namilumab 80 mg	Follow-up: Namilumab 150 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all) Wound subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0	0 / 25 (0.00%) 0 0 / 25 (0.00%) 0	0 / 25 (0.00%) 0 0 / 25 (0.00%) 0
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0	1 / 25 (4.00%) 1 0 / 25 (0.00%) 0	1 / 25 (4.00%) 1 0 / 25 (0.00%) 0
Metabolism and nutrition disorders Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 25 (0.00%) 0	0 / 25 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 July 2014	The primary purpose of this amendment was to update the protocol regarding addition of the extension period - including open-label treatment and post-treatment follow-up.
04 November 2014	The primary purpose of this amendment was to increase the study population (sample size) to 120 subjects in total. This increase is needed to help accommodate the target number of subjects willing to provide tissue biopsy samples in the Biopsy sub-study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported