



Clinical trial results:

A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Subcutaneous Abatacept in Adults with Active Primary Sjögrens Syndrome

Summary

EudraCT number	2016-001948-19
Trial protocol	SE CZ FR IT
Global end of trial date	23 July 2019

Results information

Result version number	v1 (current)
This version publication date	30 October 2020
First version publication date	30 October 2020

Trial information

Trial identification

Sponsor protocol code	IM101-603
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	21 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 August 2018
Global end of trial reached?	Yes
Global end of trial date	23 July 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to compare the mean change from baseline (Day 1) to Day 169 in ESSDAI of abatacept versus placebo in subjects with moderate to severe primary Sjögrens Syndrome (pSS).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 December 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 16
Country: Number of subjects enrolled	Australia: 33
Country: Number of subjects enrolled	Brazil: 49
Country: Number of subjects enrolled	Czech Republic: 6
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	France: 14
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	Japan: 37
Country: Number of subjects enrolled	Korea, Republic of: 10
Country: Number of subjects enrolled	Mexico: 16
Country: Number of subjects enrolled	Puerto Rico: 2
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United States: 46
Worldwide total number of subjects	249
EEA total number of subjects	40

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)	201
From 65 to 84 years	47
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

250 enrolled; 188 Randomized, 62 not Randomized: Reasons Not randomized: 6 withdrew consent, 1 lost to follow-up, 49 no longer meet study criteria, 6 screening failures

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Abatacept - Double Blind Treatment Period

Arm description:

Double Blind Treatment Period SC injection 125mg/mL in 1 mL pre-filled syringe

Arm type	Experimental
Investigational medicinal product name	Abatacept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

125 mg/mL IV syringe

Arm title	Placebo - Double Blind Treatment Period
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Arm description:

Double Blind Treatment Period SC injection in 1 mL pre-filled syringe

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

Dosage and administration details:

1 mL pre-filled syringes

Number of subjects in period 1^[1]	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period
Started	92	95
Completed	81	87
Not completed	11	8
poor/non-compliance	1	-

Participant withdrew consent	5	1
Adverse event, non-fatal	2	2
Request to discontinue treatment	1	2
Participant no longer meets criteria	2	-
Lack of efficacy	-	3

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 250 enrolled; 188 Randomized, 62 not Randomized:Reasons Not randomized: 6 withdrew consent, 1 lost to follow-up, 49 no longer meet study criteria, 6 screening failures

Baseline characteristics

Reporting groups

Reporting group title	Abatacept - Double Blind Treatment Period
Reporting group description:	
Double Blind Treatment Period SC injection 125mg/mL in 1 mL pre-filled syringe	
Reporting group title	Placebo - Double Blind Treatment Period
Reporting group description:	
Double Blind Treatment Period SC injection in 1 mL pre-filled syringe	

Reporting group values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period	Total
Number of subjects	92	95	187
Age Categorical			
Categorical Age Dispersion			
Units: Participants			
< 65 years	80	73	153
≥ 65 years	12	22	34
Age Continuous			
Units: Years			
arithmetic mean	51.2	52.9	
standard deviation	± 12.3	± 13.5	-
Sex: Female, Male			
Units: Participants			
Female	85	92	177
Male	7	3	10
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	21	23	44
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	10	9	19
White	60	60	120
More than one race	0	0	0
Unknown or Not Reported	1	3	4
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	5	7
Not Hispanic or Latino	10	13	23
Unknown or Not Reported	80	77	157

End points

End points reporting groups

Reporting group title	Abatacept - Double Blind Treatment Period
Reporting group description:	
Double Blind Treatment Period SC injection 125mg/mL in 1 mL pre-filled syringe	
Reporting group title	Placebo - Double Blind Treatment Period
Reporting group description:	
Double Blind Treatment Period SC injection in 1 mL pre-filled syringe	
Subject analysis set title	Abatacept - Open Label Treatment Period
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Open Label Treatment Period SC injection 125mg/mL in 1 mL pre-filled syringe	
Subject analysis set title	Abatacept - Open Label Treatment Period
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Double Blind Treatment Period SC injection 125mg/mL in 1 mL pre-filled syringe	

Primary: Change from Baseline in EULAR Sjogren's Syndrome Disease Activity Index (ESSDAI)

End point title	Change from Baseline in EULAR Sjogren's Syndrome Disease Activity Index (ESSDAI)
End point description:	
<p>The EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) total score is calculated as the sum of scores for activity level for each domain. The EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) Scoring Algorithm. Domain: (Score) Constitutional: (No=0, Low=3, Moderate=6) Lymphadenopathy: (No=0, Low=4, Moderate=8, High=12) Glandular: (No=0, Low=2, Moderate=4) Articular: (No=0, Low=2, Moderate=4, High=6) Cutaneous: (No=0, Low=3, Moderate=6, High=9) Pulmonary: (No=0, Low=5, Moderate=10, High=15) Renal: (No=0, Low=5, Moderate=10, High=15) Muscular: (No=0, Low=6, Moderate=12, High=18) Peripheral Nervous System (PNS): (No=0, Low=5, Moderate=10, High=15) Central Nervous System (CNS): (No=0, Moderate=10, High=15) Haematological: (No=0, Low=2, Moderate=4, High=6) Biological: (No=0, Low=1, Moderate=2) (No = No Disease Activity (DA), Low = Low DA, Moderate = Moderate DA, High = High DA) Overall score, which can range from 0 to 123, a higher score indicates more disease activity</p>	
End point type	Primary
End point timeframe:	
Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)	-3.2 (-4.6 to -1.9)	-3.7 (-5.0 to -2.4)		

Statistical analyses

Statistical analysis title	Change from baseline in EULAR
Comparison groups	Abatacept - Double Blind Treatment Period v Placebo - Double Blind Treatment Period
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4421
Method	longitudinal repeated measures analysis

Secondary: Change from Baseline in EULAR Sjogren's Syndrome Patient Reported Inde (ESSPRI)

End point title	Change from Baseline in EULAR Sjogren's Syndrome Patient Reported Inde (ESSPRI)
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End point description:

The total score EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) is calculated as the mean of the 3 individual components. Total Score Range (0 = Best outcome and 10 = Worst Outcome) The scores for the ESSPRI individual components will be used as such reported by the participants and entered in the case report form (CRF), without any further calculations. It consists of 3 questions covering cardinal symptoms of Sjögren's syndrome: dryness, fatigue and pain. Each domain scored on scale of 0-10 (0 =no symptom at all and 10 = worst symptom imaginable), and overall score is calculated as the mean of 3 individual domains.

End point type	Secondary
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End point timeframe:

Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)	-1.26 (-1.88 to -0.64)	-1.52 (-2.12 to -0.93)		

Statistical analyses

Statistical analysis title	Change from baseline in EULAR
Comparison groups	Abatacept - Double Blind Treatment Period v Placebo - Double Blind Treatment Period
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3367
Method	longitudinal repeated measures analysis

Secondary: Change from Baseline in the Stimulated Whole Salivary Flow

End point title	Change from Baseline in the Stimulated Whole Salivary Flow
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End point description:

The mean change from baseline in the stimulated whole salivary flow at Day 169

End point type	Secondary
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End point timeframe:

Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: mL/min				
arithmetic mean (confidence interval 95%)	0.057 (-0.115 to 0.230)	0.108 (-0.060 to 0.276)		

Statistical analyses

Statistical analysis title	Change from baseline
Comparison groups	Abatacept - Double Blind Treatment Period v Placebo - Double Blind Treatment Period
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5841
Method	longitudinal repeated measures analysis

Secondary: Change from Baseline of DAS28-C-reactive peptide (CRP): In The Full Population

End point title	Change from Baseline of DAS28-C-reactive peptide (CRP): In The Full Population
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End point description:

The disease activity score DAS28-CRP is a continuous variable which is a composite of 4 variables: the 28 tender joint count (tender28), the 28 swollen joint count (swollen28), CRP and participant assessment of disease activity measure on a visual analogue scale (VAS) of 100mm. $\text{DAS28-CRP} = 0.56 * \sqrt{\text{tender28}} + 0.28 * \sqrt{\text{swollen28}} + 0.36 * \ln(\text{hsCRP}+1) + 0.014 * \text{VAS} + 0.96$. (sqrt = Square root, ln = natural log) Positive Scores = Increased Disease Activity Negative Scores = Reduced Disease Activity

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Day 29	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.2)		
Day 57	-0.6 (-0.8 to -0.4)	-0.7 (-0.9 to -0.4)		
Day 85	-0.8 (-1.0 to -0.6)	-0.8 (-1.1 to -0.6)		
Day 113	-0.8 (-1.0 to -0.5)	-1.0 (-1.2 to -0.7)		
Day 141	-0.8 (-1.0 to -0.5)	-1.0 (-1.3 to -0.8)		
Day 169	-0.9 (-1.1 to -0.6)	-1.1 (-1.4 to -0.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline of DAS28-CRP: Tender Swollen joint count of at least 3

End point title	Change from Baseline of DAS28-CRP: Tender Swollen joint count of at least 3
End point description:	
The disease activity score DAS28-CRP is a continuous variable which is a composite of 4 variables: the 28 tender joint count (tender28), the 28 swollen joint count (swollen28), CRP and participant assessment of disease activity measure on a visual analogue scale (VAS) of 100mm. $DAS28-CRP = 0.56 * \sqrt{tender28} + 0.28 * \sqrt{swollen28} + 0.36 * \ln(hsCRP+1) + 0.014 * VAS + 0.96$. (sqrt = Square root, ln = natural log) Positive Scores = Increased Disease Activity Negative Scores = Reduced Disease Activity	
End point type	Secondary
End point timeframe:	
Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: Scores on a scale				

arithmetic mean (confidence interval 95%)				
Day 29	-0.5 (-0.8 to -0.2)	-0.6 (-0.9 to -0.3)		
Day 57	-0.9 (-1.2 to -0.5)	-1.0 (-1.3 to -0.6)		
Day 85	-1.1 (-1.5 to -0.7)	-1.2 (-1.5 to -0.8)		
Day 113	-1.1 (-1.4 to -0.7)	-1.4 (-1.7 to -1.0)		
Day 141	-1.2 (-1.5 to -0.8)	-1.5 (-1.8 to -1.1)		
Day 169	-1.3 (-1.7 to -0.9)	-1.5 (-1.9 to -1.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline of DAS28-CRP: Tender Swollen Joints count less than 3

End point title	Change from Baseline of DAS28-CRP: Tender Swollen Joints count less than 3
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End point description:

The disease activity score DAS28-CRP is a continuous variable which is a composite of 4 variables: the 28 tender joint count (tender28), the 28 swollen joint count (swollen28), CRP and participant assessment of disease activity measure on a visual analogue scale (VAS) of 100mm. $DAS28-CRP = 0.56 * \sqrt{tender28} + 0.28 * \sqrt{swollen28} + 0.36 * \ln(hsCRP+1) + 0.014 * VAS + 0.96$. (sqrt = Square root, ln = natural log) Positive Scores = Increased Disease Activity Negative Scores = Reduced Disease Activity

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	31		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Day 29	-0.3 (-0.6 to 0.0)	-0.2 (-0.6 to 0.1)		
Day 57	-0.2 (-0.5 to 0.1)	-0.2 (-0.5 to 0.1)		
Day 85	-0.4 (-0.6 to -0.1)	-0.4 (-0.7 to -0.1)		
Day 113	-0.3 (-0.6 to 0.0)	-0.3 (-0.6 to 0.1)		
Day 141	-0.2 (-0.5 to 0.1)	-0.4 (-0.7 to 0.0)		

Day 169	-0.3 (-0.5 to -0.0)	-0.5 (-0.7 to -0.2)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Joint component of DAS28-CRP: In the full population

End point title	Change from Baseline in the Joint component of DAS28-CRP: In the full population
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End point description:

The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. Tender Joint: Count 1-28 Swollen Joint: Count 1-28 Negative Scores = Reduced number of joints impacted Positive Scores = Increased number of joints impacted

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Joint Count				
arithmetic mean (confidence interval 95%)				
Day 29 - Tender Joint	-1.7 (-2.8 to -0.7)	-1.9 (-2.9 to -0.8)		
Day 29 - Swollen Joint	-0.5 (-1.0 to 0.1)	-0.6 (-1.1 to -0.1)		
Day 57 - Tender Joint	-2.6 (-3.7 to -1.5)	-2.9 (-4.0 to -1.9)		
Day 57 - Swollen Joint	-1.0 (-1.6 to -0.3)	-1.0 (-1.6 to -0.4)		
Day 85 - Tender Joint	-2.9 (-4.1 to -1.7)	-3.4 (-4.6 to -2.2)		
Day 85 - Swollen Joint	-1.4 (-2.0 to -0.8)	-1.4 (-2.0 to -0.9)		
Day 113 - Tender Joint	-3.1 (-4.2 to -2.0)	-3.9 (-5.0 to -2.8)		
Day 113 - Swollen Joint	-1.5 (-2.0 to -1.1)	-1.9 (-2.3 to -1.4)		
Day 141 - Tender Joint	-3.6 (-4.7 to -2.5)	-4.1 (-5.2 to -3.0)		
Day 141 - Swollen Joint	-1.4 (-1.9 to -0.8)	-1.8 (-2.4 to -1.3)		
Day 169 - Tender Joint	-2.9 (-4.0 to -1.7)	-4.4 (-5.6 to -3.3)		

Day 169 - Swollen Joint	-1.4 (-1.9 to -0.8)	-2.0 (-2.6 to -1.5)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the CRP component of DAS28-CRP: In the full population

End point title	Change from Baseline in the CRP component of DAS28-CRP: In the full population
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End point description:

The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. CRP: measured lab value Positive Number = Increased level of CRP Negative Number = Reduced Level of CRP

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: mg/L				
arithmetic mean (confidence interval 95%)				
Day 29 - CRP	0.3 (-1.4 to 2.0)	0.6 (-1.0 to 2.3)		
Day 57 - CRP	-0.1 (-2.1 to 1.8)	1.8 (-0.1 to 3.6)		
Day 85 - CRP	-0.2 (-5.0 to 4.5)	3.0 (-1.6 to 7.6)		
Day 113 - CRP	1.6 (-0.8 to 4.1)	0.3 (-2.1 to 2.6)		
Day 141 - CRP	3.5 (-1.7 to 8.8)	-0.2 (-5.2 to 4.7)		
Day 169 - CRP	-0.2 (-1.8 to 1.3)	0.0 (-1.5 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Assessment of Disease Activity component of DAS28-CRP: In the full population

End point title	Change from Baseline in the Assessment of Disease Activity component of DAS28-CRP: In the full population
End point description: The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. Assessment of Disease Activity: 0-100 scale [100=Most severe] Positive Numbers = Increased Disease Activity Negative Numbers = Decreased Disease activity	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Scores on a Scale				
arithmetic mean (confidence interval 95%)				
Day 29 - Assessment of Disease Activity	-4.0 (-9.8 to 1.7)	-7.1 (-12.7 to -1.4)		
Day 57 - Assessment of Disease Activity	-7.5 (-13.4 to -1.7)	-6.3 (-11.9 to 0.6)		
Day 85 - Assessment of Disease Activity	-10.4 (-16.3 to -4.4)	-10.2 (-16.0 to -4.4)		
Day 113 - Assessment of Disease Activity	-8.0 (-14.0 to 2.0)	-9.7 (-15.5 to 3.9)		
Day 141 - Assessment of Disease Activity	-5.1 (-11.0 to 0.8)	-11.0 (-16.7 to -5.3)		
Day 169 - Assessment of Disease Activity	-10.1 (-16.1 to -4.0)	-9.0 (-14.8 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Joint Component of DAS28-CRP: Tender Swollen joints of at least 3

End point title	Change from Baseline in the Joint Component of DAS28-CRP: Tender Swollen joints of at least 3
End point description: The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. Tender Joint: Count 1-28 Swollen Joint: Count 1-28 Negative Scores = Reduced number of joints impacted Positive Scores = Increased number of joints impacted	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: Joint Count				
arithmetic mean (confidence interval 95%)				
Day 29 - Tender Joint	-2.8 (-4.5 to - 1.0)	-3.0 (-4.7 to - 1.3)		
Day 29 - Swollen Joint	-0.7 (-1.5 to 0.2)	-0.9 (-1.7 to - 0.1)		
Day 57 - Tender Joint	-4.1 (-5.9 to - 2.3)	-4.8 (-6.5 to - 3.0)		
Day 57 - Swollen Joint	-1.5 (-2.6 to - 0.5)	-1.6 (-2.6 to - 0.5)		
Day 85 - Tender Joint	-4.4 (-6.3 to - 2.4)	-5.4 (-7.2 to - 3.6)		
Day 85 - Swollen Joint	-2.1 (-3.1 to - 1.1)	-2.2 (-3.2 to - 1.3)		
Day 113 - Tender Joint	-4.8 (-6.6 to - 2.9)	-6.0 (-7.7 to - 4.2)		
Day 113 - Swollen Joint	-2.3 (-3.2 to - 1.5)	-2.9 (-3.7 to - 2.2)		
Day 141 - Tender Joint	-5.7 (-7.5 to - 3.8)	-6.4 (-8.2 to - 4.7)		
Day 141 - Swollen Joint	-2.2 (-3.1 to - 1.3)	-3.0 (-3.8 to - 2.1)		
Day 169 - Tender Joint	-4.6 (-6.5 to - 2.7)	-6.7 (-8.5 to - 4.9)		
Day 169 - Swollen Joint	-2.2 (-3.1 to - 1.3)	-3.1 (-4.0 to - 2.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the CRP component of DAS28-CRP: Tender Swollen joints of at least 3

End point title	Change from Baseline in the CRP component of DAS28-CRP: Tender Swollen joints of at least 3
End point description: The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. CRP: measured lab value Positive Number = Increased level of CRP Negative Number = Reduced Level of CRP	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: mg/L				
arithmetic mean (confidence interval 95%)				
Day 29 - CRP	-1.5 (-3.7 to 0.7)	-0.7 (-2.8 to 1.4)		
Day 57 - CRP	-1.3 (-4.3 to 1.7)	1.3 (-1.5 to 4.0)		
Day 85 - CRP	-2.2 (-9.8 to 5.5)	3.8 (-3.4 to 11.0)		
Day 113 - CRP	1.2 (-2.7 to 5.1)	-0.4 (-4.0 to 3.2)		
Day 141 - CRP	4.5 (-4.0 to 12.9)	-1.4 (-9.0 to 6.3)		
Day 169 - CRP	-1.4 (-3.9 to 1.1)	-0.7 (-3.0 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Assessment of Disease Activity component of DAS28-CRP: Tender Swollen joints of at least 3

End point title	Change from Baseline in the Assessment of Disease Activity component of DAS28-CRP: Tender Swollen joints of at least 3
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End point description:

The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. Assessment of Disease Activity: 0-100 scale [100=Most severe] Positive Numbers = Increased Disease Activity Negative Numbers = Decreased Diseased activity

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Day 29 - Assessment of Disease Activity	0.6 (-6.9 to 8.1)	-3.5 (-10.7 to 3.7)		
Day 57 - Assessment of Disease Activity	-3.5 (-11.5 to 4.5)	-6.5 (-14.0 to 1.1)		
Day 85 - Assessment of Disease Activity	-7.5 (-15.5 to 0.4)	-7.7 (-15.3 to -0.1)		

Day 113 - Assessment of Disease Activity	-6.6 (-14.4 to 1.3)	-9.1 (-16.5 to -1.6)		
Day 141 - Assessment of Disease Activity	-1.2 (-9.0 to 6.7)	-8.1 (-15.5 to -0.7)		
Day 169 - Assessment of Disease Activity	-6.7 (-14.9 to 1.5)	-7.8 (-15.5 to -0.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Joint component of DAS28-CRP: Tender Swollen joint count less than 3

End point title	Change from Baseline in the Joint component of DAS28-CRP: Tender Swollen joint count less than 3
End point description: The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. Tender Joint: Count 1-28 Swollen Joint: Count 1-28 Negative Scores = Reduced number of joints impacted Positive Scores = Increased number of joints impacted	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	31		
Units: Joint Count				
arithmetic mean (confidence interval 95%)				
Day 29 - Tender Joint	-0.1 (-0.9 to 0.6)	-0.2 (-0.9 to 0.6)		
Day 29 - Swollen Joint	0.1 (-0.2 to 0.3)	0.1 (-0.2 to 0.4)		
Day 57 - Tender Joint	-0.2 (-0.9 to 0.6)	0.1 (-0.6 to 0.9)		
Day 57 - Swollen Joint	0.2 (-0.1 to 0.4)	0.0 (-0.2 to 0.3)		
Day 85 - Tender Joint	-0.5 (-1.3 to 0.2)	0.1 (-0.7 to 0.8)		
Day 85 - Swollen Joint	-0.0 (-0.3 to 0.2)	0.1 (-0.2 to 0.4)		
Day 113 - Tender Joint	-0.4 (-1.2 to 0.3)	-0.5 (-1.3 to 0.3)		
Day 113 - Swollen Joint	0.0 (-0.3 to 0.3)	0.1 (-0.2 to 0.4)		
Day 141 - Tender Joint	-0.2 (-1.0 to 0.6)	-0.2 (-1.0 to 0.6)		
Day 141 - Swollen Joint	0.2 (-0.1 to 0.5)	0.3 (0.0 to 0.6)		

Day 169 - Tender Joint	-0.1 (-0.9 to 0.7)	-0.7 (-1.4 to 0.1)		
Day 169 - Swollen Joint	0.2 (-0.1 to 0.5)	-0.0 (-0.3 to 0.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the CRP component of DAS28-CRP: Tender Swollen joint count less than 3

End point title	Change from Baseline in the CRP component of DAS28-CRP: Tender Swollen joint count less than 3
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End point description:

The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. CRP: measured lab value Positive Number = Increased level of CRP Negative Number = Reduced Level of CRP

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	31		
Units: mg/L				
arithmetic mean (confidence interval 95%)				
Day 29 - CRP	2.1 (-0.8 to 4.9)	1.8 (-1.2 to 4.7)		
Day 57 - CRP	0.5 (-2.3 to 3.4)	1.0 (-1.9 to 3.9)		
Day 85 - CRP	1.4 (-1.5 to 4.3)	0.1 (-2.8 to 3.1)		
Day 113 - CRP	1.3 (-1.6 to 4.1)	0.1 (-2.8 to 3.1)		
Day 141 - CRP	0.7 (-2.2 to 3.6)	0.8 (-2.1 to 3.8)		
Day 169 - CRP	0.2 (-2.7 to 3.1)	0.2 (-2.8 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Assessment of Disease Activity component of DAS28-CRP: Tender Swollen joint count less than 3

End point title	Change from Baseline in the Assessment of Disease Activity component of DAS28-CRP: Tender Swollen joint count less than 3
End point description: The mean change from baseline at all measured time points up to Day 169 in the individual components of DAS28-CRP. Assessment of Disease Activity: 0-100 scale [100=Most severe] Positive Numbers = Increased Disease Activity Negative Numbers = Decreased Diseased activity	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	31		
Units: Scores on a Scale				
arithmetic mean (confidence interval 95%)				
Day 29 - Assessment of Disease Activity	-10.3 (-19.3 to -1.4)	-11.8 (-21.3 to -2.3)		
Day 57 - Assessment of Disease Activity	-12.4 (-21.4 to -3.4)	-4.8 (-14.3 to 4.7)		
Day 85 - Assessment of Disease Activity	-14.0 (-23.0 to -5.0)	-13.5 (-23.0 to -4.0)		
Day 113 - Assessment of Disease Activity	-9.1 (-18.1 to 0.0)	-11.1 (-20.6 to -1.5)		
Day 141 - Assessment of Disease Activity	-10.6 (-19.8 to -1.5)	-15.3 (-24.8 to -5.7)		
Day 169 - Assessment of Disease Activity	-13.8 (-23.0 to -4.6)	-10.9 (-20.5 to -1.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Participants who achieve minimally clinically important change in ESSDAI in at least 3 points

End point title	Participants who achieve minimally clinically important change in ESSDAI in at least 3 points
End point description: Proportion of participants who achieve a minimally clinically important change (of at least 3 points) in the ESSDAI at all measured time points up to Day 169.	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Percentage				
number (confidence interval 95%)				
Day 29	37 (27.1 to 47.7)	34.7 (25.3 to 45.2)		
Day 57	37 (27.1 to 47.7)	44.2 (34.0 to 54.8)		
Day 85	48.9 (38.3 to 59.6)	50.5 (40.1 to 60.9)		
Day 113	55.4 (44.7 to 65.8)	50.5 (40.1 to 60.9)		
Day 141	51.1 (40.4 to 61.7)	56.8 (46.3 to 67.0)		
Day 169	55.4 (44.7 to 65.8)	57.9 (47.3 to 68.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Participants who achieve minimally clinically important change in ESSDAI in at least 5 points

End point title	Participants who achieve minimally clinically important change in ESSDAI in at least 5 points
End point description:	
Proportion of participants who achieve a minimally clinically important change (of at least 5 points) in the ESSDAI at all measured time points up to Day 169.	
End point type	Secondary
End point timeframe:	
Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Percentage				
number (confidence interval 95%)				
Day 29	19.6 (12.0 to 29.1)	13.7 (7.5 to 22.3)		
Day 57	26.1 (17.5 to 36.3)	24.2 (16.0 to 34.1)		
Day 85	34.8 (25.1 to 45.4)	32.6 (23.4 to 43.0)		
Day 113	37.0 (27.1 to 47.7)	36.8 (27.2 to 47.4)		

Day 141	37.0 (27.1 to 47.7)	36.8 (31.1 to 51.6)		
Day 169	35.9 (26.1 to 46.5)	46.3 (36.0 to 56.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Participants who achieve minimally clinically important change in ESSPRI in at least 1 point

End point title	Participants who achieve minimally clinically important change in ESSPRI in at least 1 point
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End point description:

Proportion of participants who achieve a minimally clinically important change (of at least 1 point) in the ESSPRI at all measured time points up to Day 169.

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Percentage				
number (confidence interval 95%)				
Day 29	31.5 (22.2 to 42.0)	38.9 (29.1 to 49.5)		
Day 57	42.4 (32.1 to 53.1)	47.4 (37.0 to 57.9)		
Day 85	44.6 (34.2 to 55.3)	55.8 (45.2 to 66.0)		
Day 113	42.4 (32.1 to 53.1)	52.6 (42.1 to 63.0)		
Day 141	40.2 (30.1 to 51.0)	54.7 (44.2 to 65.0)		
Day 169	41.3 (31.1 to 52.1)	52.6 (42.1 to 63.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at all measured time points in the ESSDAI

End point title	Change from baseline at all measured time points in the ESSDAI
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End point description:

The EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) total score is calculated as the sum of scores for activity level for each domain. The EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) Scoring Algorithm. Domain: (Score) Constitutional: (No=0, Low=3, Moderate=6) Lymphadenopathy: (No=0, Low=4, Moderate=8, High=12) Glandular: (No=0, Low=2, Moderate=4) Articular: (No=0, Low=2, Moderate=4, High=6) Cutaneous: (No=0, Low=3, Moderate=6, High=9) Pulmonary: (No=0, Low=5, Moderate=10, High=15) Renal: (No=0, Low=5, Moderate=10, High=15) Muscular: (No=0, Low=6, Moderate=12, High=18) Peripheral Nervous System (PNS): (No=0, Low=5, Moderate=10, High=15) Central Nervous System (CNS): (No=0, Moderate=10, High=15) Haematological: (No=0, Low=2, Moderate=4, High=6) Biological: (No=0, Low=1, Moderate=2) (No = No Disease Activity (DA), Low = Low DA, Moderate = Moderate DA, High = High DA) Overall score, which can range from 0 to 123, a higher score indicates more disease activity

End point type	Secondary
End point timeframe:	
Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Percent Change from Baseline				
arithmetic mean (confidence interval 95%)				
Day 29	-10.9 (-22.3 to 0.54)	-12.6 (-23.71 to -1.39)		
Day 57	-24.1 (-36.10 to -12.08)	-18.9 (-30.52 to -7.32)		
Day 85	-26.0 (-38.81 to -13.17)	-25.4 (-37.76 to -13.01)		
Day 113	-34.1 (-46.8 to -21.34)	-32.1 (-44.35 to -19.83)		
Day 141	-29.7 (-43.02 to -16.31)	-37.0 (-49.81 to -24.12)		
Day 169	-33.4 (-46.54 to -20.24)	-37.6 (-50.24 to -25.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline at all measured time points in the ESSPRI

End point title	Change from baseline at all measured time points in the ESSPRI
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End point description:

The total score EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) is calculated as the mean of the 3 individual components. Total Score Range (0 = Best outcome and 10 = Worst Outcome) The scores for the ESSPRI individual components will be used as such reported by the participants and entered in the case report form (CRF), without any further calculations. It consists of 3 questions covering cardinal symptoms of Sjögren's syndrome: dryness, fatigue and pain. Each domain scored on scale of 0-10 (0 =no symptom at all and 10 = worst symptom imaginable), and overall score is calculated as the mean of 3 individual domains.

End point type	Secondary
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End point timeframe:

Day 29, Day 57, Day 85, Day 113, Day 141, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Day 29	-0.32 (-0.79 to 0.16)	-0.54 (-1.00 to -0.08)		
Day 57	-0.81 (-1.32 to -0.31)	-0.82 (-1.31 to -0.33)		
Day 85	-0.83 (-1.34 to -0.32)	-1.20 (-1.70 to -0.70)		
Day 113	-0.79 (-1.32 to -0.26)	-1.37 (-1.88 to -0.86)		
Day 141	-0.87 (-1.40 to -0.35)	-1.32 (-1.83 to -0.81)		
Day 169	-1.03 (-1.55 to -0.50)	-1.30 (-1.80 to -0.79)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Components of ESSDAI

End point title	Change from Baseline in Components of ESSDAI
End point description: The EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) total score is calculated as the sum of scores for activity level for each domain. The EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) Scoring Algorithm. Domain: (Score for activity level) Constitutional: (No=0, Low=3, Moderate=6) Lymphadenopathy: (No=0, Low=4, Moderate=8, High=12) Glandular: (No=0, Low=2, Moderate=4) Articular: (No=0, Low=2, Moderate=4, High=6) Cutaneous: (No=0, Low=3, Moderate=6, High=9) Pulmonary: (No=0, Low=5, Moderate=10, High=15) Renal: (No=0, Low=5, Moderate=10, High=15) Muscular: (No=0, Low=6, Moderate=12, High=18) Peripheral Nervous System (PNS): (No=0, Low=5, Moderate=10, High=15) Central Nervous System (CNS): (No=0, Moderate=10, High=15) Haematological: (No=0, Low=2, Moderate=4, High=6) Biological: (No=0, Low=1, Moderate=2) (No = No Disease Activity, Low = Low Disease Activity, Moderate = Moderate Disease Activity, High = High Disease Activity)	
End point type	Secondary
End point timeframe: Day 29, Day 57, Day 85, Day 113, Day 141 and Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Day 29: Constitutional	-0.3 (-0.4 to - 0.1)	-0.4 (-0.5 to - 0.2)		
Day 29: Lymphadenopathy	-0.6 (-1.0 to - 0.2)	-0.5 (-0.9 to - 0.2)		
Day 29: Glandular	-0.2 (-0.4 to 0.0)	-0.2 (-0.4 to 0.0)		
Day 29: Articular	-0.4 (-0.8 to 0.0)	-0.3 (-0.7 to 0.1)		
Day 29: Cutaneous	-0.3 (-0.6 to - 0.0)	-0.2 (-0.5 to 0.1)		
Day 29: Pulmonary	0.0 (-0.3 to 0.3)	0.1 (-0.2 to 0.4)		
Day 29: Renal	-0.0 (-0.2 to 0.2)	-0.2 (-0.3 to 0.0)		
Day 29: Muscular	-0.0 (-0.1 to 0.1)	-0.0 (-0.1 to 0.1)		
Day 29: Peripheral Nervous System	-0.0 (-0.2 to 0.2)	0.0 (-0.2 to 0.20)		
Day 29: Haematological	0.2 (-0.0 to 0.4)	0.1 (-0.1 to 0.4)		
Day 29: Biological	0.1 (-0.1 to 0.2)	0.1 (-0.0 to 0.3)		
Day 57: Constitutional	-0.2 (-0.4 to - 0.0)	-0.3 (-0.5 to - 0.1)		
Day 57: Lymphadenopathy	-0.7 (-1.1 to - 0.2)	-0.6 (-1.0 to - 0.2)		
Day 57: Glandular	-0.4 (-0.7 to - 0.2)	-0.4 (-0.6 to - 0.1)		
Day 57: Articular	-0.7 (-1.1 to - 0.3)	-0.8 (-1.2 to - 0.4)		
Day 57: Cutaneous	-0.3 (-0.6 to - 0.0)	-0.2 (-0.5 to 0.1)		
Day 57: Pulmonary	-0.0 (-0.3 to 0.3)	0.2 (-0.1 to 0.5)		
Day 57: Renal	-0.0 (-0.2 to 0.2)	-0.1 (-0.3 to 0.1)		
Day 57: Muscular	-0.0 (-0.1 to 0.1)	-0.1 (-0.2 to - 0.0)		
Day 57: Peripheral Nervous System	-0.0 (-0.2 to 0.2)	0.0 (-0.2 to 0.2)		
Day 57: Haematological	0.1 (-0.1 to 0.4)	0.2 (-0.0 to 0.4)		
Day 57: Biological	-0.1 (-0.2 to 0.1)	0.0 (-0.1 to 0.2)		
Day 85: Constitutional	-0.3 (-0.5 to - 0.1)	-0.4 (-0.6 to - 0.2)		
Day 85: Lymphadenopathy	-0.7 (-1.1 to - 0.3)	-0.8 (-1.2 to - 0.4)		
Day 85: Glandular	-0.4 (-0.6 to - 0.1)	-0.5 (-0.7 to - 0.2)		
Day 85: Articular	-1.0 (-1.5 to - 0.6)	-1.1 (-1.6 to - 0.7)		

Day 85: Cutaneous	-0.4 (-0.7 to -0.0)	-0.2 (-0.5 to 0.1)		
Day 85: Pulmonary	0.0 (-0.3 to 0.4)	0.2 (-0.1 to 0.5)		
Day 85: Renal	-0.1 (-0.3 to 0.1)	-0.1 (-0.3 to 0.1)		
Day 85: Muscular	-0.1 (-0.2 to 0.0)	-0.0 (-0.1 to 0.1)		
Day 85: Peripheral Nervous System	-0.0 (-0.2 to 0.2)	0.0 (-0.2 to 0.2)		
Day 85: Haematological	0.1 (-0.1 to 0.3)	0.2 (-0.1 to 0.4)		
Day 85: Biological	0.0 (-0.1 to 0.2)	0.2 (0.0 to 0.3)		
Day 113: Constitutional	-0.3 (-0.5 to -0.0)	-0.3 (-0.5 to -0.1)		
Day 113: Lymphadenopathy	-0.8 (-1.2 to -0.4)	-0.9 (-1.3 to -0.5)		
Day 113: Glandular	-0.5 (-0.7 to -0.3)	-0.5 (-0.8 to -0.3)		
Day 113: Articular	-1.3 (-1.8 to -0.8)	-1.3 (-1.7 to -0.8)		
Day 113: Cutaneous	-0.4 (-0.7 to -0.1)	-0.4 (-0.7 to -0.1)		
Day 113: Pulmonary	0.0 (-0.3 to 0.4)	0.1 (-0.2 to 0.5)		
Day 113: Renal	-0.1 (-0.3 to 0.1)	0.0 (-0.2 to 0.2)		
Day 113: Muscular	-0.0 (-0.1 to 0.1)	-0.1 (-0.2 to 0.0)		
Day 113: Peripheral Nervous System	-0.0 (-0.2 to 0.2)	-0.0 (-0.2 to 0.1)		
Day 113: Haematological	0.1 (-0.2 to 0.3)	0.2 (-0.0 to 0.4)		
Day 113: Biological	-0.0 (-0.2 to 0.1)	0.1 (-0.0 to 0.3)		
Day 141: Constitutional	-0.2 (-0.4 to 0.0)	-0.4 (-0.6 to -0.2)		
Day 141: Lymphadenopathy	-0.6 (-1.1 to -0.2)	-0.9 (-1.4 to -0.5)		
Day 141: Glandular	-0.5 (-0.7 to -0.2)	-0.6 (-0.8 to -0.4)		
Day 141: Articular	-1.2 (-1.7 to -0.8)	-1.4 (-1.9 to -1.0)		
Day 141: Cutaneous	-0.4 (-0.7 to -0.1)	-0.5 (-0.8 to -0.3)		
Day 141: Pulmonary	-0.0 (-0.4 to 0.3)	0.1 (-0.2 to 0.4)		
Day 141: Renal	-0.0 (-0.2 to 0.2)	-0.1 (-0.3 to 0.1)		
Day 141: Muscular	-0.1 (-0.2 to 0.0)	-0.1 (-0.2 to 0.0)		
Day 141: Peripheral Nervous System	-0.1 (-0.3 to 0.1)	-0.0 (-0.2 to 0.1)		
Day 141: Haematological	0.1 (-0.1 to 0.4)	0.1 (-0.1 to 0.4)		
Day 141: Biological	-0.0 (-0.2 to 0.1)	0.1 (-0.0 to 0.2)		
Day 169: Constitutional	-0.3 (-0.5 to -0.1)	-0.4 (-0.6 to -0.2)		
Day 169: Lymphadenopathy	-0.9 (-1.3 to -0.5)	-1.1 (-1.4 to -0.7)		

Day 169: Glandular	-0.4 (-0.6 to -0.1)	-0.5 (-0.8 to -0.3)		
Day 169: Articular	-1.4 (-1.8 to -0.9)	-1.8 (-2.2 to -1.4)		
Day 169: Cutaneous	-0.3 (-0.7 to 0.0)	-0.5 (-0.9 to -0.2)		
Day 169: Pulmonary	-0.0 (-0.4 to 0.3)	0.1 (-0.2 to 0.4)		
Day 169: Renal	-0.0 (-0.2 to 0.2)	0.0 (-0.2 to 0.2)		
Day 169: Muscular	-0.0 (-0.1 to 0.1)	-0.1 (-0.2 to 0.0)		
Day 169: Peripheral Nervous	-0.1 (-0.3 to 0.1)	-0.0 (-0.2 to 0.2)		
Day 169: Haematological	0.1 (-0.2 to 0.3)	0.3 (0.1 to 0.5)		
Day 169: Biological	0.0 (-0.1 to 0.2)	0.2 (0.0 to 0.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in ESSPRI Components

End point title	Change from Baseline in ESSPRI Components
End point description:	
The total score EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) is calculated as the mean of the 3 individual components. Total Score Range (0 = Best outcome and 10 = Worst Outcome) The scores for the ESSPRI individual components will be used as such reported by the participants and entered in the case report form (CRF), without any further calculations. It consists of 3 questions covering cardinal symptoms of Sjögren's syndrome: dryness, fatigue and pain. Each domain scored on scale of 0-10 (0 =no symptom at all and 10 = worst symptom imaginable), and overall score is calculated as the mean of 3 individual domains.	
End point type	Secondary
End point timeframe:	
Day 29, Day 57, Day 85, Day 113, Day 141, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Day 29: Dryness Score	-0.21 (-0.76 to 0.34)	-0.26 (-0.80 to 0.28)		
Day 29: Fatigue Score	-0.57 (-1.18 to 0.03)	-1.01 (-1.60 to -0.42)		
Day 29: Pain Score	-0.34 (-0.96 to 0.27)	-0.53 (-1.13 to 0.07)		

Day 57: Dryness Score	-0.92 (-1.51 to -0.33)	-0.52 (-1.09 to 0.05)		
Day 57: Fatigue Score	-1.09 (-1.70 to -0.48)	-1.22 (-1.81 to -0.63)		
Day 57: Pain Score	-0.60 (-1.24 to 0.05)	-0.90 (-1.52 to -0.27)		
Day 85: Dryness Score	-0.68 (-1.25 to -0.11)	-0.91 (-1.46 to -0.36)		
Day 85: Fatigue Score	-1.27 (-1.91 to -0.63)	-1.56 (-2.18 to -0.94)		
Day 85: Pain Score	-0.70 (-1.35 to -0.05)	-1.31 (-1.93 to -0.68)		
Day 113: Dryness Score	-0.74 (-1.36 to -0.12)	-1.19 (-1.79 to -0.60)		
Day 113: Fatigue Score	-1.02 (-1.65 to -0.39)	-1.76 (-2.37 to -1.15)		
Day 113: Pain Score	-0.76 (-1.40 to -0.11)	-1.37 (-1.99 to -0.74)		
Day 141: Dryness Score	-0.89 (-1.49 to -0.28)	-1.05 (-1.63 to -0.46)		
Day 141: Fatigue Score	-1.18 (-1.83 to -0.53)	-1.73 (-2.36 to -1.11)		
Day 141: Pain Score	-0.70 (-1.34 to -0.07)	-1.39 (-2.00 to -0.78)		
Day 169: Dryness Score	-0.84 (-1.46 to -0.23)	-1.04 (-1.63 to -0.44)		
Day 169: Fatigue Score	-1.28 (-1.93 to -0.64)	-1.57 (-2.19 to -0.95)		
Day 169: Pain Score	-1.11 (-1.75 to -0.47)	-1.45 (-2.06 to -0.83)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Schirmer's test

End point title	Change from Baseline in Schirmer's test
End point description: The Mean change from baseline in Schirmer's Test at all measured time points up to day 169 The length in millimeters that the strip wets during the 5 minute test period for each eye. Collection is done separately for each eye.	
End point type	Secondary
End point timeframe: Day 85, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: millimeters				
arithmetic mean (confidence interval)				

95%)				
Day 85: Study Eye	1.9 (-0.0 to 3.9)	1.5 (-0.5 to 3.5)		
Day 85: Non-Study Eye	0.1 (-2.0 to 2.2)	0.8 (-1.2 to 2.9)		
Day 85: Average of Both Eyes	1.10 (-0.75 to 2.96)	1.41 (-0.43 to 3.24)		
Day 169: Study Eye	1.7 (-0.4 to 3.9)	1.0 (-1.1 to 3.2)		
Day 169: Non-Study Eye	0.6 (-1.3 to 2.4)	0.2 (-1.7 to 2.1)		
Day 169: Average of Both Eyes	1.21 (-0.59 to 3.00)	0.82 (-0.97 to 2.61)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Ocular Staining Score (OSS)

End point title	Change from Baseline in the Ocular Staining Score (OSS)
End point description:	
The Mean change from baseline in OSS at all measured time points up to day 169 Score of 0 = No Staining Score of 12 = diffuse staining The total score will be calculated as the sum of the score for these parameters for each eye. Medial Nasal Bulbar Conjunctiva (MNBC) [score scale: 0 - 3], Corneal (CORN) Staining of Punctate Epithelial Erosions (PEE) [score scale: 0 - 3], Lateral Temporal Bulbar Conjunctiva (LTBC) [score scale: 0 - 3], Patches of Confluent Staining (CONF) [score scale: 0 - 1], PEE observed in the pupil region, i.e. central 4mm diameter portion of the cornea (PUPL) [score scale: 0 - 1], one of more filaments seen anywhere on the cornea (FILA) [score scale: 0 - 1]	
End point type	Secondary
End point timeframe:	
Day 85, Day 169	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Day 85: Study Eye	-1.7 (-2.5 to -0.9)	-0.5 (-1.3 to 0.3)		
Day 85: Non-Study Eye	-0.6 (-1.4 to 0.2)	0.4 (-0.4 to 1.2)		
Day 85: Average of Both Eyes	-1.15 (-1.91 to -0.39)	-0.06 (-0.81 to 0.68)		
Day 169: Study Eye	-1.5 (-2.3 to -0.6)	-0.7 (-1.6 to 0.1)		
Day 169: Non-Study Eye	-0.5 (-1.3 to 0.3)	0.3 (-0.5 to 1.2)		
Day 169: Average of Both Eyes	-0.99 (-1.79 to -0.19)	-0.19 (-0.98 to 0.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Tear Break-up Time

End point title	Change from Baseline in Tear Break-up Time
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End point description:

The Mean change from baseline in Tear Break-up Time at all measured time points up to day 169 The CRF collects the time in seconds to first appearance of a random dry spot on the corneal surface for 3 repetitions in each eye. The average time will be calculated for each eye averaging the 3 measurements for each eye separately. In case only 2 measurements are available, the average of the 2 measurements will be calculated. In case there is only 1 measurement, that measurement will be used for the analysis.

End point type	Secondary
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End point timeframe:

Day 85, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Seconds				
arithmetic mean (confidence interval 95%)				
Day 85: Study Eye	-0.13 (-0.99 to 0.73)	0.18 (-0.67 to 1.04)		
Day 85: Non-Study Eye	-0.70 (-1.59 to 0.18)	-0.12 (-1.01 to 0.76)		
Day 85: Average of Both Eyes	-0.41 (-1.24 to 0.43)	0.09 (-0.74 to 0.92)		
Day 169: Study Eye	-0.23 (-1.11 to 0.64)	-0.32 (-1.19 to 0.56)		
Day 169: Non-Study Eye	-0.79 (-1.62 to 0.03)	-0.62 (-1.46 to 0.21)		
Day 169: Average of Both Eyes	-0.50 (-1.32 to 0.31)	-0.43 (-1.25 to 0.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Unstimulated Salivary Flow

End point title	Change from Baseline in Unstimulated Salivary Flow
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End point description:

The mean change from baseline in unstimulated whole salivary flow at all measured time points up to Day 169.

End point type	Secondary
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End point timeframe:

Day 85, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: mL/min				
arithmetic mean (confidence interval 95%)				
Day 85	0.106 (-0.037 to 0.249)	0.158 (0.022 to 0.295)		
Day 169	0.051 (-0.100 to 0.203)	0.105 (-0.042 to 0.251)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Stimulated Salivary Flow

End point title	Change from Baseline in Stimulated Salivary Flow
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End point description:

The mean change from baseline in Stimulated whole salivary flow at all measured time points up to Day 169.

End point type	Secondary
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End point timeframe:

Day 85, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: mL/min				
arithmetic mean (confidence interval 95%)				
Day 85	0.11 (-0.039 to 0.262)	0.169 (0.024 to 0.314)		
Day 169	0.056 (-0.104 to 0.216)	0.108 (-0.048 to 0.263)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Numeric Rating Scale for Mouth Dryness

End point title	Change from Baseline in Numeric Rating Scale for Mouth Dryness
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End point description:

The mean change from baseline in participant symptoms using the Numeric Rating Scale (NRS) for mouth dryness at all measured time points up to Day 169. The oral and ocular dryness are each assessed by the patients with numeric rating scales from 0 to 10 with 0 representing no dryness and 10 representing maximal dryness

End point type	Secondary
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End point timeframe:

Day 1, 29, 57, 85, 113, 141, 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (full range (min-max))				
Day 29	-0.8 (-8 to 3)	-0.5 (-7 to 6)		
Day 57	-1.3 (-8 to 5)	-0.9 (-7 to 6)		
Day 85	-1.3 (-9 to 4)	-1.1 (-6 to 8)		
Day 113	-1.2 (-9 to 3)	-1.3 (-8 to 4)		
Day 141	-1.3 (-8 to 5)	-1.1 (-6 to 6)		
Day 169	-1.3 (-8 to 3)	-1.2 (-6 to 8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Numeric Rating Scale for Eye Dryness

End point title	Change from Baseline in Numeric Rating Scale for Eye Dryness
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End point description:

The mean change from baseline in patient symptoms using the Numeric Rating Scale (NRS) for eye dryness at all measured time points up to Day 169. The oral and ocular dryness are each assessed by the patients with numeric rating scales from 0 to 10 with 0 representing no dryness and 10 representing maximal dryness

End point type	Secondary
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End point timeframe:

Day 1, 29, 57, 85, 113, 141, 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (full range (min-max))				
Day 29	-0.4 (-8 to 5)	-0.3 (-6 to 5)		
Day 57	-0.9 (-7 to 5)	-0.6 (-6 to 5)		
Day 85	-0.9 (-7 to 6)	-0.8 (-7 to 8)		
Day 113	-1.0 (-7 to 7)	-1.1 (-8 to 4)		
Day 141	-0.8 (-7 to 7)	-1.0 (-7 to 4)		
Day 169	-0.9 (-5 to 6)	-1.0 (-7 to 5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in participant assessment of disease activity

End point title	Change from Baseline in participant assessment of disease activity
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End point description:

The participant global assessment of disease activity are assessed with visual analog scales. The participant marks a vertical line through a horizontal line, where the beginning of the horizontal line represents the best situation, and the end of the horizontal line represents the very worst situation. The CRF collects the distance in millimeters from the start of the scale that is marked as well as the length of the scale in millimeters. In cases that the length of the scale is in less or more than 100 millimeters, then the participants measurement will be rescaled to the equivalent of 100 millimeters using the formula below: Rescale Measurement in mm = (measurement as reported on CRF in mm/length of the line on CRF in mm) * 100mm A negative score = participant assessment of disease activity has improved A positive score = participant assessment of disease activity has worsened

End point type	Secondary
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End point timeframe:

Day 29, 57, 85, 113, 141, 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on VAS 0-100mm scale				
arithmetic mean (confidence interval 95%)				

Day 29	-4.0 (-9.8 to 1.7)	-7.1 (-12.7 to 1.4)		
Day 57	-7.5 (-13.4 to 1.7)	-6.3 (-11.9 to 0.6)		
Day 85	-10.4 (-16.3 to -4.4)	-10.2 (-16.0 to -4.4)		
Day 113	-8.0 (-14.0 to 2.0)	-9.7 (-15.5 to 3.9)		
Day 141	-5.1 (-11.0 to 0.8)	-11.0 (-16.7 to -5.3)		
Day 169	-10.1 (-16.1 to -4.0)	-9.0 (-14.8 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in physician global assessment of disease activity

End point title	Change from Baseline in physician global assessment of disease activity
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End point description:

The physician global assessment of disease activity are assessed with visual analog scales. The physician marks a vertical line through a horizontal line, where the beginning of the horizontal line represents the best situation, and the end of the horizontal line represents the very worst situation. The CRF collects the distance in millimeters from the start of the scale that is marked as well as the length of the scale in millimeters. In cases that the length of the scale is in less or more than 100 millimeters, then the participants measurement will be rescaled to the equivalent of 100 millimeters using the formula below:
Rescale Measurement in mm = (measurement as reported on CRF in mm/length of the line on CRF in mm) * 100mm
A negative score = physician assessment of disease activity has improved
A positive score = physician assessment of disease activity has worsened

End point type	Secondary
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End point timeframe:

Day 29, 57, 85, 113, 141, 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on VAS 0-100mm Scale				
arithmetic mean (confidence interval 95%)				
Day 29	-10.3 (-14.8 to -5.8)	-10.5 (-14.9 to -6.1)		
Day 57	-16.2 (-20.8 to -11.7)	-16.7 (-21.1 to -12.3)		
Day 85	-20.8 (-25.6 to -16.0)	-19.4 (-24.0 to -14.7)		
Day 113	-22.8 (-27.9 to -17.8)	-19.8 (-24.6 to -14.9)		
Day 141	-23.7 (-28.6 to -18.8)	-21.7 (-26.5 to -17.0)		

Day 169	-23.0 (-27.8 to -18.2)	-23.7 (-28.3 to -19.0)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Patient Fatigue

End point title	Change from Baseline in Patient Fatigue
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End point description:

The mean change from baseline in patient fatigue using Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue assessment of disease activity at all measured time points up to Day 169. PROMIS Fatigue instruments 10 Questions ranging from a score 0 to 40. Sum of the values gives you the raw sum. The raw is inputted into this formula to give you the raw score: Raw Score = (Raw sum*number of items on the short form)/(Number of items that were actually answered) Raw score is translated to a T-Score using a table. T-Score is used as the final score. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10. The standardized T-score is reported as the final score for each participant. A negative T Score = Better Prognosis A positive T Score = Worse prognosis

End point type	Secondary
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End point timeframe:

Day 29, 57, 85, 113, 141, 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: T-Score				
arithmetic mean (confidence interval 95%)				
Day 29	-3.08 (-5.22 to -0.95)	-3.99 (-6.09 to -1.88)		
Day 57	-4.12 (-6.27 to -1.97)	-4.02 (-6.12 to -1.91)		
Day 85	-4.85 (-7.05 to -2.64)	-5.48 (-7.64 to -3.32)		
Day 113	-4.17 (-6.37 to -1.97)	-5.32 (-7.48 to -3.17)		
Day 141	-4.84 (-7.06 to -2.62)	-5.68 (-7.85 to -3.52)		
Day 169	-5.56 (-7.83 to -3.28)	-5.59 (-7.82 to -3.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Female Sexual Function using the Female Sexual Function Index (FSFI)

End point title	Change from Baseline in Female Sexual Function using the Female Sexual Function Index (FSFI)
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End point description:

For the FSFI, is a 19 item instrument used for assessing key dimensions of female sexual function over the past 4 weeks with 6 domains being analyzed. The specific domains (desire, arousal, lubrication, orgasm, satisfaction, and pain) analyzed in the FSFI are scored on a scale ranging from 0 to 5, with higher scores indicating better performance. Domain scores are calculated by summing the scores of the individual questions that make up the domain and multiplying the sum by the factor in the table below. The full scale score is the sum of the six domain scores. Full Scale Score range: 2.0(minimum score) - 36.0 (maximum score) Negative Score = Reduced functioning Positive Score = Improved functioning

End point type	Secondary
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End point timeframe:

Day 85, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: Scores on a Scale				
arithmetic mean (confidence interval 95%)				
Day 85	-2.44 (-5.67 to 0.78)	-1.56 (-4.90 to 1.77)		
Day 169	-2.32 (-5.73 to 1.09)	-1.87 (-5.42 to 1.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in 36-item Short Form Health Survey (SF-36)

End point title	Change from Baseline in 36-item Short Form Health Survey (SF-36)
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End point description:

The SF-36 determines participants' overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Scores on each item are summed and averaged (range: 0=worst to 100=best). Increases from baseline indicate improvement

End point type	Secondary
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End point timeframe:

Day 85, Day 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Day 85: Physical Function	1.908 (-0.240 to 4.056)	1.523 (-0.568 to 3.614)		
Day 85: Role Physical	5.248 (3.112 to 7.383)	4.416 (2.321 to 6.511)		
Day 85: Bodily Pain	3.200 (0.910 to 5.490)	3.721 (1.464 to 5.978)		
Day 85: General Health	4.042 (1.938 to 6.146)	3.409 (1.363 to 5.456)		
Day 85: Vitality	3.827 (1.269 to 6.384)	3.859 (1.335 to 6.382)		
Day 85: Social Functioning	3.020 (0.296 to 5.744)	4.771 (2.117 to 7.426)		
Day 85: Role-Emotional	3.024 (0.214 to 5.834)	4.834 (2.093 to 7.576)		
Day 85: Mental Health	2.942 (0.458 to 5.425)	2.287 (-0.135 to 4.709)		
Day 85: Physical component Summary	3.430 (1.615 to 5.244)	2.686 (0.904 to 4.468)		
Day 85: Mental component Summary	2.693 (0.160 to 5.226)	3.672 (1.208 to 6.136)		
Day 169: Physical Function	2.927 (0.593 to 5.261)	1.742 (-0.505 to 3.989)		
Day 169: Role-Physical	5.853 (3.756 to 7.949)	4.626 (2.604 to 6.649)		
Day 169: Bodily Pain	3.842 (1.432 to 6.252)	3.458 (1.114 to 5.801)		
Day 169: General Health	3.880 (1.700 to 6.060)	3.764 (1.665 to 5.862)		
Day 169: Vitality	3.742 (1.160 to 6.324)	4.523 (2.005 to 7.041)		
Day 169: Social functioning	4.125 (1.320 to 6.929)	4.471 (1.773 to 7.169)		
Day 169: Role-Emotional	4.653 (1.943 to 7.364)	4.930 (2.334 to 7.526)		
Day 169: Mental Health	2.375 (-0.116 to 4.866)	2.972 (0.581 to 5.363)		
Day 169: Physical Component Summary	3.998 (2.045 to 5.951)	2.650 (0.756 to 4.543)		
Day 169: Mental Component Summary	2.940 (0.368 to 5.512)	4.112 (1.648 to 6.577)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric mean of trough concentration (Cmin) of Abatacept

End point title	Geometric mean of trough concentration (Cmin) of Abatacept
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End point description:

Geometric mean of trough concentration (Cmin) of abatacept at all measured time points.

End point type	Secondary
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End point timeframe:

Day 29, 85, 113, 141, 169

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	0 ^[1]		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Day 29	21.401 (± 36)	()		
Day 85	27.543 (± 38.4)	()		
Day 113	25.567 (± 42.1)	()		
Day 141	25.870 (± 40.8)	()		
Day 169	24.522 (± 42.7)	()		

Notes:

[1] - Data is only applicable for study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Positive Antibody Response

End point title	Percentage of Participants with a Positive Antibody Response
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End point description:

Percentage of participants with at least one positive immunogenicity response up to Day 169 and during 3 months follow up (for participants who discontinue during the 6-months double-blind).

End point type	Secondary
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End point timeframe:

Day 85 db, day 169 db, post treatment day 85

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	0 ^[2]		
Units: Percentage				
number (not applicable)				
Study Day 169	1.2			
Post Treatment Day 85 (DB)	0			
Post Treatment Day 169 (DB)	0			

Notes:

[2] - data only applicable for study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of Adverse Events: Double Blind Period

End point title	Summary of Adverse Events: Double Blind Period
End point description:	
Percentage of participants with adverse events, deaths, serious adverse events and adverse events leading to discontinuation	
End point type	Secondary
End point timeframe:	
Day 1 up to first dose of Open Label Treatment Period (OLTP) abatacept or up to 56 post last dose in double -blind for those not in OL.	

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	95		
Units: Percentage				
number (not applicable)				
Adverse Events (AEs)	85.9	71.6		
Deaths	0	1.1		
Serious Adverse Events	9.8	3.2		
Discontinuation due to AEs	3.3	2.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Laboratory Marked Abnormalities: Double Blind Period

End point title	Laboratory Marked Abnormalities: Double Blind Period
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End point description:

Laboratory values meeting the marked abnormality criteria 9999 = not available

End point type	Secondary
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End point timeframe:

Day 1 up to first dose of OL abatacept or up to 56 post last dose in double -blind for those not in OL.

End point values	Abatacept - Double Blind Treatment Period	Placebo - Double Blind Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	95		
Units: Percentage				
number (not applicable)				
Hematocrit High	9999	9999		
Hematocrit Low	0	0		
Hemoglobin High	9999	9999		
Hemoglobin Low	0	0		
Platelet count High	0	0		
Platelet count low	0	0		
Leukocytes high	1.1	0		
Leukocytes low	12.1	8.4		
Basophils high	0	0		
Basophils Low	9999	9999		
Eosinophils High	4.4	1.1		
Eosinophils Low	9999	9999		
lymphocytes high	0	0		
lymphocytes low	9.9	14.7		
Monocytes high	0	0		
Monocytes Low	9999	9999		
Neutrophils+Bands High	9999	9999		
Neutrophils+Bands Low	6.6	1.1		
Alanine Aminotransferase High	1.1	2.1		
Alkaline Phosphatase High	0	0		
Aspartate Aminotransferase High	1.1	3.2		
Bilirubin, Total High	0	0		
G-Glutamyl Transferase High	6.6	1.1		
Blood Urea Nitrogen High	1.1	1.1		
Creatinine High	0	0		
Calcium High	0	0		
Calcium Low	1.1	0		
Chloride High	0	0		
Chloride Low	1.1	0		
Phosphorus High	0	0		
Phosphorus Low	0	1.1		
Potassium High	0	0		
Potassium Low	1.1	0		
Sodium High	0	1.1		
Sodium Low	2.2	0		
Glucose, Serum High	0	1.1		

Glucose, Serum Low	2.2	5.3		
Albumin High	9999	9999		
Albumin Low	2.2	1.1		
Protein, Total High	2.2	3.2		
Protein, Total Low	1.1	0		
Creatine Kinase High	0	4.2		
Blood, Urine High	14.3	9.5		
Blood, Urine Low	9999	9999		
Glucose, Urine High	0	0		
Glucose, Urine Low	9999	9999		
Protein, Urine High	2.2	3.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of Adverse Events: Open Label Cumulative Abatacept Period

End point title	Summary of Adverse Events: Open Label Cumulative Abatacept Period
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End point description:

Percentage of participants with adverse events, deaths, serious adverse events and adverse events leading to discontinuation

End point type	Secondary
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End point timeframe:

Day 1 up to first dose of Open Label Treatment Period (OLTP) abatacept or up to 56 post last dose in double -blind for those not in OL.

End point values	Abatacept - Open Label Treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	178			
Units: Percentage				
number (not applicable)				
Adverse Events (AEs)	78.7			
Deaths	0.6			
Serious Adverse Events (SAEs)	14.6			
Discontinuation due to AEs	5.6			
Related Serious Adverse Events	3.4			
Discontinued due to SAEs	3.4			
Related AEs	40.4			

Statistical analyses

Secondary: Laboratory Marked Abnormalities: Open Label Cumulative Abatacept Period

End point title	Laboratory Marked Abnormalities: Open Label Cumulative Abatacept Period
End point description: Laboratory values meeting the marked abnormality criteria	
End point type	Secondary
End point timeframe: Day 1 up to first dose of OL abatacept or up to 56 post last dose in double -blind for those not in OL.	

End point values	Abatacept - Open Label Treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	177			
Units: Percentage				
number (not applicable)				
Hematocrit High	9999			
Hematocrit Low	0			
Hemoglobin High	9999			
Hemoglobin Low	0.6			
Platelet count High	0			
Platelet count low	0.6			
Leukocytes high	0.6			
Leukocytes low	18.6			
Basophils high	0.6			
Basophils Low	9999			
Eosinophils High	5.6			
Eosinophils Low	9999			
lymphocytes high	0			
lymphocytes low	12.4			
Monocytes high	0			
Monocytes Low	9999			
Neutrophils+Bands High	9999			
Neutrophils+Bands Low	7.3			
Alanine Aminotransferase High	1.7			
Alkaline Phosphatase High	0.6			
Aspartate Aminotransferase High	1.1			
Bilirubin, Total High	0			
G-Glutamyl Transferase High	5.6			
Blood Urea Nitrogen High	1.7			
Creatinine High	0.6			
Calcium High	0			
Calcium Low	1.1			
Chloride High	0			
Chloride Low	1.1			
Phosphorus High	0.6			

Phosphorus Low	1.1			
Potassium High	0.6			
Potassium Low	0.6			
Sodium High	0.6			
Sodium Low	1.7			
Glucose, Serum High	0.6			
Glucose, Serum Low	5.1			
Albumin High	9999			
Albumin Low	1.7			
Protein, Total High	4.0			
Protein, Total Low	0.6			
Creatine Kinase High	2.3			
Blood, Urine High	14.7			
Blood, Urine Low	9999			
Glucose, Urine High	0			
Glucose, Urine Low	9999			
Protein, Urine High	5.6			
WBC, Urine High	100.0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) were reported from start treatment up to 56 days post last treatment of double blind period.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects were subcutaneously administered with matching placebo of Abatacept in 1 mL pre-filled syringe once a week.

Reporting group title	Abatacept
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Reporting group description:

Subjects were subcutaneously administered with 125 milligrams per millilitre of Abatacept in 1 mL pre-filled syringe once a week.

Serious adverse events	Placebo	Abatacept	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 95 (3.16%)	9 / 92 (9.78%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 95 (1.05%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			

Anaphylactoid reaction			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 95 (1.05%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic cyst ruptured			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia bacterial			

subjects affected / exposed	0 / 95 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 95 (1.05%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

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

Non-serious adverse events	Placebo	Abatacept	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 95 (42.11%)	47 / 92 (51.09%)	
Nervous system disorders			
Headache			
subjects affected / exposed	9 / 95 (9.47%)	10 / 92 (10.87%)	
occurrences (all)	9	21	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 95 (0.00%)	5 / 92 (5.43%)	
occurrences (all)	0	5	
Diarrhoea			
subjects affected / exposed	4 / 95 (4.21%)	11 / 92 (11.96%)	
occurrences (all)	4	24	
Nausea			
subjects affected / exposed	4 / 95 (4.21%)	9 / 92 (9.78%)	
occurrences (all)	4	21	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 95 (4.21%)	5 / 92 (5.43%)	
occurrences (all)	4	5	
Oropharyngeal pain			
subjects affected / exposed	1 / 95 (1.05%)	6 / 92 (6.52%)	
occurrences (all)	1	6	
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	1 / 95 (1.05%) 1	5 / 92 (5.43%) 5	
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	2 / 95 (2.11%) 2	5 / 92 (5.43%) 5	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	18 / 95 (18.95%) 22 7 / 95 (7.37%) 7 8 / 95 (8.42%) 9	11 / 92 (11.96%) 13 9 / 92 (9.78%) 9 6 / 92 (6.52%) 8	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 August 2016	<p>To provide clear differentiate between discontinuation of study treatment from discontinuation from the study.</p> <ul style="list-style-type: none">o Subjects who discontinue investigational product during the Double-Blind Treatment Period should continue to comply with all protocol specified procedures during the Double-Blind Treatment Period.o Define the assessments required for the collection of follow-up data. <p>To clarify inclusion/exclusion criteria To clarify testing for stimulated salivary flow Add allowable window for obtaining the optional biopsy samples. Modify laboratory testing to limit to the most critical tests and to adjust for feasibility issues. Add additional secondary and exploratory endpoints. Increase the total number of subjects targeted for enrollment in order to increase statistical power and the overall size of the safety database. Revise appendices to include most current versions. Corrections to minor typographical errors</p>
22 November 2016	<p>Updated ACR EULAR Classification Criteria for Primary Sjögren's syndrome from proposed 2015 criteria to 2016 criteria. Corrected typographical error for stimulated salivary flow procedure Corrected Appendix 11 with correct example of PROMIS Fatigue questionnaire</p>
17 March 2017	<p>Update contact information for the Medical Monitor, add Study Director and contact information. Update the Study Design Section and Schematic to include Day 169. Add stratification criteria for Japan. Clarify potential reason for extended screening visit. Clarify exclusion criteria for DMARDs and eye surgeries and clarify restrictions for corticosteroids Allow for the use of glaucoma eye drops and autologous serum eye drops. Clarify criteria for discontinuation of study therapy. Update Study Assessments and procedure clarifications Update the statistical section with stratification for Japan and HA request from Germany. Add Appendix 14 for Topical corticosteroids (low potency/Class VI and VII) Corrections to typographical errors and reconcile inconsistencies.</p>

06 June 2017	<p>Clarify exclusion criterion for severe renal involvement.</p> <p>Add exclusion criterion for herbal supplements and remedies.</p> <p>Add restriction for use of contact lenses</p> <p>Clarify corticosteroid use</p> <p>Add restriction for use of hyaluronate eye drops</p> <p>Add domain by domain guidance and/or clarification to non-protocol specified procedures and tests.</p> <p>Add lab testing for serum protein electrophoresis and cryoglobulins to all visits at which the ESSDAI is assessed.</p> <p>Corrections to typographical errors and reconcile inconsistencies.</p>
23 July 2018	<p>Correct description of ESSDAI change 5</p> <p>Update definition for Serious Breach</p> <p>Align language for the post dose follow-up visits</p> <p>Modify use of anti-histamines</p> <p>Provide guidance for concomitant medication use for subjects continuing beyond Day 365 or Day 533 in Japan.</p> <p>Clarify number of missed consecutive doses resulting in discontinuation.</p> <p>Correct section text for collection of weight to align with Time and Events table</p> <p>Modify footnote to Table 5.6.1-1 to align with Time and Events schedule.</p> <p>Minor formatting and typographical corrections</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported