Clinical trial results:
A Phase 2, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Lulizumab Pegol vs. Placebo on a Background of Limited Standard of Care in the Treatment of Subjects With Active Systemic Lupus Erythematosus

Summary

EudraCT number	2014-002184-14
Trial protocol	ES DE HU IT NL
Global end of trial date	26 October 2017

Results information

Result version number	v1 (current)
This version publication date	10 November 2018
First version publication date	10 November 2018

Trial information

Trial identification

Sponsor protocol code	IM128-027

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02265744
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	26 October 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 October 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary study objective was to compare the proportion of patients who achieved BICLA response (BICLA response rate) at Day 169 following 24-week treatment with BMS-931699 or placebo administered on a stable background therapy.

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	13 November 2014
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	United States: 53
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Colombia: 8
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Argentina: 20
Country: Number of subjects enrolled	Korea, Republic of: 6
Country: Number of subjects enrolled	Taiwan: 9
Country: Number of subjects enrolled	Chile: 17
Country: Number of subjects enrolled	Poland: 14
Country: Number of subjects enrolled	Brazil: 58
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	South Africa: 15
Country: Number of subjects enrolled	Peru: 25
Country: Number of subjects enrolled	Mexico: 62
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Japan: 25

Country: Number of subjects enrolled	Russian Federation: 5
Worldwide total number of subjects	346
EEA total number of subjects	38

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)	336
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

730 participants were enrolled and 349 were randomized. 3 were randomized but not treated.Of the 381 who were not randomized,3 had an adverse event, 16 withdrew consent, 1 was lost to follow-up, 339 did not meet study entry criteria and 22 due to other reasons.

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental:12.5mg SC BMS-931699 Weekly

Arm description:

12.5mg subcutaneous (SC) injection Weekly dosing

Arm type	Experimental
Investigational medicinal product name	BMS-931699
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

12.5mg subcutaneous (SC) injection Weekly dosing

Arm title	Experimental:12.5mg SC BMS-931699 Every other Week

Arm description:

12.5mg SC injection Every other Week dosing

Arm type	Experimental
Investigational medicinal product name	BMS-931699
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

12.5mg SC injection Every other Week dosing

Arm title	Experimental: 5mg SC BMS-931699 Every other Week

Arm description:

5mg SC injection Every other Week dosing

Arm type	Experimental
Investigational medicinal product name	BMS-931699
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details: 5mg SC injection Every other Week dosing	

Arm title	Experimental: 1.25mg SC BMS-931699 Every other Week
Arm description: 1.25mg SC injection Every other Week dosing	
Arm type	Experimental
Investigational medicinal product name	5mg SC injection Every other Week dosing
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 1.25mg SC injection Every other Week dosing	
Arm title	Placebo Comparator: 0mg SC BMS-931699 Weekly
Arm description: 0mg SC injection Weekly dosing	
Arm type	Placebo
Investigational medicinal product name	BMS-391699 Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 0mg SC injection weekly dosing	

Number of subjects in period 1	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week
Started	69	68	68
Completed	49	53	51
Not completed	20	15	17
Reason not provided by investigator	1	-	-
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	-	-
Adverse event, non-fatal	8	4	9
Participant request to discontinue	2	2	2
Pregnancy	1	2	1
Poor/Non-compliance	1	1	-
Lost to follow-up	-	-	-
Subject no longer meets study criteria	-	-	-
Lack of efficacy	2	4	3

Administrative reason by sponsor	3	2	2

Number of subjects in period 1	Experimental: 1.25mg SC BMS-931699 Every other	Placebo Comparator: 0mg SC BMS-931699 Weekly
Started	70	71
Completed	47	58
Not completed	23	13
Reason not provided by investigator	2	-
Adverse event, serious fatal	2	-
Consent withdrawn by subject	2	-
Adverse event, non-fatal	8	2
Participant request to discontinue	-	-
Pregnancy	1	-
Poor/Non-compliance	-	2
Lost to follow-up	1	-
Subject no longer meets study criteria	-	1
Lack of efficacy	4	5
Administrative reason by sponsor	3	3

Baseline characteristics

Reporting groups	
Reporting group title	Experimental:12.5mg SC BMS-931699 Weekly
Reporting group description:	
12.5mg subcutaneous (SC) injection Weekly dosing	
Reporting group title	Experimental:12.5mg SC BMS-931699 Every other Week
Reporting group description:	
12.5mg SC injection Every other Week dosing	
Reporting group title	Experimental: 5mg SC BMS-931699 Every other Week
Reporting group description:	
5mg SC injection Every other Week dosing	
Reporting group title	Experimental: 1.25mg SC BMS-931699 Every other Week
Reporting group description:	
1.25mg SC injection Every other Week dosing	
Reporting group title	Placebo Comparator: 0mg SC BMS-931699 Weekly
Reporting group description:	
0mg SC injection Weekly dosing	

Reporting group values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week
Number of subjects	69	68	68
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)	69	67	64
From 65-84 years	0	1	4
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	41.0	39.1	41.9
full range (min-max)	18 to 64	19 to 68	19 to 69
Sex: Female, Male			
Units: Subjects			
Female	67	66	65
Male	2	2	3
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	9	7	10
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	9	7

White	38	46	41
More than one race	0	0	0
Unknown or Not Reported	16	6	9
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	2	3
Not Hispanic or Latino	6	9	9
Unknown or Not Reported	60	57	56

Reporting group values	Experimental: 1.25mg SC BMS-931699 Every other	Placebo Comparator: 0mg SC BMS-931699 Weekly	Total
Number of subjects	70	71	346
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)	68	68	336
From 65-84 years	2	3	10
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	38.0	40.6	
full range (min-max)	19 to 69	18 to 68	-
Sex: Female, Male Units: Subjects			
Female	66	65	329
Male	4	6	17
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	2
Asian	9	8	43
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	7	12	41
White	43	41	209
More than one race	0	0	0
Unknown or Not Reported	10	10	51
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	6	3	17
Not Hispanic or Latino	7	5	36
Unknown or Not Reported	57	63	293

End points

End points reporting groups

Reporting group title	Experimental:12.5mg SC BMS-931699 Weekly
Reporting group description: 12.5mg subcutaneous (SC) injection Weekly dosing	
Reporting group title	Experimental:12.5mg SC BMS-931699 Every other Week
Reporting group description: 12.5mg SC injection Every other Week dosing	
Reporting group title	Experimental: 5mg SC BMS-931699 Every other Week
Reporting group description: 5mg SC injection Every other Week dosing	
Reporting group title	Experimental: 1.25mg SC BMS-931699 Every other Week
Reporting group description: 1.25mg SC injection Every other Week dosing	
Reporting group title	Placebo Comparator: 0mg SC BMS-931699 Weekly
Reporting group description: 0mg SC injection Weekly dosing	

Primary: Percentage of subjects who achieve BICLA response (BICLA response rate) at Day 169.

End point title	Percentage of subjects who achieve BICLA response (BICLA response rate) at Day 169.

End point description:

BICLA is defined as: British Isle Lupus Assessment Group improvement, defined as BILAG As at Baseline improved to B/C/D, and BILAG Bs at baseline improved to C/D, and no BILAG worsening in other BILAG organ systems such that there are no new BILAG As or greater than 1 new BILAG B; and no worsening in the SLEDAI-2K total score compared to Baseline (defined as no increase in SLEDAI total score); and no worsening in the physician's global assessment (MDGA) of disease activity ("no worsening" is defined as less than 10% worsening, equivalent to a 10mm increase on a 100mm visual analog scale [VAS]) compared to Baseline; No changes in concomitant medications according to the following criteria: No increase of or addition of a new immunosuppressant agent (azathioprine,mycophenolic acid/mycophenolate mofetil, methotrexate, anti-malarial, leflunomide) over baseline levels; No increase in corticosteroid dose above baseline level outside of those allowed per protocol.

End point type	Primary

End point timeframe:

At Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (confidence interval 90%)	59.4 (49.7 to 69.1)	63.2 (53.6 to 72.9)	57.4 (47.5 to 67.2)	58.6 (48.9 to 68.3)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (confidence interval 90%)	59.2 (49.6 to 68.8)			

Statistical analyses

Statistical analysis title	P-value of Chi-sq test of 12.5mg dose Wkly vs. pbo
Comparison groups	Experimental:12.5mg SC BMS-931699 Weekly v Placebo Comparator: 0mg SC BMS-931699 Weekly
Number of subjects included in analysis	140
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9745
Method	Chi-squared

Statistical analysis title	P-value of Chi-sq test of 12.5mg dose EOW vs. pbo
Comparison groups	Experimental:12.5mg SC BMS-931699 Every other Week v Placebo Comparator: 0mg SC BMS-931699 Weekly
Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6217
Method	Chi-squared

Statistical analysis title	P-value of Chi-sq test of 5mg dose EOW vs. pbo
Comparison groups	Experimental: 5mg SC BMS-931699 Every other Week v Placebo Comparator: 0mg SC BMS-931699 Weekly
Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8295
Method	Chi-squared

Statistical analysis title	P-value of Chi-sq test of 1.25mg dose EOW vs. pbo

Comparison groups	Placebo Comparator: 0mg SC BMS-931699 Weekly v Experimental: 1.25mg SC BMS-931699 Every other Week
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9439
Method	Chi-squared

Secondary: Percentage of subjects who meet response criteria for the SLE Responder Index(4) [SRI(4)], SRI(5) and SRI(6) at Day 169

End point title	Percentage of subjects who meet response criteria for the SLE Responder Index(4) [SRI(4)], SRI(5) and SRI(6) at Day 169

End point description:

SRI is the Systemic Lupus Erythematosus Responder Index. An SRI(X) Response is defined as: a reduction in Day 1 SLEDAI-2K disease activity score of >= X points; no worsening of disease (defined as an increase of >= 30mm on a 100mm VAS from Day 1 as measured by the MDGA; and no new BILAG-2004 Index A organ system score and no more than one new or worsening BILAG-2004 Index B organ system scores

End point type	Secondary

End point timeframe:

At Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (confidence interval 90%)				
SRI (4)|	55.1 (45.2 to 64.9)	48.5 (38.6 to 58.5)	39.7 (29.9 to 49.5)	44.3 (34.5 to 54.1)
SRI (5)|	37.7 (28.1 to 47.3)	29.4 (20.3 to 38.5)	27.9 (19.0 to 36.9)	31.4 (22.3 to 40.6)
SRI (6)|	33.8 (24.6 to 43.0)	31.4 (22.3 to 40.6)	27.9 (19.0 to 36.9)	26.5 (17.7 to 35.3)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (confidence interval 90%)				
SRI (4)|	49.3 (39.5 to 59.1)			

SRI (5)|	33.8 (24.6 to 43.0)			
SRI (6)|	37.7 (28.1 to 47.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects who meet response criteria for the SLE Responder Index(4) [SRI(4)], SRI(5) and SRI(6) at Day 85

End point title	Percentage of subjects who meet response criteria for the SLE Responder Index(4) [SRI(4)], SRI(5) and SRI(6) at Day 85

End point description:

SRI is the Systemic Lupus Erythematosus (SLE) Responder Index; SRI is the Systemic Lupus Erythematosus Responder Index. An SRI(X) Response is defined as: a reduction in Day 1 SLEDAI-2K disease activity score of >= X points; no worsening of disease (defined as an increase of >= 30mm on a 100mm VAS from Day 1 as measured by the MDGA; and no new BILAG-2004 Index A organ system score and no more than one new or worsening BILAG-2004 Index B organ system scores

End point type	Secondary

End point timeframe:

At Day 85

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (confidence interval 90%)				
SRI (4)|	49.3 (39.4 to 59.2)	48.5 (38.6 to 58.5)	41.2 (31.4 to 51.0)	47.1 (37.3 to 57.0)
SRI (5)|	29.0 (20.0 to 38.0)	32.4 (23.0 to 41.7)	25.0 (16.4 to 33.6)	31.4 (22.3 to 40.6)
SRI (6)|	29.0 (20.0 to 38.0)	30.9 (21.7 to 40.1)	25.0 (16.4 to 33.6)	31.4 (22.3 to 40.6)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (confidence interval 90%)				
SRI (4)|	43.7 (34.0 to 53.3)			

SRI (5)| SRI (6)|	28.2 (19.4 to 36.9) 26.8 (18.1 to 35.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with BICLA response (BICLA response rate) at Day 85

End point title	Percentage of subjects with BICLA response (BICLA response rate) at Day 85

End point description:

BICLA is defined as: British Isle Lupus Assessment Group improvement, defined as BILAG As at Baseline improved to B/C/D, and BILAG Bs at baseline improved to C/D, and no BILAG worsening in other BILAG organ systems such that there are no new BILAG As or greater than 1 new BILAG B; and no worsening in the SLEDAI-2K total score compared to Baseline (defined as no increase in SLEDAI total score); and no worsening in the physician's global assessment (MDGA) of disease activity ("no worsening" is defined as less than 10% worsening, equivalent to a 10mm increase on a 100mm visual analog scale [VAS]) compared to Baseline; No changes in concomitant medications according to the following criteria: No increase of or addition of a new immunosuppressant agent (azathioprine,mycophenolic acid/mycophenolate mofetil, methotrexate, anti-malarial, leflunomide) over baseline levels; No increase in corticosteroid dose above baseline level outside of those allowed per protocol.

End point type	Secondary

End point timeframe:

At Day 85

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (confidence interval 90%)	69.6 (60.5 to 78.7)	64.7 (55.2 to 74.2)	57.4 (47.5 to 67.2)	57.1 (47.4 to 66.9)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (confidence interval 90%)	54.9 (45.2 to 64.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in CLASI score

End point title	Mean change from baseline in CLASI score

End point description:

Mean change from baseline, CLASI = Cutaneous Lupus Erythematosus Disease Area and Severity Index. Scores can range from 0 to 70 for CLASI activity and 0 to 70 for CLASI damage, with higher scores denoting greater disease activity or damage.

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Score				
arithmetic mean (standard deviation)				
Day 85|	-2.31 (± 3.107)	-3.20 (± 4.718)	-1.69 (± 2.319)	-1.82 (± 4.515)
Day 169|	-3.17 (± 4.387)	-3.78 (± 5.555)	-2.47 (± 2.824)	-2.94 (± 4.897)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Score				
arithmetic mean (standard deviation)				
Day 85|	-3.11 (± 4.239)			
Day 169|	-3.57 (± 4.177)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with an improvement of >4 or a decrease of >50% from baseline in their Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) score

End point title	Percentage of subjects with an improvement of >4 or a decrease of >50% from baseline in their Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) score

End point description:

CLASI = Cutaneous Lupus Erythematosus Disease Area and Severity Index. Scores can range from 0 to 70 for CLASI activity and 0 to 70 for CLASI damage, with higher scores denoting greater disease activity or damage.

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (confidence interval 90%)	39.3 (29.1 to 49.6)	46.9 (36.6 to 57.1)	34.5 (24.2 to 44.7)	36.1 (26.0 to 46.2)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (confidence interval 90%)	42.4 (32.4 to 52.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in arthritis, as assessed by American College of Rheumatology (ACR) 28-joint count of tender and swollen joints

End point title	Change from baseline in arthritis, as assessed by American College of Rheumatology (ACR) 28-joint count of tender and swollen joints

End point description:

Mean Change from Baseline Over Time; Measured by Disease Activity Score 28: A single score on a continuous scale (0–9.4). The level of RA disease activity can be interpreted as low (DAS28 <=3.2),moderate (3.2 < DAS28 <=5.1), or as high disease activity (DAS28 > 5.1)

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Disease Activity Score 28				
arithmetic mean (standard deviation)	-4.63 (± 4.719)	-4.63 (± 5.311)	-4.75 (± 4.985)	-4.42 (± 5.626)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Disease Activity Score 28				
arithmetic mean (standard deviation)	-3.84 (± 4.922)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in BILAG-2004 score of systemic lupus erythematosus (SLE) activity over time

End point title	Change from baseline in BILAG-2004 score of systemic lupus erythematosus (SLE) activity over time

End point description:

Overall British Isles Lupus Assessment Group-2004 score, BILAG Scores: A=Severe disease activity, B=Moderate disease activity, C=Mild disease, D=Inactive disease but previously affected, E=System never involved.The categories are converted to a numeric score (A=9, B=3, C=1, D=0, E=0) and treated as a continuous variable. Higher score= more severe disease activity.

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Score				
arithmetic mean (standard deviation)				
BILAG-2004 Score Day 85|	-10.31 (± 7.480)	-8.83 (± 7.749)	-7.07 (± 7.299)	-8.66 (± 6.598)
BILAG-2004 Score Day 169|	-11.50 (± 6.983)	-10.46 (± 7.808)	-8.98 (± 6.719)	-9.73 (± 5.478)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Score				
arithmetic mean (standard deviation)				
BILAG-2004 Score Day 85|	-7.94 (± 8.008)			
BILAG-2004 Score Day 169|	-9.78 (± 7.590)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative corticosteroid and immunosuppressant use over time

End point title	Cumulative corticosteroid and immunosuppressant use over time

End point description:

The cumulative corticosteroids use and immunosuppressants use over time

End point type	Secondary

End point timeframe:

Up to one day prior to the first dose of long-term extension period or up to 42 days post last short-term dose date, which ever is earlier

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (not applicable)				
Corticosteroids: Oral|	89.9	82.4	86.8	84.3
Corticosteroids: Oral inhalation|	0	0	1.5	0
Immunosuppressant|	46.4	63.2	38.2	51.4
Immunosuppressant Azathioprine|	23.2	29.4	14.7	28.6
Immunosuppressant Methotrexate|	26.1	35.3	25.0	24.3

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (not applicable)				
Corticosteroids: Oral|	94.4			
Corticosteroids: Oral inhalation|	0			
Immunosuppressant|	59.2			
Immunosuppressant Azathioprine|	33.8			
Immunosuppressant Methotrexate|	26.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Adverse Events (AEs), Serious adverse events (SAEs), and pre-established Events of Special Interest

End point title	Number of subjects with Adverse Events (AEs), Serious adverse events (SAEs), and pre-established Events of Special Interest

End point description:

Although there are no identified risks for BMS-931699, BMS has developed a list of events of special interest for the BMS-931699 program based on the known biologic class effects, the mechanism of action of BMS-931699, overall potential consequences of mmunosuppression, and preliminary data from unblinded clinical trials. Event categories of special interest for this study may include, but are not limited to: Infections, Autoimmunity, Malignancies, Injection-related reactions

End point type	Secondary

End point timeframe:

On or after the first dose date of short-term study medication and up to 42 days post last short-term dose date or up to the day prior to the first dose of long-term extension period, whichever is earlier

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Serious Adverse Events|	5	5	9	8
Related SAEs|	3	3	5	0
Related Adverse Events|	33	30	29	19
AEs of Malignancies|	0	0	0	0
AEs of Infections and Infestations|	38	41	35	39
AEs Leading to Discontinuation|	8	5	9	9
Adverse Events of Autoimmunity|	4	0	0	0
Most Common Adverse Events|	59	56	60	59
Adverse Events of Local Injection Reactions|	10	8	10	3

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Serious Adverse Events|	6			
Related SAEs|	1			
Related Adverse Events|	19			
AEs of Malignancies|	0			
AEs of Infections and Infestations|	30			
AEs Leading to Discontinuation|	3			
Adverse Events of Autoimmunity|	1			
Most Common Adverse Events|	62			
Adverse Events of Local Injection Reactions|	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with clinically significant changes in vital signs

End point title	Percentage of subjects with clinically significant changes in vital signs

End point description:

HEART RATE (BPM): HR > 100 AND CHG FROM BSL > 30 OR HR < 55 AND CHG FROM BSL < -15;

SYSTOLIC BLOOD PRESSURE (MMHG) SYSBP > 140 AND CHG FROM BSL > 20 OR SYSBP < 90 AND CHG FROM BSL < -20; DIABP > 90 AND CHG FROM BSL > 10 OR DIABP < 55 AND CHG FROM BSL < -10; RESPIRATION RATE (PER MIN) RESP > 16 OR RESP CHG FROM BSL > 10; TEMPERATURE (C) TEMP > 38.3 OR TEMP CHG FROM BSL > 1.6

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Percentage				
number (not applicable)				
HEART RATE (BPM) SITTING|	2.9	5.9	2.9	2.9
HEART RATE (BPM) STANDING|	4.3	5.9	7.4	7.1
HEART RATE (BPM) SUPINE|	0	0	0	0
SYSTOLIC BLOOD PRESSURE (MMHG) SITTING|	11.6	17.6	10.3	10.0
SYSTOLIC BLOOD PRESSURE (MMHG) STANDING|	14.5	14.7	8.8	11.4
SYSTOLIC BLOOD PRESSURE (MMHG) SUPINE|	0	0	0	0
DIASTOLIC BLOOD PRESSURE (MM HG) SITTING|	26.1	17.6	11.8	17.1
DIASTOLIC BLOOD PRESSURE (MM HG) STANDING|	18.8	27.9	25.0	21.4
DIASTOLIC BLOOD PRESSURE (MM HG) SUPINE|	0	0	0	0
RESPIRATION RATE (PER MIN)|	85.5	82.4	75.0	70.0
TEMPERATURE (C)|	0	0	1.5	1.4

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
number (not applicable)				
HEART RATE (BPM) SITTING|	5.6			
HEART RATE (BPM) STANDING|	5.7			
HEART RATE (BPM) SUPINE|	0			
SYSTOLIC BLOOD PRESSURE (MMHG) SITTING|	15.5			
SYSTOLIC BLOOD PRESSURE (MMHG) STANDING|	20.0			
SYSTOLIC BLOOD PRESSURE (MMHG) SUPINE|	0			

DIASTOLIC BLOOD PRESSURE (MM HG) SITTING|	9.9			
DIASTOLIC BLOOD PRESSURE (MM HG) STANDING|	20.0			
DIASTOLIC BLOOD PRESSURE (MM HG) SUPINE|	0			
RESPIRATION RATE (PER MIN)|	81.7			
TEMPERATURE (C)|	1.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant electrocardiogram (ECG) abnormalities

End point title	Number of subjects with clinically significant electrocardiogram (ECG) abnormalities

End point description:

QTC Fridericia, PR Interval, QRS Interval and Change from baseline in QTCF

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of short-term double-blind study medication or up to the day prior to the start of long-term extension period, whichever is earlier.

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
QTC Fredericia (msec) <= 450|	56	58	58	56
QTC Fredericia (msec) 450< To <= 480|	12	8	5	11
QTC Fredericia (msec) 480 < to <= 500|	0	1	2	0
QTC Fredericia (msec) > 500|	1	1	3	3
PR Interval (msec) <= 200|	69	68	64	66
PR Interval (msec) > 200|	0	0	4	4
QRS Interval (msec) <= 120|	68	67	66	67
QRS Interval (msec) > 120|	1	1	2	3
Change from baseline in QTCF (msec) <= 30|	66	59	54	55
Change from baseline in QTCF (msec) 30 To <= 60|	2	7	7	2
Change from baseline in QTCF (msec) > 60|	0	2	3	3

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
QTC Fredericia (msec) <= 450|	65			
QTC Fredericia (msec) 450< To <= 480|	5			
QTC Fredericia (msec) 480 < to <= 500|	1			
QTC Fredericia (msec) > 500|	0			
PR Interval (msec) <= 200|	68			
PR Interval (msec) > 200|	3			
QRS Interval (msec) <= 120|	70			
QRS Interval (msec) > 120|	1			
Change from baseline in QTCF (msec) <= 30|	62			
Change from baseline in QTCF (msec) 30 To <= 60|	5			
Change from baseline in QTCF (msec) > 60|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough: Trough level serum concentration of BMS-931699 at time points specified

End point title	Ctrough: Trough level serum concentration of BMS-931699 at time points specified

End point description:

Pharmacokinetics of BMS-931699 derived from serum concentration versus time data; Pharmacokinetic Population: defined as all subjects who receive any study medication and have any available concentration-time data.

End point type	Secondary

End point timeframe:

Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	68	68	70

Units: ng/mL				
arithmetic mean (standard deviation)	2040 (± 945.57)	640.8 (± 436.35)	207.1 (± 149.53)	62.2 (± 56.83)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: ng/mL				
arithmetic mean (standard deviation)	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum biomarkers C3, C4

End point title	Serum biomarkers C3, C4

End point description:

Serum biomarkers C3, C4, anti-double-stranded deoxyribonucleic acid (anti-dsDNA), anti-nuclear antibody (ANA) and other autoantibodies were measured from blood serum samples collected on Day 85 and Day 169

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: g/L				
arithmetic mean (standard deviation)				
C3, Baseline|	1.068 (± 0.3405)	1.029 (± 0.3265)	0.990 (± 0.3318)	1.028 (± 0.3149)
C3, Day 85|	1.037 (± 0.3024)	1.014 (± 0.3428)	1.030 (± 0.3225)	1.083 (± 0.3124)
C3, Day 169|	1.045 (± 0.3405)	1.010 (± 0.3557)	1.027 (± 0.3528)	1.077 (± 0.3256)
C4, Baseline|	0.201 (± 0.1084)	0.185 (± 0.1088)	0.177 (± 0.0861)	0.202 (± 0.0984)
C4, Day 85|	0.206 (± 0.1037)	0.195 (± 0.1079)	0.190 (± 0.0875)	0.215 (± 0.0965)
C4, Day 169|	0.212 (± 0.1161)	0.185 (± 0.1014)	0.187 (± 0.0941)	0.207 (± 0.0927)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: g/L				
arithmetic mean (standard deviation)				
C3, Baseline|	0.991 (± 0.2641)			
C3, Day 85|	0.986 (± 0.3005)			
C3, Day 169|	0.992 (± 0.2981)			
C4, Baseline|	0.183 (± 0.0824)			
C4, Day 85|	0.179 (± 0.0824)			
C4, Day 169|	0.184 (± 0.0896)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum biomarkers: Anti-Nuclear Antibodies (ANA)

End point title	Serum biomarkers: Anti-Nuclear Antibodies (ANA)

End point description:

Serum biomarkers C3, C4, anti-double-stranded deoxyribonucleic acid (anti-dsDNA), anti-nuclear antibody (ANA) and other autoantibodies were measured from blood serum samples collected on Day 85 and Day 169. No anti-dsDNA data was available for this report

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	66	67
Units: Percentage				
number (not applicable)				
Baseline Negative Day 85 Negative|	62.5	57.1	100.0	50.0
Baseline Negative Day 85 Positive|	37.5	42.9	0	50.0
Baseline Positive Day 85 Negative|	11.3	3.4	1	2.0

Baseline Positive Day 85 Positive|	88.7	96.6	98.2	98.0
Baseline Negative Day 169 Negative|	71.4	33.3	100.0	57.1
Baseline Negative Day 169 Positive|	28.6	66.7	0	42.9
Baseline Positive Day 169 Negative|	9.3	2.0	5.8	4.3
Baseline Positive Day 169 Positive|	90.7	98.0	94.2	95.7

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Percentage				
number (not applicable)				
Baseline Negative Day 85 Negative|	60.0			
Baseline Negative Day 85 Positive|	40.0			
Baseline Positive Day 85 Negative|	0			
Baseline Positive Day 85 Positive|	100.0			
Baseline Negative Day 169 Negative|	40.0			
Baseline Negative Day 169 Positive|	60.0			
Baseline Positive Day 169 Negative|	1.8			
Baseline Positive Day 169 Positive|	98.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Short term: Receptor occupancy over time

End point title	Short term: Receptor occupancy over time
End point description:	
Percent CD4+ Receptor Occupancy and percent CD8+ Receptor Occupancy	
End point type	Secondary
End point timeframe:	
At Day 85 and Day 169	

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	66	67
Units: Percentage				
arithmetic mean (standard deviation)				
%CD4+ RO Baseline|	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

%CD4+ RO Day 85|	95.722 (± 12.1298)	83.244 (± 28.9616)	70.520 (± 32.9107)	37.155 (± 31.2927)
%CD4+ RO Day 169|	92.390 (± 22.1377)	77.210 (± 29.3976)	74.286 (± 28.5105)	44.115 (± 34.3707)
%CD8+ RO Baseline|	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
%CD8+ RO Day 85|	95.831 (± 7.6571)	81.730 (± 30.4345)	68.960 (± 32.0543)	32.516 (± 29.7242)
%CD8+ RO Day 169|	92.043 (± 20.6963)	74.726 (± 33.0060)	69.850 (± 30.5880)	40.989 (± 31.9867)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Percentage				
arithmetic mean (standard deviation)				
%CD4+ RO Baseline|	0 (± 0)			
%CD4+ RO Day 85|	0.350 (± 0.5997)			
%CD4+ RO Day 169|	0.334 (± 0.4460)			
%CD8+ RO Baseline|	0 (± 0)			
%CD8+ RO Day 85|	0.160 (± 0.3120)			
%CD8+ RO Day 169|	0.235 (± 0.5438)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with BMS-931699 induced antibody response over time point specified

End point title	Percentage of subjects with BMS-931699 induced antibody response over time point specified

End point description:

Immunogenicity defined as positive for anti-drug antibodies post-baseline measurement if baseline missing or negative. If baseline is positive, then immunogenicity is defined as a positive post-baseline measurement with titer value 4 times greater than baseline. (A) all subjects with a laboratory reported positive antibody responses to BMS-931699 during the short-term double-blind treatment period are included. Overall: At least one positive sample relative to baseline during short-term double-blind and follow-up period.

End point type	Secondary

End point timeframe:

Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	34	34	41
Units: Percentage				
number (not applicable)				
% with Neutralizing activity|	23.1	41.2	64.7	34.1
% with Neutralizing activity (Baseline)|	0	5.9	0	0
% with Neutralizing activity (Overall)|	23.1	35.3	64.7	34.1

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	0[1]			
Units: Percentage				
number (not applicable)				
% with Neutralizing activity|				
% with Neutralizing activity (Baseline)|				
% with Neutralizing activity (Overall)|				

Notes:

[1] - No BMS-931699 induced antibody response observed for placebo

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests: HEMATOLOGY I

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests: HEMATOLOGY I

End point description:

HEMATOLOGY I: ERYTHROCYTE/PLATELET ATTRIBUTES HEMOGLOBIN HB G/L L < 0.85×PRE-RX; HEMATOCRIT HCT VOL L < 0.85×PRE-RX; PLATELET COUNT PLAT X10*9 C/L H > 1.5×ULN IF PRE-RX IS MISSING OR > 1.5×ULN PLATELET COUNT PLAT X10*9 C/L L < 0.85×LLN IF PRE-RX IS MISSING OR < 0.85×LLN IF PRE-RX >= LLN OR < 0.85×PRE-RX IF PRE-RX < LLN; ERYTHROCYTES RBC X10*12 C/L L < 0.85×PRE-RX HEMATOLOGY II QUANTITATIVE WBC : LEUKOCYTES WBC X10*9 C/L H > 1.2×ULN IF PRE-RX IS MISSING OR > 1.2×ULN IF LLN <= PRE-RX <= ULN OR > 1.5×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN; LEUKOCYTES WBC X10*9 C/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF LLN <= PRE-RX <= ULN OR < 0.85×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Erythrocytes Low|	4	4	6	3
Erythrocytes High|	9999	9999	9999	9999
Hematocrit Low|	6	10	5	5
Hematocrit High|	9999	9999	9999	9999
Hemoglobin Low|	4	4	5	4
Hemoglobin High|	9999	9999	9999	9999
Platelet count low|	1	1	1	1
Platelet count high|	0	0	0	1
Quantitative WBC: Leukocytes low|	12	18	12	16
Quantitative WBC: Leukocytes high|	1	1	0	3

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Erythrocytes Low|	5			
Erythrocytes High|	9999			
Hematocrit Low|	8			
Hematocrit High|	9999			
Hemoglobin Low|	5			
Hemoglobin High|	9999			
Platelet count low|	2			
Platelet count high|	0			
Quantitative WBC: Leukocytes low|	16			
Quantitative WBC: Leukocytes high|	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests: HEMATOLOGY II

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests: HEMATOLOGY II

End point description:

WBC DIFFERENTIAL COUNT: BASOPHILS (ABSOLUTE) BASOA X10*9 C/L H > 0.4; BLASTS (ABSOLUTE) BLASA X10*9 C/L H > 0; EOSINOPHILS (ABSOLUTE) EOSA X10*9 C/L H > 0.75; LYMPHOCYTES (ABSOLUTE) LYMPA X10*9 C/L H > 7.5; LYMPHOCYTES (ABSOLUTE) LYMPA X10*9 C/L L < 0.75; MONOCYTES (ABSOLUTE) MONOA X10*9 C/L H > 2; NEUTROPHILS (ABSOLUTE) NEUTA X10*9 C/L L <

1.5 IF PRE-RX IS MISSING OR < 1.5 IF PRE-RX >= 1.5 OR < 0.85×PRE-RX IF PRE-RX < 1.5; COAGULATION APTT SEC H > 1.5×ULN; INTL NORMALIZED RATIO (INR) INR FRACTION H > 1.5×ULN PROTHROMBIN TIME (PT) PT SEC H > 1.5×ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Basophils (Absolute) Low|	9999	9999	9999	9999
Basophils (Absolute) High|	0	0	0	0
Blasts (Absolute) Low|	0	9999	0	0
Blasts (Absolute) High|	0	0	0	0
Eosinophils (Absolute) Low|	9999	9999	9999	9999
Eosinophils (Absolute) High|	3	0	0	2
Lymphocytes (Absolute) Low|	21	29	24	25
Lymphocytes (Absolute) High|	0	0	0	0
Monocytes (Absolute) High|	9999	9999	9999	9999
Monocytes (Absolute) Low|	0	0	0	0
Neutrophils (Absolute) Low|	10	8	5	7
Neutrophils (Absolute) High|	9999	9999	9999	9999

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Basophils (Absolute) Low|	9999			
Basophils (Absolute) High|	0			
Blasts (Absolute) Low|	0			
Blasts (Absolute) High|	0			
Eosinophils (Absolute) Low|	9999			
Eosinophils (Absolute) High|	1			
Lymphocytes (Absolute) Low|	25			
Lymphocytes (Absolute) High|	0			
Monocytes (Absolute) High|	9999			
Monocytes (Absolute) Low|	0			
Neutrophils (Absolute) Low|	4			
Neutrophils (Absolute) High|	9999			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests : LIVER FUNCTION TESTS

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests : LIVER FUNCTION TESTS

End point description:

LIVER FUNCTION TESTS:ALKALINE PHOSPHATASE (ALP) ALP U/L H > 1.25×ULN IF PRE-RX IS MISSING OR > 1.25×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN; ALANINE AMINOTRANSFERASE (ALT) ALT U/L H > 1.25×ULN IF PRE-RX IS MISSING OR > 1.25×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN; ASPARTATE AMINOTRANSFERASE (AST) AST U/L H > 1.25×ULN IF PRE-RX IS MISSING OR > 1.25×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN; BILIRUBIN, DIRECT DBILI UMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN G-GLUTAMYL TRANSFERASE (GGT) GGT U/L H > 1.15×ULN IF PRE-RX IS MISSING OR > 1.15×ULN IF PRE-RX <= ULN OR > 1.2×PRE-RX IF PRE-RX > ULN BILIRUBIN, TOTAL TBILI UMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Alanine Aminotransferase Low|	9999	9999	9999	9999
Alanine Aminotransferase High|	12	17	6	9
Alkaline Phosphatase Low|	9999	9999	9999	9999
Alkaline Phosphatase High|	2	3	2	5
Aspartate Aminotransferase Low|	9999	9999	9999	9999
Aspartate Aminotransferase High|	10	13	11	8
Bilirubin, Direct Low|	9999	9999	9999	9999
Bilirubin Direct, High|	0	13	0	1
Bilirubin Total, Low|	9999	9999	9999	9999
Bilirubin Total, High|	0	0	0	1
G-Glutamyl Transferase, Low|	9999	9999	9999	9999
G-Glutamyl Transferase, High|	18	14	16	15

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Alanine Aminotransferase Low|	9999			
Alanine Aminotransferase High|	8			
Alkaline Phosphatase Low|	9999			
Alkaline Phosphatase High|	8			
Aspartate Aminotransferase Low|	9999			
Aspartate Aminotransferase High|	10			
Bilirubin, Direct Low|	9999			
Bilirubin Direct, High|	0			
Bilirubin Total, Low|	9999			
Bilirubin Total, High|	1			
G-Glutamyl Transferase, Low|	9999			
G-Glutamyl Transferase, High|	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests: KIDNEY FUNCTION TESTS

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests: KIDNEY FUNCTION TESTS

End point description:

KIDNEY FUNCTION TESTS:BLOOD UREA NITROGEN BUN MMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.2×PRE-RX IF PRE-RX > ULN CREATININE CREAT UMOL/L H > 1.5×ULN IF PRE-RX IS MISSING OR > 1.5×ULN IF PRE-RX <= ULN OR > 1.33×PRE-RX IF PRE-RX > ULN GLOMERULAR FILTRATION RATE, CALC. (MDRD) GFRC ML/S/M*2 L < 0.8×PRE-RX; UREA UREA MMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.2×PRE-RX IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Blood Urea Nitrogen, Low|	9999	9999	9999	9999
Blood Urea Nitrogen, High|	9	11	3	14
Creatinine, Low|	9999	9999	9999	9999

Creatinine, High|	2	0	0	2
GLOMERULAR FILTRATION RATE, CALC. Low|	0	0	0	0
GLOMERULAR FILTRATION RATE, CALC. High|	9999	9999	9999	9999
Urea, Low|	9999	9999	9999	9999
Urea, High|	0	0	0	0

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Blood Urea Nitrogen, Low|	9999			
Blood Urea Nitrogen, High|	10			
Creatinine, Low|	9999			
Creatinine, High|	1			
GLOMERULAR FILTRATION RATE, CALC. Low|	0			
GLOMERULAR FILTRATION RATE, CALC. High|	9999			
Urea, Low|	9999			
Urea, High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests ELECTROLYTES 1

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests ELECTROLYTES 1

End point description:

CALCIUM, TOTAL CA MMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.1×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN; CALCIUM, TOTAL CA MMOL/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF PRE-RX >= LLN OR < 0.9×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN; CHLORIDE, SERUM CL MMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.1×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN; CHLORIDE, SERUM CL MMOL/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF PRE-RX >= LLN OR < 0.9×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN;

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Calcium, Total, Low|	0	0	1	0
Calcium, Total, High|	0	0	0	0
Chloride, Serum, Low|	0	0	0	0
Chloride, Serum, High|	0	0	0	0

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Calcium, Total, Low|	0			
Calcium, Total, High|	0			
Chloride, Serum, Low|	0			
Chloride, Serum, High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests: ELECTROLYTES 2

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests: ELECTROLYTES 2

End point description:

BICARBONATE HCO3 MMOL/L H > 1.2×ULN IF PRE-RX IS MISSING OR > 1.2×ULN IF PRE-RX <= ULN OR > 1.2×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN; BICARBONATE HCO3 MMOL/L L < 0.8×LLN IF PRE-RX IS MISSING OR < 0.8×LLN IF PRE-RX >= LLN OR < 0.8×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN; POTASSIUM, SERUM K MMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.1×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN; POTASSIUM, SERUM K MMOL/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF PRE-RX >= LLN OR < 0.9×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN; MAGNESIUM, SERUM MG MMOL/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.1×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN MAGNESIUM, SERUM MG MMOL/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF PRE-RX >= LLN OR < 0.9×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Bicarbonate, Low|	0	0	0	0
Bicarbonate, High|	0	0	0	0
Magnesium, Serum, Low|	0	0	0	0
Magnesium, Serum, High|	0	0	0	0
Potassium, Serum, Low|	1	0	1	1
Potassium, Serum, High|	0	0	1	1

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Bicarbonate, Low|	0			
Bicarbonate, High|	0			
Magnesium, Serum, Low|	0			
Magnesium, Serum, High|	0			
Potassium, Serum, Low|	1			
Potassium, Serum, High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests: ELECTROLYTES 3

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests: ELECTROLYTES 3

End point description:

SODIUM, SERUM NA MMOL/L H > 1.05×ULN IF PRE-RX IS MISSING OR > 1.05×ULN IF PRE-RX <= ULN OR > 1.05×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN SODIUM, SERUM NA MMOL/L L < 0.95×LLN IF PRE-RX IS MISSING OR < 0.95×LLN IF PRE-RX >= LLN OR < 0.95×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN PHOSPHORUS, INORGANIC PHOS MMOL/L H > 1.25×ULN IF PRE-RX IS MISSING OR > 1.25×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN PHOSPHORUS, INORGANIC PHOS MMOL/L L < 0.85×LLN IF PRE-RX IS MISSING OR < 0.85×LLN IF PRE-RX >=LLN OR < 0.85×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Sodium, Serum Low|	0	0	0	0
Sodium, Serum High|	0	0	0	0
Phosphorus, Inorganic, Low|	0	2	4	1
Phosphorus, Inorganic, High|	0	0	0	1

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Sodium, Serum Low|	0			
Sodium, Serum High|	0			
Phosphorus, Inorganic, Low|	0			
Phosphorus, Inorganic, High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests : OTHER CHEMISTRY TESTING 1

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests : OTHER CHEMISTRY TESTING 1

End point description:

GLUCOSE TESTS:GLUCOSE, FASTING SERUM GLUCF MMOL/L H > 1.3×ULN IF PRE-RX IS MISSING OR > 1.3×ULN IF PRE-RX <= ULN OR > 2×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN GLUCOSE, FASTING SERUM GLUCF MMOL/L L < 0.8×LLN IF PRE-RX IS MISSING OR < 0.8×LLN IF PRE-RX >= LLN OR < 0.8×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN; PROTEIN TESTS:ALBUMIN ALB G/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF PRE-RX >= LLN OR < 0.9×PRE-RX IF PRE-RX < LLN PROTEIN, TOTAL TPRO G/L H > 1.1×ULN IF PRE-RX IS MISSING OR > 1.1×ULN IF PRE-RX <= ULN OR > 1.1×PRE-RX IF PRE-RX > ULN OR > ULN IF PRE-RX < LLN PROTEIN, TOTAL TPRO G/L L < 0.9×LLN IF PRE-RX IS MISSING OR < 0.9×LLN IF PRE-RX >= LLN OR < 0.9×PRE-RX IF PRE-RX < LLN OR < LLN IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Glucose, Fasting serum, Low|	1	3	0	4
Glucose, Fasting Serum, High|	3	3	0	0
Albumin, Low|	1	2	2	2
Albumin, High|	0	0	0	0
Protein, Total, Low|	0	0	1	1
Protein, Total, High|	0	0	1	1

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Glucose, Fasting serum, Low|	5			
Glucose, Fasting Serum, High|	4			
Albumin, Low|	1			
Albumin, High|	0			
Protein, Total, Low|	0			
Protein, Total, High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests : OTHER CHEMISTRY TESTING 2

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests : OTHER CHEMISTRY TESTING 2

End point description:

OTHER CHEMISTRY TESTING LIPID TESTS: CHOLESTEROL, TOTAL (TC) CHOL MMOL/L H > 1.2×ULN IF PRE-RX IS MISSING OR > 1.2×ULN IF PRE-RX <= ULN OR > 1.2×PRE-RX IF PRE-RX > ULN TRIGLYCERIDES, FASTING TRIGF MMOL/L H > 1.25×ULN IF PRE-RX IS MISSING OR > 1.25×ULN IF PRE-RX <= ULN OR > 1.5×PRE-RX IF PRE-RX > ULN PANCREATIC TESTS: AMYLASE, TOTAL AMYL U/L H > 1.5×ULN; LIPASE, TOTAL (TURBIDIMETRIC ASSAY) LIPA U/L H > 1.5×ULN; LIPASE, TOTAL (COLORIMETRIC ASSAY) LIPAC U/L H > 1.5×ULN; ENDOCRINE TESTS:CORTISOL, AM CORTA NMOL/L L < 138 THYROID STIMULATING HORMONE (TSH) TSH MU/L H > 1.5×ULN IF PRE-RX IS MISSING OR > 1.5×ULN IF PRE-RX <= ULN OR > 2×PRE-RX IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Cholesterol, Total (TC) Low|	9999	9999	9999	9999
Cholesterol, Total (TC) High|	5	4	12	10
Triglycerides, Fasting Low|	9999	9999	9999	9999
Triglycerides, Fasting High|	12	13	12	10
Amylase, Total Low|	9999	9999	9999	9999
Amylase, Total High|	0	0	0	0
Lipase, Total (Colorimetric Assay) Low|	9999	9999	9999	9999
Lipase, Total (Colorimetric Assay) High|	0	0	1	0
Lipase, Total (Turbidimetric Assay) Low|	9999	9999	9999	9999
Lipase, Total (Turbidimetric Assay) High|	0	0	1	0
Thyroid Stimulating Hormone, Low|	9999	9999	9999	9999
Thyroid Stimulating Hormone, High|	0	0	0	0

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Cholesterol, Total (TC) Low|	9999			
Cholesterol, Total (TC) High|	8			
Triglycerides, Fasting Low|	9999			
Triglycerides, Fasting High|	8			
Amylase, Total Low|	9999			
Amylase, Total High|	0			
Lipase, Total (Colorimetric Assay) Low|	9999			
Lipase, Total (Colorimetric Assay) High|	0			
Lipase, Total (Turbidimetric Assay) Low|	9999			
Lipase, Total (Turbidimetric Assay) High|	0			
Thyroid Stimulating Hormone, Low|	9999			
Thyroid Stimulating Hormone, High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests : OTHER CHEMISTRY TESTING 3

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests : OTHER CHEMISTRY TESTING 3

End point description:

OTHER CHEMISTRY TESTING CARDIAC TESTS: CREATINE KINASE (CK) CK U/L H > 1.5×ULN IF PRE-RX IS MISSING OR > 1.5×ULN IF PRE-RX <= ULN OR > 1.5×PRE-RX IF PRE-RX > ULN; TROPONIN-I, CARDIAC SPECIFIC TROI UG/L H > ULN; METABOLITE TESTS:URIC ACID URIC MMOL/L H > 1.2×ULN IF PRE-RX IS MISSING OR > 1.2×ULN IF PRE-RX <= ULN OR > 1.25×PRE-RX IF PRE-RX > ULN; CHEM TEST, MULTI INDICATIONS : LACTATE DEHYDROGENASE (LD) LD U/L H > 1.25×ULN IF PRE-RX IS MISSING OR > 1.25×ULN IF PRE-RX <= ULN OR > 1.5×PRE-RX IF PRE-RX > ULN

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Creatine Kinase Low|	9999	9999	9999	9999
Creatine Kinase High|	5	5	3	3
TROPONIN-I, CARDIAC SPECIFIC Low|	9999	9999	9999	9999
TROPONIN-I, CARDIAC SPECIFIC High|	0	0	0	0
Uric Acid, Low|	9999	9999	9999	9999
Uric Acid, High|	0	0	0	0
Lactate dehydrogenase (LD) low|	9999	9999	9999	9999
Lactate dehydrogenase (LD) high|	0	0	0	0

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Creatine Kinase Low|	9999			
Creatine Kinase High|	1			
TROPONIN-I, CARDIAC SPECIFIC Low|	9999			
TROPONIN-I, CARDIAC SPECIFIC High|	0			
Uric Acid, Low|	9999			
Uric Acid, High|	0			
Lactate dehydrogenase (LD) low|	9999			

Lactate dehydrogenase (LD) high|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests : IMMUNOLOGY

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests : IMMUNOLOGY

End point description:

IMMUNE ACTIVATION MARKERS:C-REACTIVE PROTEIN (CRP) CRP MG/L H > 1.5×ULN; CRP, HIGH SENSITIVITY CRPHS MG/L H > 1.5×ULN;

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
C-Reactive Protein (CRP) Low|	9999	9999	9999	9999
C-Reactive Protein (CRP) High|	19	18	22	18
CRP, High Sensitivity Low|	9999	9999	9999	9999
CRP, High Senstivity High|	0	0	1	0

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
C-Reactive Protein (CRP) Low|	9999			
C-Reactive Protein (CRP) High|	22			
CRP, High Sensitivity Low|	9999			
CRP, High Senstivity High|	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with clinically significant abnormalities in general laboratory tests : URINALYSIS

End point title	Number of subjects with clinically significant abnormalities in general laboratory tests : URINALYSIS

End point description:

QUALITATIVE URINE CHEMISTRY: BLOOD, URINE UBLD N/A H >= 2 IF PRE-RX IS MISSING OR >= 2 IF PRE-RX < 1 OR >= 2×PRE-RX IF PRE-RX >= 1 GLUCOSE, URINE UGLU N/A H >= 1 IF PRE-RX IS MISSING OR >= 1 IF PRE-RX < 1 OR >= 2×PRE-RX IF PRE-RX >= 1 PROTEIN, URINE UPRO UNKNOWN H >= 2 IF PRE-RX IS MISSING OR >= 2 IF PRE-RX < 1 OR >= 2×PRE-RX IF PRE-RX >= 1 URINALYSIS II URINE WBC + RBC ; RBC, URINE URBC HPF H >= 2 IF PRE-RX IS MISSING OR >= 2 IF PRE-RX < 2 OR >= 4 IF PRE-RX >= 2 WBC, URINE UWBC HPF H >= 2 IF PRE-RX IS MISSING OR >= 2 IF PRE-RX < 2 OR >= 4 IF PRE-RX >= 2

End point type	Secondary

End point timeframe:

Up to 42 days post last dose of study medication in short-term or long-term extension period

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Subjects				
Blood, Urine, Low|	9999	9999	9999	9999
Blood, Urine, High|	18	21	20	21
Glucose, Urine, Low|	9999	9999	9999	9999
Glucose, Urine, High|	2	2	0	0
Protein, Urine, Low|	9999	9999	9999	9999
Protein, Urine, High|	7	7	13	7
RBC, Urine, Low|	9999	9999	9999	9999
RBC, Urine, High|	18	19	13	17
WBC, Urine, Low|	9999	9999	9999	9999
WBC, Urine, High|	28	29	31	31

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Subjects				
Blood, Urine, Low|	9999			
Blood, Urine, High|	20			
Glucose, Urine, Low|	9999			
Glucose, Urine, High|	1			
Protein, Urine, Low|	9999			

Protein, Urine, High|	10			
RBC, Urine, Low|	9999			
RBC, Urine, High|	18			
WBC, Urine, Low|	9999			
WBC, Urine, High|	25			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the SLEDAI-2K score of SLE activity over time

End point title	Change from baseline in the SLEDAI-2K score of SLE activity over time

End point description:

Systemic Lupus Erythematosus Disease Activity Index, SLEDAI; Version 2000, also known as SLEDAI-2K. The SLEDAI-2K score is a weighted, cumulative index of lupus disease activity. SLEDAI-2K is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Score				
arithmetic mean (standard deviation)				
SLEDAI-2K Score Day 85	-3.61 (± 3.345)	-3.24 (± 3.320)	-3.17 (± 3.304)	-4.02 (± 3.960)
SLEDAI-2K Score Day 169	-4.88 (± 3.370)	-4.17 (± 4.064)	-3.98 (± 3.478)	-4.82 (± 4.078)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Score				
arithmetic mean (standard deviation)				
SLEDAI-2K Score Day 85	-3.29 (± 3.953)			
SLEDAI-2K Score Day 169	-4.15 (± 3.728)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment of Disease Activity (MDGA) over time

End point title	Change From Baseline in Physician Global Assessment of Disease Activity (MDGA) over time

End point description:

Physician Global Assessment of Arthritis was measured by asking the physician to assess the participant's current arthritis disease activity by placing a vertical line on a 0 to 10 centimeter (cm) visual anlalog scale (VAS), where 0 cm = very good and 10 cm = very bad.

End point type	Secondary

End point timeframe:

At Day 85 and Day 169

End point values	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week	Experimental: 1.25mg SC BMS-931699 Every other Week
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	70
Units: Score				
arithmetic mean (standard deviation)				
MDGA Score Day 85	-28.77 (± 18.193)	-23.87 (± 20.321)	-21.00 (± 20.596)	-20.55 (± 17.233)
MDGA Score Day 169	-29.30 (± 17.371)	-26.87 (± 21.284)	-28.68 (± 19.919)	-26.71 (± 18.182)

End point values	Placebo Comparator: 0mg SC BMS-931699 Weekly			
Subject group type	Reporting group			
Number of subjects analysed	71			
Units: Score				
arithmetic mean (standard deviation)				
MDGA Score Day 85	-23.83 (± 20.752)			
MDGA Score Day 169	-25.28 (± 19.952)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All non-serious adverse events (NSAEs) and serious adverse events (SAEs) are reported from onset on or after the first dose date of study medication and up to 42 days post last dose.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Experimental:12.5mg SC BMS-931699 Weekly

Reporting group description:

Subjects received 0 milligram (mg) subcutaneous (SC) injection of matching placebo weekly.

Reporting group title	Experimental:12.5mg SC BMS-931699 Every other Week

Reporting group description:

Subjects received 1.25 mg lulizumab pegol SC injection EOW.

Reporting group title	Experimental: 5mg SC BMS-931699 Every other Week

Reporting group description:

Subjects received 5 mg SC injection of lulizumab pegol EOW.

Reporting group title	Experimental: 1.25mg SC BMS-931699 Every other Week

Reporting group description:

Subjects received 12.5 mg SC injection of lulizumab pegol EOW.

Reporting group title	Placebo Comparator: 0mg SC BMS-931699 Weekly

Reporting group description:

Subjects received 12.5 mg SC injection of lulizumab pegol weekly.

Serious adverse events	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 71 (8.45%)	8 / 70 (11.43%)	9 / 68 (13.24%)
number of deaths (all causes)	0	2	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Imminent abortion			

subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Immune system disorders			
Serum sickness			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 71 (1.41%)	0 / 70 (0.00%)	0 / 68 (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
Injury, poisoning and procedural complications			
Incisional hernia			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Cardiac failure congestive			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Putamen haemorrhage			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Lupus enteritis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 71 (1.41%)	0 / 70 (0.00%)	0 / 68 (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
Renal and urinary disorders			
Lupus nephritis			
subjects affected / exposed	2 / 71 (2.82%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 71 (0.00%)	2 / 70 (2.86%)	2 / 68 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	3 / 71 (4.23%)	0 / 70 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Infected skin ulcer			
subjects affected / exposed	1 / 71 (1.41%)	0 / 70 (0.00%)	0 / 68 (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
Infectious mononucleosis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	0 / 68 (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
Zika virus infection			
subjects affected / exposed	0 / 71 (0.00%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Experimental: 1.25mg SC BMS-931699 Every other	Placebo Comparator: 0mg SC BMS-931699 Weekly	

Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 68 (7.35%)	5 / 69 (7.25%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 68 (1.47%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Imminent abortion			
subjects affected / exposed	1 / 68 (1.47%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 68 (1.47%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Serum sickness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Incisional hernia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic neuritis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Putamen haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Lupus enteritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Lupus nephritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain			

subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	1 / 68 (1.47%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 68 (1.47%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious mononucleosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 68 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Zika virus infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Experimental:12.5mg SC BMS-931699 Weekly	Experimental:12.5mg SC BMS-931699 Every other Week	Experimental: 5mg SC BMS-931699 Every other Week
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 71 (87.32%)	59 / 70 (84.29%)	60 / 68 (88.24%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 71 (4.23%)	5 / 70 (7.14%)	1 / 68 (1.47%)
occurrences (all)	4	5	1
Headache			
subjects affected / exposed	10 / 71 (14.08%)	5 / 70 (7.14%)	7 / 68 (10.29%)
occurrences (all)	10	5	13
Migraine			
subjects affected / exposed	2 / 71 (2.82%)	1 / 70 (1.43%)	4 / 68 (5.88%)
occurrences (all)	2	1	4
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 71 (0.00%)	3 / 70 (4.29%)	3 / 68 (4.41%)
occurrences (all)	0	4	3
Lymphopenia			
subjects affected / exposed	0 / 71 (0.00%)	2 / 70 (2.86%)	3 / 68 (4.41%)
occurrences (all)	0	2	4
General disorders and administration			

site conditions			
Chest pain			
subjects affected / exposed	4 / 71 (5.63%)	1 / 70 (1.43%)	2 / 68 (2.94%)
occurrences (all)	4	1	2
Injection site pain			
subjects affected / exposed	4 / 71 (5.63%)	2 / 70 (2.86%)	4 / 68 (5.88%)
occurrences (all)	9	27	6
Injection site reaction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 70 (0.00%)	3 / 68 (4.41%)
occurrences (all)	0	0	5
Pyrexia			
subjects affected / exposed	2 / 71 (2.82%)	4 / 70 (5.71%)	3 / 68 (4.41%)
occurrences (all)	2	5	7
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	11 / 71 (15.49%)	5 / 70 (7.14%)	5 / 68 (7.35%)
occurrences (all)	12	5	7
Nausea			
subjects affected / exposed	4 / 71 (5.63%)	5 / 70 (7.14%)	5 / 68 (7.35%)
occurrences (all)	5	8	5
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 71 (5.63%)	2 / 70 (2.86%)	1 / 68 (1.47%)
occurrences (all)	4	2	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 71 (5.63%)	0 / 70 (0.00%)	1 / 68 (1.47%)
occurrences (all)	5	0	2
Back pain			
subjects affected / exposed	3 / 71 (4.23%)	2 / 70 (2.86%)	1 / 68 (1.47%)
occurrences (all)	3	3	1
Neck pain			
subjects affected / exposed	2 / 71 (2.82%)	4 / 70 (5.71%)	1 / 68 (1.47%)
occurrences (all)	2	4	1
Systemic lupus erythematosus			

subjects affected / exposed	2 / 71 (2.82%)	1 / 70 (1.43%)	3 / 68 (4.41%)
occurrences (all)	2	1	6
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 71 (4.23%)	1 / 70 (1.43%)	3 / 68 (4.41%)
occurrences (all)	4	1	3
Gastroenteritis			
subjects affected / exposed	1 / 71 (1.41%)	1 / 70 (1.43%)	2 / 68 (2.94%)
occurrences (all)	1	1	2
Influenza			
subjects affected / exposed	2 / 71 (2.82%)	2 / 70 (2.86%)	3 / 68 (4.41%)
occurrences (all)	2	2	3
Nasopharyngitis			
subjects affected / exposed	5 / 71 (7.04%)	6 / 70 (8.57%)	8 / 68 (11.76%)
occurrences (all)	5	8	11
Pharyngitis			
subjects affected / exposed	4 / 71 (5.63%)	3 / 70 (4.29%)	7 / 68 (10.29%)
occurrences (all)	6	4	8
Upper respiratory tract infection			
subjects affected / exposed	3 / 71 (4.23%)	9 / 70 (12.86%)	7 / 68 (10.29%)
occurrences (all)	3	9	8
Urinary tract infection			
subjects affected / exposed	4 / 71 (5.63%)	11 / 70 (15.71%)	9 / 68 (13.24%)
occurrences (all)	4	12	10
Vaginal infection			
subjects affected / exposed	1 / 71 (1.41%)	1 / 70 (1.43%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	1 / 71 (1.41%)	2 / 70 (2.86%)	4 / 68 (5.88%)
occurrences (all)	2	2	4

Non-serious adverse events	Experimental: 1.25mg SC BMS-931699 Every other	Placebo Comparator: 0mg SC BMS-931699 Weekly	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 68 (82.35%)	59 / 69 (85.51%)	

Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 68 (4.41%)	3 / 69 (4.35%)	
occurrences (all)	3	3	
Headache			
subjects affected / exposed	9 / 68 (13.24%)	10 / 69 (14.49%)	
occurrences (all)	13	11	
Migraine			
subjects affected / exposed	1 / 68 (1.47%)	0 / 69 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	3 / 68 (4.41%)	5 / 69 (7.25%)	
occurrences (all)	4	6	
Lymphopenia			
subjects affected / exposed	4 / 68 (5.88%)	4 / 69 (5.80%)	
occurrences (all)	6	5	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 68 (1.47%)	1 / 69 (1.45%)	
occurrences (all)	1	1	
Injection site pain			
subjects affected / exposed	3 / 68 (4.41%)	2 / 69 (2.90%)	
occurrences (all)	7	27	
Injection site reaction			
subjects affected / exposed	2 / 68 (2.94%)	4 / 69 (5.80%)	
occurrences (all)	3	7	
Pyrexia			
subjects affected / exposed	1 / 68 (1.47%)	1 / 69 (1.45%)	
occurrences (all)	1	2	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 68 (1.47%)	7 / 69 (10.14%)	
occurrences (all)	1	8	
Nausea			

subjects affected / exposed	0 / 68 (0.00%)	5 / 69 (7.25%)	
occurrences (all)	0	6	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	3 / 68 (4.41%)	2 / 69 (2.90%)	
occurrences (all)	3	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 68 (1.47%)	2 / 69 (2.90%)	
occurrences (all)	1	4	
Back pain			
subjects affected / exposed	4 / 68 (5.88%)	5 / 69 (7.25%)	
occurrences (all)	4	5	
Neck pain			
subjects affected / exposed	0 / 68 (0.00%)	3 / 69 (4.35%)	
occurrences (all)	0	3	
Systemic lupus erythematosus			
subjects affected / exposed	2 / 68 (2.94%)	5 / 69 (7.25%)	
occurrences (all)	2	5	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 68 (1.47%)	4 / 69 (5.80%)	
occurrences (all)	1	4	
Gastroenteritis			
subjects affected / exposed	3 / 68 (4.41%)	8 / 69 (11.59%)	
occurrences (all)	3	8	
Influenza			
subjects affected / exposed	4 / 68 (5.88%)	0 / 69 (0.00%)	
occurrences (all)	4	0	
Nasopharyngitis			
subjects affected / exposed	4 / 68 (5.88%)	9 / 69 (13.04%)	
occurrences (all)	4	18	
Pharyngitis			
subjects affected / exposed	5 / 68 (7.35%)	2 / 69 (2.90%)	
occurrences (all)	6	3	
Upper respiratory tract infection			

subjects affected / exposed	3 / 68 (4.41%)	7 / 69 (10.14%)	
occurrences (all)	3	7	
Urinary tract infection			
subjects affected / exposed	11 / 68 (16.18%)	6 / 69 (8.70%)	
occurrences (all)	16	6	
Vaginal infection			
subjects affected / exposed	5 / 68 (7.35%)	2 / 69 (2.90%)	
occurrences (all)	5	2	
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	4 / 68 (5.88%)	4 / 69 (5.80%)	
occurrences (all)	4	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 April 2015	The main purposes of this amendment are to 10 add a long term extension (LTE), 2) address regulatory requests, 3) update the generic name. In addition, editorial adjustments to provide clarification or fix typographical errors.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported