



Clinical trial results:

A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy and Safety of BMS-986165 in Subjects With Systemic Lupus Erythematosus

Summary

EudraCT number	2017-001203-79
Trial protocol	HU PL DE ES RO
Global end of trial date	28 October 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	IM011-021
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 January 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of BMS-986165 in subjects with Systemic Lupus Erythematosus

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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 September 2017
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	Japan: 19
Country: Number of subjects enrolled	Argentina: 19
Country: Number of subjects enrolled	Brazil: 32
Country: Number of subjects enrolled	Colombia: 24
Country: Number of subjects enrolled	Mexico: 33
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	United States: 85
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Hungary: 11
Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Poland: 51
Country: Number of subjects enrolled	Romania: 14
Country: Number of subjects enrolled	Russian Federation: 44
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	Taiwan: 16
Worldwide total number of subjects	363
EEA total number of subjects	84

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)	354
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

363 Participants randomized and treated

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, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo
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Arm description:

Placebo PO BID

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo Matching BMS-986165

Arm title	BMS-986165 3 mg
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Arm description:

BMS-986165 3 mg PO BID

Arm type	Experimental
Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3 mg PO BID

Arm title	BMS-986165 6 mg
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Arm description:

BMS-986165 6 mg PO BID

Arm type	Experimental
Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

6 mg PO BID

Arm title	BMS-986165 12 mg
Arm description: BMS-986165 12 mg PO QD	
Arm type	Experimental
Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Intratumoral use, Oral use
Dosage and administration details: 12 mg PO QD	

Number of subjects in period 1	Placebo	BMS-986165 3 mg	BMS-986165 6 mg
Started	90	91	93
Completed	66	71	76
Not completed	24	20	17
Consent withdrawn by subject	8	4	4
Adverse event, non-fatal	3	8	6
Other Reasons	2	5	5
Pregnancy	2	1	-
Lost to follow-up	2	-	-
Lack of efficacy	7	2	2

Number of subjects in period 1	BMS-986165 12 mg
Started	89
Completed	62
Not completed	27
Consent withdrawn by subject	4
Adverse event, non-fatal	12
Other Reasons	4
Pregnancy	1
Lost to follow-up	2
Lack of efficacy	4

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Placebo PO BID	
Reporting group title	BMS-986165 3 mg
Reporting group description: BMS-986165 3 mg PO BID	
Reporting group title	BMS-986165 6 mg
Reporting group description: BMS-986165 6 mg PO BID	
Reporting group title	BMS-986165 12 mg
Reporting group description: BMS-986165 12 mg PO QD	

Reporting group values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg
Number of subjects	90	91	93
Age categorical Units:			

Age Continuous Units: years arithmetic mean standard deviation	40.1 ± 13.1	40.2 ± 11.9	40.9 ± 12.5
Sex: Female, Male Units: Participants			
Female	80	85	88
Male	10	6	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	4	3	5
Asian	10	9	15
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	10	8
White	60	62	55
More than one race	0	0	0
Unknown or Not Reported	10	7	10
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	31	31	29
Not Hispanic or Latino	58	60	64
Unknown or Not Reported	1	0	0

Reporting group values	BMS-986165 12 mg	Total	
Number of subjects	89	363	

Age categorical Units:			
Age Continuous Units: years arithmetic mean standard deviation	39.0 ± 10.6	-	
Sex: Female, Male Units: Participants			
Female	81	334	
Male	8	29	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	14	
Asian	10	44	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	9	33	
White	57	234	
More than one race	0	0	
Unknown or Not Reported	11	38	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	36	127	
Not Hispanic or Latino	53	235	
Unknown or Not Reported	0	1	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Placebo PO BID	
Reporting group title	BMS-986165 3 mg
Reporting group description: BMS-986165 3 mg PO BID	
Reporting group title	BMS-986165 6 mg
Reporting group description: BMS-986165 6 mg PO BID	
Reporting group title	BMS-986165 12 mg
Reporting group description: BMS-986165 12 mg PO QD	

Primary: Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 32

End point title	Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 32
End point description: SRI(4) responder is defined as a patient whose disease course fulfills all of the following: (1) A 4-point or greater reduction from baseline in SLEDAI-2K score (2) No new British Isles Lupus Assessment Group (BILAG) A (severe disease activity) and not more than 1 new BILAG B (moderate disease activity) organ domain grade (3) No worsening from baseline in the Physician's Global Assessment of Disease Activity Scale by more than 0.3 points on a 3-point visual analog scale from no disease activity to severe disease activity	
End point type	Primary
End point timeframe: At week 32	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants	31	53	46	40

Statistical analyses

Statistical analysis title	Odds Ratio BMS-986165 3 mg vs Placebo
Statistical analysis description: BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg

Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0006
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	5.1

Statistical analysis title	Odds Ratio BMS-986165 12 mg vs Placebo
Statistical analysis description: BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0781
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	2.9

Statistical analysis title	Odds Ratio BMS-986165 6 mg vs Placebo
Statistical analysis description: BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.021
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	3.4

Secondary: Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 48

End point title	Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 48
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End point description:

SRI(4) responder is defined as a patient whose disease course fulfills all of the following:

- (1) A 4-point or greater reduction from baseline in SLEDAI-2K score
- (2) No new British Isles Lupus Assessment Group (BILAG) A (severe disease activity) or not more than 1 new BILAG B (moderate disease activity) organ domain grade
- (3) No worsening from baseline in the Physician's Global Assessment of Disease Activity Scale by more than 0.3 points on a 3-point visual analog scale from no disease activity to severe disease activity

End point type	Secondary
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End point timeframe:

At week 48

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants	31	52	44	42

Statistical analyses

Statistical analysis title	Odds Ratio BMS-986165 3 mg vs Placebo
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Statistical analysis description:

BMS-986165 3 mg vs Placebo

Comparison groups	Placebo v BMS-986165 3 mg
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Number of subjects included in analysis	181
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Analysis specification	Pre-specified
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Analysis type	
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P-value	= 0.0011
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Method	Regression, Logistic
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Parameter estimate	Odds ratio (OR)
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Point estimate	2.6
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	1.4
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upper limit	4.8
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Statistical analysis title	Odds Ratio BMS-986165 6 mg vs Placebo
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Statistical analysis description:

BMS-986165 6 mg vs Placebo

Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0434
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	3.1

Statistical analysis title

Odds Ratio BMS-986165 12 mg vs Placebo

Statistical analysis description:

BMS-986165 12 mg vs Placebo

Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0439
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	3.1

Secondary: Number of Participants Who Achieve British Isles Lupus Assessment Group-Based Composite Lupus Assessment (BICLA) Response

End point title	Number of Participants Who Achieve British Isles Lupus Assessment Group-Based Composite Lupus Assessment (BICLA) Response
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End point description:

BICLA responder is defined as a patient whose disease course fulfills all of the following:

- (1) Improvement in all organ systems with activity graded as BILAG-2004 A (severe disease activity) or B (moderate disease activity) at baseline
- (2) No new organ system with activity graded as BILAG A; no more than 1 new organ system with activity graded as BILAG B
- (3) No increase from baseline in Systemic Lupus Erythematosus SLEDAI-2K score (≤ 0 points for change from baseline score)
- (4) No increase $\geq 10\%$ in the Physician's Global Assessment of Disease Activity on a 3-point visual analog scale from no disease activity to severe disease activity
- (5) No discontinuation of investigational product or use of restricted medications beyond the protocol allowed threshold before assessment

End point type	Secondary
End point timeframe:	
At week 48	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants	23	43	33	32

Statistical analyses

Statistical analysis title	Odds Ratio BMS-986165 3 mg vs Placebo
Statistical analysis description: BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0012
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	5.1

Statistical analysis title	Odds Ratio BMS-986165 12 mg vs Placebo
Statistical analysis description: BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0673
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	3.2

Statistical analysis title	Odds Ratio BMS-986165 6 mg vs Placebo
Statistical analysis description: BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0795
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	3

Secondary: Number of Participants Who Achieve Lupus Low Disease Activity State (LLDAS)

End point title	Number of Participants Who Achieve Lupus Low Disease Activity State (LLDAS)
End point description: LLDAS is defined as follows: (1) SLEDAI-2K \leq 4, with no activity in major organ systems (renal, central nervous system, cardiopulmonary, vasculitis, fever) and no hemolytic anemia or gastrointestinal activity measured as maintaining a D (no disease activity but suggests the system had previously been affected) or E (no current or previous disease activity) score in BILAG Gastrointestinal Body System (2) No new lupus disease activity compared with the previous assessment measured as no new or worsening individual BILAG parameters (3) Physician's Global Assessment of Disease Activity \leq 1 on a 3-point visual analog scale from no disease activity to severe disease activity (4) A current prednisolone (or equivalent) dose \leq 7.5 mg daily (5) Well-tolerated standard maintenance doses of immunosuppressive drugs and approved biological agents	
End point type	Secondary
End point timeframe: At Week 48	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants	12	33	22	23

Statistical analyses

Statistical analysis title	Odds Ratio BMS-986165 3 mg vs Placebo
Statistical analysis description: BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	8.5

Statistical analysis title	Odds Ratio BMS-986165 12 mg vs Placebo
Statistical analysis description: BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0168
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	5.1

Statistical analysis title	Odds Ratio BMS-986165 6 mg vs Placebo
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Statistical analysis description: BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0371
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	4.5

Secondary: Number of Participants With a $\geq 50\%$ Reduction in CLASI Activity Score in the Sub-group With Baseline CLASI Activity Score ≥ 10

End point title	Number of Participants With a $\geq 50\%$ Reduction in CLASI Activity Score in the Sub-group With Baseline CLASI Activity Score ≥ 10
End point description: Number of participants with a Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) activity score ≥ 10 at baseline who achieve a CLASI response, defined as a decrease of $\geq 50\%$ from baseline CLASI activity score (ranges from 0-70, where a higher score is associated with high disease activity). CLASI assesses by body surface area; points are given for presence of erythema, scale, hypertrophy, mucous membrane lesions, recent hair loss, and physician-observed alopecia	
End point type	Secondary
End point timeframe: At week 48	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	23	25	29
Units: Participants	4	16	14	18

Statistical analyses

Statistical analysis title	Odds Ratio BMS-986165 3 mg vs Placebo
Statistical analysis description: BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg

Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0006
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	43

Statistical analysis title	Odds Ratio BMS-986165 12 mg vs Placebo
Statistical analysis description: BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0009
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	8.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	31

Statistical analysis title	Odds Ratio BMS-986165 6 mg vs Placebo
Statistical analysis description: BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0058
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	22

Secondary: Change from Baseline in the 40-Joint Count

End point title	Change from Baseline in the 40-Joint Count
End point description:	
Change from baseline in the following 40-joint count: phalangeal joints of the hand, second through fifth metacarpophalangeal joints of the hand, and individual metatarsophalangeal joints of the feet, Bilateral first metacarpophalangeal joints and shoulders. Each of 40 joints count is evaluated based upon the presence or absence of: (1) Tender joint count (0 to 40) (2) Swollen joint count (0 to 40) (3) Tender and swollen joint count (0 to 40) A larger joint count indicates more severe disease.	
End point type	Secondary
End point timeframe:	
Baseline and week 48	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Units on a scale				
arithmetic mean (standard deviation)				
Tender	-11.2 (± 8.0)	-12.2 (± 7.5)	-11.7 (± 9.5)	-12.3 (± 7.1)
Swollen	-8.3 (± 6.9)	-8.5 (± 4.2)	-8.8 (± 7.2)	-9.9 (± 6.1)
Tender + Swollen	-8.2 (± 6.7)	-8.2 (± 4.3)	-8.5 (± 7.0)	-9.7 (± 5.9)

Statistical analyses

Statistical analysis title	Odd Ratio Tender BMS-986165 3 mg vs Placebo
Statistical analysis description:	
Tender BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0131
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	-0.3
Variability estimate	Standard error of the mean
Dispersion value	1.04

Statistical analysis title	Odd Ratio Tender BMS-986165 6 mg vs Placebo
Statistical analysis description: Tender BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4156
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.8
Variability estimate	Standard error of the mean
Dispersion value	1.04

Statistical analysis title	Odd Ratio Tender BMS-986165 12 mg vs Placebo
Statistical analysis description: Tender BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0151
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	-0.2
Variability estimate	Standard error of the mean
Dispersion value	1.09

Statistical analysis title	Odd Ratio Swollen BMS-986165 3 mg vs Placebo
Statistical analysis description: Swollen BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg

Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0029
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	-0.4
Variability estimate	Standard error of the mean
Dispersion value	0.45

Statistical analysis title	Odd Ratio Swollen BMS-986165 6 mg vs Placebo
Statistical analysis description:	
Swollen BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0516
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	0.46

Statistical analysis title	OR Tender + Swollen BMS-986165 3 mg vs Placebo
Statistical analysis description:	
Tender + Swollen BMS-986165 3 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 3 mg
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	-0.5
Variability estimate	Standard error of the mean
Dispersion value	0.4

Statistical analysis title	Odd Ratio Swollen BMS-986165 12 mg vs Placebo
Statistical analysis description: Swollen BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0298
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.48

Statistical analysis title	OR Tender + Swollen BMS-986165 6 mg vs Placebo
Statistical analysis description: Tender + Swollen BMS-986165 6 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 6 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0343
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	0.1
Variability estimate	Standard error of the mean
Dispersion value	0.4

Statistical analysis title	OR Tender + Swollen BMS-986165 12 mg vs Placebo
Statistical analysis description: Tender + Swollen BMS-986165 12 mg vs Placebo	
Comparison groups	Placebo v BMS-986165 12 mg
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.005
Method	Longitudinal Repeated Measures
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	-0.3
Variability estimate	Standard error of the mean
Dispersion value	0.42

Secondary: Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)
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End point description:

Number of participants with any grade adverse events (AEs) and any grade serious adverse events (SAEs). An adverse event (AE) including SAEs is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in participants that do not necessarily have causal relationship with treatment

End point type	Secondary
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End point timeframe:

From first dose to 30 days post last dose (Up to 52 weeks)

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants				
AEs	79	85	81	75
SAEs	11	7	8	7

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Laboratory Abnormalities in Specific Liver Tests

End point title	Number of Participants with Laboratory Abnormalities in Specific Liver Tests
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End point description:

Number of participants with laboratory abnormalities in specific liver tests based on US conventional units. The potential drug-induced liver injury is defined by the presence of all of the following:

(1) Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) elevation > 3× Upper Limit of Normal (ULN)

(2) Total bilirubin > 2× ULN, without initial findings of cholestasis (elevated serum alkaline phosphatase)

(3) No other immediately apparent possible causes of AST or AST elevation and hyperbilirubinemia, including, but not limited to, viral hepatitis, preexisting chronic or acute liver disease, or the administration of other drug(s) known to be hepatotoxic

End point type	Secondary
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End point timeframe:

From first dose to 30 days post last dose (Up to 52 weeks)

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants				
ALT or AST > 3XULN	2	5	3	2
ALT or AST > 5XULN	2	1	1	1
Total Bilirubin > 2XULN	0	0	0	0
ALT or AST>3XULN and Total Bilirubin>2XULN	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormalities in Vital Signs

End point title	Number of Participants with Abnormalities in Vital Signs
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End point description:

Number of participants with abnormalities in vital signs including heart rate, systolic blood pressure, and diastolic blood pressure

End point type	Secondary
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End point timeframe:

From first dose to 30 days post last dose (Up to 52 weeks)

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	88	91	87
Units: Participants				
Wk 2: HR: Value>100 and change from baseline>30	0	0	0	0
Wk 2: HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 2 SBP: Value>140 and change from baseline>20	1	1	0	1
Wk 2 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 2 DBP: Value>90 and change from baseline>10	0	0	1	1
Wk 2 DBP: Value<55 and change from baseline<-10	0	2	1	0
Wk 4 HR: Value>100 and change from baseline>30	0	0	1	0
Wk 4 HR: Value<55 and change from baseline<-15	0	1	0	0
Wk 4 SBP: Value>140 and change from baseline>20	0	0	0	1
Wk 4 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 4 DBP: Value>90 and change from baseline>10	2	0	0	1
Wk 4 DBP: Value<55 and change from baseline<-10	0	0	0	0
Wk 8 HR: Value>100 and change from baseline>30	1	2	0	0
Wk 8 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 8 SBP: Value>140 and change from baseline>20	1	1	1	0
Wk 8 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 8 DBP: Value>90 and change from baseline>10	0	1	3	1
Wk 8 DBP: Value<55 and change from baseline<-10	0	1	0	0
Wk 12 HR: Value>100 and change from baseline>30	0	0	0	0
Wk 12 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 12 SBP: Value>140 and change from baseline>20	1	1	0	0
Wk 12 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 12 DBP: Value>90 and change from baseline>10	0	3	2	1
Wk 12 DBP: Value<55 and change from baseline<-10	1	1	1	0
Wk 16 HR: Value>100 and change from baseline>30	0	0	0	0
Wk 16 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 16 SBP: Value>140 and change from baseline>20	0	0	0	1
Wk 16 SBP: Value<90 and change from baseline<-20	1	0	0	0

Wk 16 DBP: Value>90 and change from baseline>10	0	1	0	2
Wk 16 DBP: Value<55 and change from baseline<-10	0	0	0	0
Wk 20: HR: Value>100 and change from baseline>30	0	0	0	0
Wk 20 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 20 SBP: Value>140 and change from baseline>20	1	1	0	1
Wk 20 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 20 DBP: Value>90 and change from baseline>10	2	2	0	2
Wk 20 DBP: Value<55 and change from baseline<-10	0	0	0	0
Wk 24 HR: Value>100 and change from baseline>30	1	0	0	0
Wk 24 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 24 SBP: Value>140 and change from baseline>20	0	1	0	1
Wk 24 SBP: Value<90 and change from baseline<-20	0	1	0	0
Wk 24 DBP: Value>90 and change from baseline>10	0	1	0	2
Wk 24 DBP: Value<55 and change from baseline<-10	0	1	0	0
Wk 28 HR Value>100 and change from baseline>30	0	0	0	0
Wk 28 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 28 SBP: Value>140 and change from baseline>20	1	3	1	3
Wk 28 SBP: Value<90 and change from baseline<-20	0	0	1	0
Wk 28 DBP: Value>90 and change from baseline>10	1	4	0	2
Wk 28 DBP: Value<55 and change from baseline<-10	0	1	0	0
Wk 32 HR: Value>100 and change from baseline>30	0	2	1	0
Wk 32 HR Value<55 and change from baseline<-15	0	0	0	0
Wk 32 SBP: Value>140 and change from baseline>20	1	1	0	3
Wk 32 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 32 DBP: Value>90 and change from baseline>10	1	1	2	3
Wk 32 DBP: Value<55 and change from baseline<-10	0	1	0	0
Wk 36 HR: Value>100 and change from baseline>30	0	1	0	0
Wk 36 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 36 SBP: Value>140 and change from baseline>20	0	0	0	1
Wk 36 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 36 DBP: Value>90 and change from baseline>10	1	1	1	2

Wk 36 DBP: Value<55 and change from baseline<-10	0	0	0	0
Wk 40 HR: Value>100 and change from baseline>30	0	0	0	0
Wk 40 HR: Value<55 and change from baseline<-15	1	0	0	0
Wk 40 SBP: Value>140 and change from baseline>20	1	0	0	2
Wk 40 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 40 DBP: Value>90 and change from baseline>10	0	2	1	1
Wk 40 DBP: Value<55 and change from baseline<-10	0	0	0	0
Wk 44 HR: Value>100 and change from baseline>30	0	0	0	0
Wk 44 HR: Value<55 and change from baseline<-15	0	0	1	0
Wk 44 SBP: Value>140 and change from baseline>20	0	0	0	0
Wk 44 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 44 DBP: Value>90 and change from baseline>10	0	0	1	2
Wk 44 DBP: Value<55 and change from baseline<-10	1	1	0	0
Wk 48 HR: Value>100 and change from baseline>30	0	0	0	0
Wk 48 HR: Value<55 and change from baseline<-15	0	0	0	0
Wk 48 SBP: Value>140 and change from baseline>20	2	0	0	0
Wk 48: SBP: Value<90 and change from baseline<-20	0	1	0	0
Wk 48 DBP: Value>90 and change from baseline>10	2	1	0	0
Wk 48 DBP: Value<55 and change from baseline<-10	0	0	0	0
Wk 52 HR: Value>100 and change from baseline>30	0	0	0	0
Wk 52 HR: Value<55 and change from baseline<-15	0	1	0	0
Wk 52 SBP: Value>140 and change from baseline>20	0	0	0	0
Wk 52 SBP: Value<90 and change from baseline<-20	0	0	0	0
Wk 52 DBP: Value>90 and change from baseline>10	0	0	0	1
Wk 52 DBP: Value<55 and change from baseline<-10	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormalities in Electrocardiograms (ECGs)

End point title	Number of Participants with Abnormalities in Electrocardiograms (ECGs)
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End point description:

Number of participants with abnormalities in electrocardiograms (ECGs) assessed by QTcF, PR interval, and QRS interval

End point type	Secondary
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End point timeframe:

From baseline to up to week 48

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	89	90	92	89
Units: Participants				
Baseline: QTcF 450 to < 480	9	3	6	5
Baseline: QTcF 480 to < 500	1	1	0	0
Baseline: QTcF >= 500	0	0	1	0
Baseline: PR Interval >= 200	5	4	6	6
Baseline: QRS Interval >=200	0	0	0	0
Week 4: QTcF 450 to < 480	5	6	5	6
Week 4: QTcF 480 to < 500	0	2	1	0
Week4: QTcF >= 500	0	0	0	1
Week 4: PR Interval >= 200	7	7	4	5
Week 4: QRS Interval: >= 200	0	0	0	0
Week 8: QTcF 450 to < 480	7	5	6	1
Week 8: QTcF 480 to < 500	0	0	1	2
Week 8: QTcF >=500	0	0	0	0
Week 8: PR Interval >= 200	5	6	5	6
Week 8 QRS Interval >=200	0	0	0	0
Week 12: QTcF 450 to < 480	3	4	6	8
Week 12: QTcF 480 to < 500	0	0	0	0
Week 12: QTcF >= 500	0	0	0	1
Week 12: PR Interval >= 200	6	8	4	4
Week 12: QRS Interval >=200	0	0	0	0
Week 32: QTcF 450 to < 480	5	5	2	5
Week 32: QTcF 480 to < 500	0	0	2	0
Week 32: QTcF >=500	0	0	0	0
Week 32: PR Interval >= 200	5	7	5	5
Week 32: QRS Interval >= 200	0	0	0	0
Week 48: QTcF: 450 to < 480	7	2	8	5
Week 48: QTcF 480 to < 500	0	0	0	0
Week 48: QTcF >=500	0	0	0	0
Week 48: PR Interval: >= 200	4	7	6	3
Week 48: QRS Interval: >= 200	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986165 and its Active Metabolite BMT-153261 Maximum Observed Plasma Concentration (Cmax)

End point title	BMS-986165 and its Active Metabolite BMT-153261 Maximum Observed Plasma Concentration (Cmax) ^[1]
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End point description:

Maximum observed plasma concentration (Cmax) for the following treatments: BMS-986165 and its active metabolite BMT-153261. Geometric coefficient of variation was not calculated and the arithmetic coefficient of variation (% CV) is being reported.

End point type	Secondary
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End point timeframe:

Pre-dose, 0.5, 2, 4, and 6 hours post dose on week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only pre-specified arms planned for this endpoint

End point values	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	73	47	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
BMS-986165	38.033 (± 57.72)	76.400 (± 37.72)	96.249 (± 46.80)	
Metabolite BMT-153261	6.358 (± 67.77)	12.133 (± 37.72)	11.748 (± 67.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986165 and its Active Metabolite BMT-153261 Time of Maximum Observed Plasma Concentration (Tmax)

End point title	BMS-986165 and its Active Metabolite BMT-153261 Time of Maximum Observed Plasma Concentration (Tmax) ^[2]
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End point description:

Time of maximum observed plasma concentration (Tmax) for the following treatments: BMS-986165 and its active metabolite BMT-153261.

End point type	Secondary
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End point timeframe:

Pre-dose, 0.5, 2, 4, 6, and 10 hours post dose on week 12

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only pre-specified arms planned for this endpoint

End point values	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	73	47	
Units: Hours				
median (full range (min-max))				
BMS-986165	2.0000 (0.467 to 6.000)	2.0000 (0.500 to 7.533)	2.0000 (0.500 to 5.100)	
Metabolite BMT-153261	4.0000 (0.550 to 7.500)	4.0000 (1.017 to 9.533)	3.7330 (0.500 to 6.067)	

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986165 and its Active Metabolite BMT-153261 Trough Observed Plasma Concentration (C_{trough})

End point title	BMS-986165 and its Active Metabolite BMT-153261 Trough Observed Plasma Concentration (C _{trough}) ^[3]
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End point description:

Trough observed plasma concentration (C_{trough}) for the following treatments: BMS-986165 and its active metabolite BMT-153261. Geometric coefficient of variation was not calculated and the arithmetic coefficient of variation (% CV) is being reported.

End point type	Secondary
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End point timeframe:

Pre-dose, 0.5, 2, 4, and 6 hours post dose on week 2, 4, 8, 12, 24, 32, and 48

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only pre-specified arms planned for this endpoint

End point values	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	52	64	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
BMS-986165 week 2	14.3737 (± 60.790)	29.2909 (± 47.588)	30.8135 (± 70.340)	
BMS-986165 week 4	14.6095 (± 53.234)	22.9170 (± 51.043)	20.1182 (± 81.084)	
BMS-986165 week 8	13.0328 (± 69.792)	12.9587 (± 64.799)	26.7961 (± 67.090)	
BMS-986165 week 12	10.7517 (± 93.540)	28.7751 (± 47.282)	22.1237 (± 85.920)	
BMS-986165 week 24	10.2546 (± 66.763)	13.9273 (± 67.922)	21.8720 (± 78.559)	
BMS-986165 week 32	8.5293 (± 60.425)	15.5285 (± 61.704)	24.5060 (± 75.647)	
BMS-986165 week 48	6.8493 (± 70.206)	21.7890 (± 53.718)	15.9576 (± 102.367)	
Metabolite BMT-153261 week 2	4.2667 (± 48.679)	8.4841 (± 54.717)	8.7920 (± 61.993)	

Metabolite BMT-153261 week 4	5.0886 (\pm 56.764)	7.7803 (\pm 53.563)	7.2703 (\pm 70.461)	
Metabolite BMT-153261 week 8	4.1293 (\pm 62.816)	5.2290 (\pm 71.924)	8.1451 (\pm 57.216)	
Metabolite BMT-153261 week 12	3.7325 (\pm 96.323)	9.3281 (\pm 54.823)	7.4071 (\pm 82.009)	
Metabolite BMT-153261 week 24	3.3669 (\pm 56.381)	5.2229 (\pm 71.104)	6.6608 (\pm 63.748)	
Metabolite BMT-153261 week 32	2.9759 (\pm 55.379)	5.2925 (\pm 63.200)	6.8734 (\pm 77.329)	
Metabolite BMT-153261 week 48	2.8708 (\pm 73.450)	6.8838 (\pm 58.302)	5.8602 (\pm 75.536)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels

End point title	Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels
End point description:	
Percent change from baseline in interferon-regulated gene (IRG) expression levels. IRG-high vs. IRG-low was determined using a 5-interferon (IFN) gene set during the sample collected at screening period. Baseline values are defined as the last measurement before the first dose.	
End point type	Secondary
End point timeframe:	
From baseline to week 44	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Percent Change from Baseline arithmetic mean (standard deviation)				
IFN High	-0.8130 (\pm 6.5323)	-39.7478 (\pm 13.0087)	-55.5691 (\pm 21.5313)	-47.5561 (\pm 12.2125)
IFN Low	4.7381 (\pm 8.8696)	-18.0641 (\pm 27.0491)	-36.4510 (\pm 22.4759)	-41.7645 (\pm 26.1519)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels at Week 32

End point title	Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels at Week 32
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End point description:

Percent change from baseline in interferon-regulated gene (IRG) expression levels. IRG-high vs. IRG-low was determined using a 5-interferon (IFN) gene set during the sample collected at screening period. Baseline values are defined as the last measurement before the first dose.

End point type	Secondary
End point timeframe:	
From baseline to week 32	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)				
IFN High	-4.3993 (± 5.2234)	-40.7944 (± 13.5929)	-54.6988 (± 16.7734)	-61.0515 (± 13.8367)
IFN Low	-2.6555 (± 9.2649)	-27.4897 (± 20.0078)	-42.8107 (± 19.7669)	-42.9701 (± 23.8323)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Complement Proteins C3 and C4 Levels

End point title	Percent Change from Baseline in Complement Proteins C3 and C4 Levels
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End point description:

Percent change from baseline in complement proteins C3 and C4 levels. Baseline values are defined as the last measurement before the first dose.

End point type	Secondary
End point timeframe:	
From baseline to week 52	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	10	12	14
Units: mg/L				
arithmetic mean (standard error)				
C3	3.57 (± 12.225)	5.33 (± 6.216)	7.60 (± 5.315)	14.74 (± 9.619)
C4	84.52 (± 88.618)	3.57 (± 7.146)	24.96 (± 20.508)	20.43 (± 12.767)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Complement (C3, C4) Levels at Week 32

End point title	Percent Change from Baseline in Complement (C3, C4) Levels at Week 32
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End point description:

Percent change from baseline in complement proteins C3 and C4 levels. Baseline values are defined as the last measurement before the first dose.

End point type	Secondary
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End point timeframe:

From baseline to week 32

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	66	75	78	63
Units: mg/L				
arithmetic mean (standard error)				
C3	-0.58 (± 3.038)	5.78 (± 3.161)	12.42 (± 2.748)	10.84 (± 2.896)
C4	-3.27 (± 3.297)	12.32 (± 4.455)	16.71 (± 5.012)	25.13 (± 6.988)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Antibodies Levels

End point title	Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Antibodies Levels
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End point description:

Percent change from baseline in anti-double-stranded DNA (dsDNA) levels. Baseline values are defined as the last measurement before the first dose.

End point type	Secondary
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End point timeframe:

From baseline to week 52

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	10	12	14
Units: U/mL				
arithmetic mean (standard error)	276.26 (\pm 316.713)	16.51 (\pm 28.265)	-31.79 (\pm 10.209)	-19.32 (\pm 8.722)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Levels Antibodies at Week 32

End point title	Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Levels Antibodies at Week 32
End point description: Percent change from baseline in anti-double-stranded DNA (dsDNA) levels. Baseline values are defined as the last measurement before the first dose.	
End point type	Secondary
End point timeframe: From baseline to week 32	

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	75	77	63
Units: U/mL				
arithmetic mean (standard error)	21.36 (\pm 15.135)	-15.24 (\pm 4.910)	-11.31 (\pm 6.323)	-24.17 (\pm 4.781)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Global Systemic Lupus Erythematosus (SLE) Clinical Response Based on Interferon-Regulated Gene (IRG) Status

End point title	Number of Participants With Global Systemic Lupus Erythematosus (SLE) Clinical Response Based on Interferon-Regulated Gene (IRG) Status
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End point description:

Global systemic lupus erythematosus (SLE) clinical response in participants based on interferon-regulated gene (IRG) status (high versus low IRG signature). IRG-high vs. IRG-low was determined using a 5-interferon (IFN) gene set during the sample collected at screening period. SRI(4) responder is defined as a patient whose disease course fulfills all of the following:

- (1) A 4-point or greater reduction from baseline in SLEDAI-2K score
- (2) No new British Isles Lupus Assessment Group (BILAG) A (severe disease activity) or not more than 1 new BILAG B (moderate disease activity) organ domain grade
- (3) No worsening from baseline in the Physician's Global Assessment of Disease Activity Scale by more

than 0.3 points on a 3-point visual analog scale from no disease activity to severe disease activity

End point type	Secondary
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End point timeframe:

At week 32

End point values	Placebo	BMS-986165 3 mg	BMS-986165 6 mg	BMS-986165 12 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	91	93	89
Units: Participants				
IFN Low	10	7	11	5
IFN High	21	46	35	35

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious Adverse Events (NSAEs) and Serious Adverse Events (SAEs) are collected from first dose to 30 days post last dose (Up to 52 weeks). Subjects were assessed for Deaths (all causes) from date of randomization to study completion (Up to 49 months)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo PO BID

Reporting group title	BMS-986165 3 mg BID
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Reporting group description:

BMS-986165 3 mg PO BID

Reporting group title	BMS-986165 6 mg BID
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Reporting group description:

BMS-986165 6 mg PO BID

Reporting group title	BMS-986165 12 mg QD
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Reporting group description:

BMS-986165 12 mg PO QD

Serious adverse events	Placebo	BMS-986165 3 mg BID	BMS-986165 6 mg BID
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 90 (12.22%)	7 / 91 (7.69%)	8 / 93 (8.60%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (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
Squamous cell carcinoma of the vagina			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Hypertensive crisis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
General disorders and administration site conditions			
Generalised oedema			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
Oedema peripheral			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (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
Reproductive system and breast disorders			
Endometrial hyperplasia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (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
Uterine haemorrhage			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 93 (1.08%)
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			
Dyspnoea			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (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
Interstitial lung disease			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dysarthria			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
Epilepsy			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
Optic neuritis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (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

Spinal cord disorder			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (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
Deficiency anaemia			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (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
Eye disorders			
Scleritis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
Pancreatitis acute			
subjects affected / exposed	1 / 90 (1.11%)	1 / 91 (1.10%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (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
Hepatitis acute			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	2 / 93 (2.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 93 (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
Herpes zoster			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS-986165 12 mg QD		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 89 (7.87%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of the vagina			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous incomplete			

subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Generalised oedema			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Endometrial hyperplasia			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine haemorrhage			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Forearm fracture			

subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Dysarthria			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Optic neuritis			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord disorder			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Deficiency anaemia			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Scleritis			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Drug eruption			

subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxic skin eruption			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis chronic			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Urinary tract infection			
subjects affected / exposed	1 / 89 (1.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo	BMS-986165 3 mg BID	BMS-986165 6 mg BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 90 (87.78%)	85 / 91 (93.41%)	81 / 93 (87.10%)
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 90 (3.33%)	4 / 91 (4.40%)	3 / 93 (3.23%)
occurrences (all)	3	4	3
Nervous system disorders			
Headache			
subjects affected / exposed	15 / 90 (16.67%)	7 / 91 (7.69%)	8 / 93 (8.60%)
occurrences (all)	20	8	9
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 90 (5.56%)	4 / 91 (4.40%)	8 / 93 (8.60%)
occurrences (all)	6	4	8
Nausea			
subjects affected / exposed	8 / 90 (8.89%)	6 / 91 (6.59%)	5 / 93 (5.38%)
occurrences (all)	8	8	6
Vomiting			
subjects affected / exposed	6 / 90 (6.67%)	3 / 91 (3.30%)	4 / 93 (4.30%)
occurrences (all)	6	3	6
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	5 / 90 (5.56%)	1 / 91 (1.10%)	0 / 93 (0.00%)
occurrences (all)	5	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	4 / 90 (4.44%)	3 / 91 (3.30%)	8 / 93 (8.60%)
occurrences (all)	4	3	8
Rash			

subjects affected / exposed occurrences (all)	0 / 90 (0.00%) 0	2 / 91 (2.20%) 3	3 / 93 (3.23%) 3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 90 (1.11%)	5 / 91 (5.49%)	1 / 93 (1.08%)
occurrences (all)	1	5	1
Back pain			
subjects affected / exposed	6 / 90 (6.67%)	1 / 91 (1.10%)	8 / 93 (8.60%)
occurrences (all)	6	1	8
Infections and infestations			
Bronchitis			
subjects affected / exposed	6 / 90 (6.67%)	3 / 91 (3.30%)	5 / 93 (5.38%)
occurrences (all)	6	3	5
Cystitis			
subjects affected / exposed	0 / 90 (0.00%)	5 / 91 (5.49%)	1 / 93 (1.08%)
occurrences (all)	0	9	1
Nasopharyngitis			
subjects affected / exposed	11 / 90 (12.22%)	8 / 91 (8.79%)	13 / 93 (13.98%)
occurrences (all)	21	11	19
Oral herpes			
subjects affected / exposed	0 / 90 (0.00%)	4 / 91 (4.40%)	4 / 93 (4.30%)
occurrences (all)	0	7	8
Pharyngitis			
subjects affected / exposed	2 / 90 (2.22%)	7 / 91 (7.69%)	5 / 93 (5.38%)
occurrences (all)	2	8	8
Sinusitis			
subjects affected / exposed	2 / 90 (2.22%)	4 / 91 (4.40%)	5 / 93 (5.38%)
occurrences (all)	2	4	5
Urinary tract infection			
subjects affected / exposed	3 / 90 (3.33%)	10 / 91 (10.99%)	6 / 93 (6.45%)
occurrences (all)	3	13	9
Upper respiratory tract infection			
subjects affected / exposed	8 / 90 (8.89%)	13 / 91 (14.29%)	18 / 93 (19.35%)
occurrences (all)	13	17	21

Non-serious adverse events	BMS-986165 12 mg QD		
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Total subjects affected by non-serious adverse events subjects affected / exposed	73 / 89 (82.02%)		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	6 / 89 (6.74%) 6		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	11 / 89 (12.36%) 19		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	3 / 89 (3.37%) 4 4 / 89 (4.49%) 4 1 / 89 (1.12%) 1		
Respiratory, thoracic and mediastinal disorders Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 89 (1.12%) 1		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all)	7 / 89 (7.87%) 9 7 / 89 (7.87%) 8		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain	0 / 89 (0.00%) 0		

subjects affected / exposed	2 / 89 (2.25%)		
occurrences (all)	2		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	2 / 89 (2.25%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	8 / 89 (8.99%)		
occurrences (all)	8		
Oral herpes			
subjects affected / exposed	5 / 89 (5.62%)		
occurrences (all)	5		
Pharyngitis			
subjects affected / exposed	2 / 89 (2.25%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	0 / 89 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	6 / 89 (6.74%)		
occurrences (all)	7		
Upper respiratory tract infection			
subjects affected / exposed	8 / 89 (8.99%)		
occurrences (all)	12		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 January 2018	Updated endpoints, treatment frequency, and inclusion/exclusion criteria
28 January 2019	Updated endpoints and inclusion/exclusion criteria
11 June 2019	Updated endpoints and clarified inclusion criteria
15 April 2020	Updated contact information and endpoints

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported