



Clinical trial results:

A Prospective, Double-blind, Randomized, Placebo-controlled, Repeated dose, Multicentre Phase IIa Proof-of-Concept Study with BT063 in Subjects with Systemic Lupus Erythematosus (BT063 in SLE)

Summary

EudraCT number	2014-005526-35
Trial protocol	PL
Global end of trial date	25 October 2017

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	990
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02554019
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Biotest AG
Sponsor organisation address	Landsteinerstr. 5, Dreieich, Germany, 63303
Public contact	Director Operations & Systems, Corporate Clinical Research & Development, Biotest AG, 49 61038010, peter.roettgen@biotest.com
Scientific contact	Director Operations & Systems, Corporate Clinical Research & Development, Biotest AG, 49 61038010, peter.roettgen@biotest.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	25 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 October 2017
Global end of trial reached?	Yes
Global end of trial date	25 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study has 2 parts.

The primary objective of Part I of this study is to evaluate the safety and tolerability of 3 months of treatment with 50 mg BT063 versus placebo in subjects with SLE.

The primary objective of Part II of this study is to evaluate the safety and tolerability of either 25 mg, 50, mg or 100 mg BT063 versus placebo in subjects with SLE. The dose level for Part II will be determined based on an interim analysis conducted after the last subject of Part I has completed the treatment.

Protection of trial subjects:

After the end of the first 2-hour infusion of IMP (D0 [baseline]), the subject must stay at the investigational site for at least an additional 2 hours to enable monitoring for a type I hypersensitivity reaction. At all subsequent visits the subject should be observed for at least half an hour after the infusion of IMP.

Adverse Events of Special Interest

Adverse Events of special interest (AESI; serious or nonserious) are events that are of scientific and medical concern specific to the Sponsor's product for which close monitoring and rapid communication by the investigator to the Sponsor is appropriate. For this study, the following AEs of special interest will be recorded:

- Aphthous mouth ulcers (new, recurrent or aggravation of pre-existing lesions)
- Any other GI ulcers or significant GI symptoms (e.g., pain, blood in stool, dyspepsia or similar)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	3 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belarus: 9
Country: Number of subjects enrolled	Georgia: 6
Country: Number of subjects enrolled	Serbia: 7
Country: Number of subjects enrolled	Poland: 14
Worldwide total number of subjects	36
EEA total number of subjects	14

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)	33
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment period: 01 Sep 2015 to 05 Apr 2017.

A total of 12 study sites enrolled subjects into the study in 4 countries: Georgia, Poland, Belarus, and Serbia.

Pre-assignment

Screening details:

Adult subjects had SLE as defined by ACR criteria such that ≥ 4 of the 11 criteria were met for ≥ 3 months before screening, moderate to severe SLE disease activity at screening and baseline demonstrated by SLEDAI-2K total score ≥ 6 , including skin and joint involvement (CLASI ≥ 5 or at least 5 of 66/68 joints with pain and signs of inflammation)

Period 1

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

Blinding implementation details:

Subjects, investigators, and study personnel will remain blinded with regard to the randomized treatment assignment until after database lock.

An interactive web response system (IWRS) will be implemented and used for randomization and IMP re supply.

Arms

Are arms mutually exclusive?	Yes
Arm title	BT063 Placebo

Arm description:

End formulation buffer without BT063 drug product

Arm type	Placebo
Investigational medicinal product name	BT063 Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

The IMP was available in single-use vials containing 1.0 mL placebo. During Part I of the study, 1.0 mL IMP was diluted in 20 mL of a physiological sodium chloride solution (0.9% NaCl solution). During Part II 2.0 mL IMP was used. The diluted IMP was infused completely via a perfusor pump at an infusion rate of 10 mL/h.

Arm title	BT063 50mg
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Arm description:

BT063 provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)

Arm type	Experimental
Investigational medicinal product name	BT063 50 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

BT063 50mg: The IMP was available in single-use vials containing 1.0 mL BT063 (50mg/ml). During Part

I of the study, 1.0 mL IMP was diluted in 20 mL of a physiological sodium chloride solution (0.9% NaCl solution). The diluted IMP was infused completely via a perfusor pump at an infusion rate of 10 mL/h.

Arm title	BT063 100mg
Arm description: BT063 will be provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)	
Arm type	Experimental
Investigational medicinal product name	BT063 100mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

BT063 100mg: The IMP was available in single-use vials containing 1.0 mL BT063 (50mg/ml). During Part II of the study, 2.0 mL IMP was diluted in 20 mL of a physiological sodium chloride solution (0.9% NaCl solution). The diluted IMP was infused completely via a perfusor pump at an infusion rate of 10 mL/h.

Number of subjects in period 1	BT063 Placebo	BT063 50mg	BT063 100mg
Started	12	12	12
Completed	10	10	12
Not completed	2	2	0
Consent withdrawn by subject	2	1	-
Adverse event, non-fatal	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	BT063 Placebo
Reporting group description:	
End formulation buffer without BT063 drug product	
Reporting group title	BT063 50mg
Reporting group description:	
BT063 provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)	
Reporting group title	BT063 100mg
Reporting group description:	
BT063 will be provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)	

Reporting group values	BT063 Placebo	BT063 50mg	BT063 100mg
Number of subjects	12	12	12
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
age of 18-75 years (inclusive)			
Units: years			
median	43.5	35.5	53.0
full range (min-max)	30 to 68	21 to 61	38 to 59
Gender categorical			
Male or Female			
Units: Subjects			
Female	12	10	11
Male	0	2	1
Have a family history of lupus			
subject number and proportion, who had a family history of lupus, were collected			
Units: Subjects			
Yes	1	0	0
No	10	11	11
Unknown	1	1	1
Race			
Units: Subjects			
white	12	12	12

Reporting group values	Total		
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Number of subjects	36		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
age of 18-75 years (inclusive)			
Units: years			
median			
full range (min-max)	-		
Gender categorical			
Male or Female			
Units: Subjects			
Female	33		
Male	3		
Have a family history of lupus			
subject number and proportion, who had a family history of lupus, were collected			
Units: Subjects			
Yes	1		
No	32		
Unknown	3		
Race			
Units: Subjects			
white	36		

Subject analysis sets

Subject analysis set title	Safety Set
Subject analysis set type	Full analysis

Subject analysis set description:

The safety set comprises all subjects who have received the study medication at least once.

Subject analysis set title	Intention-to-treat set:
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The intention-to treat (ITT) set consists of all subjects who have received any study medication and have at least 1 post-baseline efficacy measurement.

Reporting group values	Safety Set	Intention-to-treat set:	
Number of subjects	36	36	
Age categorical			
Units: Subjects			
In utero			

Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
age of 18-75 years (inclusive)			
Units: years			
median	44.5	44.5	
full range (min-max)	21 to 68	21 to 68	
Gender categorical			
Male or Female			
Units: Subjects			
Female	33	33	
Male	3	3	
Have a family history of lupus			
subject number and proportion, who had a family history of lupus, were collected			
Units: Subjects			
Yes	1	1	
No	32	32	
Unknown	3	3	
Race			
Units: Subjects			
white	36	36	

End points

End points reporting groups

Reporting group title	BT063 Placebo
Reporting group description:	End formulation buffer without BT063 drug product
Reporting group title	BT063 50mg
Reporting group description:	BT063 provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)
Reporting group title	BT063 100mg
Reporting group description:	BT063 will be provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)
Subject analysis set title	Safety Set
Subject analysis set type	Full analysis
Subject analysis set description:	The safety set comprises all subjects who have received the study medication at least once.
Subject analysis set title	Intention-to-treat set:
Subject analysis set type	Intention-to-treat
Subject analysis set description:	The intention-to treat (ITT) set consists of all subjects who have received any study medication and have at least 1 post-baseline efficacy measurement.

Primary: Incidence of AEs

End point title	Incidence of AEs ^[1]
End point description:	Incidence of AEs (including SAEs and AEs leading to discontinuation) from baseline (week 0) to week 14
End point type	Primary
End point timeframe:	From baseline (week 0) to week 14

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: events	14	12	32	58

Statistical analyses

No statistical analyses for this end point

Primary: Changes in safety parameters

End point title	Changes in safety parameters ^[2]
End point description:	Changes from baseline in the following safety parameters were assessed:
	<ul style="list-style-type: none">Physical examinations

- Vital signs
- ECGs
- Safety laboratory parameters (full blood count including white differential count, clinical chemistry, thyroid hormones, urinalysis, and faecal occult blood test)
- Development of anti-drug antibodies against BT063 (anti-BT063)
- Immunological status of potential viral and bacterial infections (HBV, HCV, HIV, tetanus, diphtheria tuberculosis)
- EBV / CMV Serology
- Premature withdrawals

End point type	Primary
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End point timeframe:

From baseline (week 0) to week 14

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subject with any safety relevant change	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Subject with TEAEs

End point title	Subject with TEAEs ^[3]
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End point description:

End point type	Primary
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End point timeframe:

From baseline (week 0) to week 14

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subjects	8	5	8	21

Statistical analyses

No statistical analyses for this end point

Primary: Subjects with TEAEs leading to early termination

End point title	Subjects with TEAEs leading to early termination ^[4]
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End point description:

End point type	Primary
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End point timeframe:

From baseline (week 0) to week 14

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subjects	0	1	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Subjects with treatment-emergent SAEs

End point title	Subjects with treatment-emergent SAEs ^[5]
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End point description:

End point type	Primary
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End point timeframe:

From baseline (week 0) to week 14

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subjects	0	1	1	2

Statistical analyses

No statistical analyses for this end point

Primary: Subjects with drug-related TEAEs

End point title	Subjects with drug-related TEAEs ^[6]
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End point description:

End point type Primary

End point timeframe:

From baseline (week 0) to week 14

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subjects	0	1	2	3

Statistical analyses

No statistical analyses for this end point

Primary: Subjects with severe TEAEs

End point title Subjects with severe TEAEs^[7]

End point description:

End point type Primary

End point timeframe:

From baseline (week 0) to week 28

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Subjects with TEAEs leading to death

End point title Subjects with TEAEs leading to death^[8]

End point description:

End point type Primary

End point timeframe:

From baseline (week 0) to week 14

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Explorative descriptive statistics were used for all variables. No statistical tests were performed.

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	Safety Set
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12	12	12	36
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% Improvement of Swollen/Tender Joints or in CLASI at Week 28

End point title	Subjects with 50% Improvement of Swollen/Tender Joints or in CLASI at Week 28
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End point description:

subjects who had at least 50% improvement of swollen/tender joints or 50% improvement in CLASI score at week 28 for the ITT set

End point type	Secondary
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End point timeframe:

from baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: subjects	6	8	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% Improvement of Swollen/Tender Joints or in CLASI at Week 14

End point title	Subjects with 50% Improvement of Swollen/Tender Joints or in CLASI at Week 14
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End point description:

Subjects who had at least 50% improvement of swollen/tender joints or 50% improvement in CLASI score at week 14 for the ITT set

End point type	Secondary
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End point timeframe:

From baseline (week 0) to End of Treatment Visit (week 14)

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: subjects	6	7	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% Improvement in Swollen Joints at week 14

End point title | Subjects with 50% Improvement in Swollen Joints at week 14

End point description:

Subjects with 50% improvement in swollen joints at week 14 for ITT set

End point type | Secondary

End point timeframe:

From baseline (week 0) to End of Treatment Visit (week 14)

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	12	12	
Units: subjects	8	8	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% Improvement in Swollen Joints at week 28

End point title | Subjects with 50% Improvement in Swollen Joints at week 28

End point description:

subjects with 50% improvement in swollen joints from baseline to week 28 in swollen joints for ITT set

End point type | Secondary

End point timeframe:

From baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: subjects	7	7	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% improvement in tender joints at week 14

End point title	Subjects with 50% improvement in tender joints at week 14			
End point description:	Subjects with 50% improvement in tender joints from baseline to week 14 in tender joints for ITT set			
End point type	Secondary			
End point timeframe:	From baseline (week 0) to End of Treatment Visit (week 14)			

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	12	12	
Units: subjects	6	5	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% improvement in tender joints at week 28

End point title	Subjects with 50% improvement in tender joints at week 28			
End point description:	subjects with 50% improvement in tender joints from baseline to week 28 in tender joints for ITT set			
End point type	Secondary			
End point timeframe:	from baseline (week 0) to week 28			

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: subjects	6	7	6	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% Improvement in CLASI Score at week 14

End point title | Subjects with 50% Improvement in CLASI Score at week 14

End point description:

Subjects who had at least 50% improvement in CLASI at week 14 for ITT set

End point type | Secondary

End point timeframe:

From baseline (week 0) to End of Treatment Visit (week 14)

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	12	12	
Units: subjects	3	6	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects with 50% Improvement in CLASI Score at week 28

End point title | Subjects with 50% Improvement in CLASI Score at week 28

End point description:

Subjects who had at least 50% improvement in CLASI at week 28 for ITT set

End point type | Secondary

End point timeframe:

from baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: subjects	3	7	4	

Statistical analyses

No statistical analyses for this end point

Secondary: SLEDAI-2K Responders at week 14

End point title	SLEDAI-2K Responders at week 14
End point description:	SLEDAI-2K Response was defined as subjects with more than a 3-point reduction from baseline in SLEDAI-2K score. SLEDAI-2K Responders at week 14 for ITT set
End point type	Secondary
End point timeframe:	From baseline (week 0) to End of Treatment Visit (week 14)

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	12	12	
Units: subjects	4	5	4	

Statistical analyses

No statistical analyses for this end point

Secondary: SLEDAI-2K Responders at week 28

End point title	SLEDAI-2K Responders at week 28
End point description:	SLEDAI-2K Response was defined as subjects with more than a 3-point reduction from baseline in SLEDAI-2K score. SLEDAI-2K Responders at week 28 for ITT set
End point type	Secondary
End point timeframe:	From baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: subjects	3	5	7	

Statistical analyses

No statistical analyses for this end point

Secondary: BILAG Response and Partial Response at week 14

End point title	BILAG Response and Partial Response at week 14			
End point description:	<p>BILAG=British Isles Lupus Assessment Group Response was defined as loss of "A" or "B" scores in all systems without the development of any new "A" or "B" scores. Partial response was defined as a loss of "A" scores but with "B" scores persisting or developing while in treatment. Subjects with BILAG Response or Partial Response at week 14 for ITT set</p>			
End point type	Secondary			
End point timeframe:	From baseline (week 0) to End of Treatment Visit (week 14)			

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	12	12	
Units: subjects				
Response	2	4	2	
Partial Response	6	3	8	
No Response	3	5	2	

Statistical analyses

No statistical analyses for this end point

Secondary: BILAG Response and Partial Response at week 28

End point title	BILAG Response and Partial Response at week 28			
End point description:	<p>BILAG=British Isles Lupus Assessment Group Response was defined as loss of "A" or "B" scores in all systems without the development of any new "A" or "B" scores. Partial response was defined as a loss of "A" scores but with "B" scores persisting or developing while in treatment. Subjects with BILAG Response or Partial Response at week 28 for ITT set</p>			
End point type	Secondary			

End point timeframe:
From baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: subjects				
Response	2	3	2	
Partial Response	6	5	8	
No Response	2	3	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change in ECLAM from Baseline to week 14

End point title | Percent Change in ECLAM from Baseline to week 14

End point description:

Mean percent change from baseline in ECLAM scores at week 14

End point type | Secondary

End point timeframe:

From Baseline (week 0) to End of Treatment (week 14)

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	12	12	
Units: percent changed score point				
arithmetic mean (standard deviation)	-25.4 (± 32.47)	-15.5 (± 42.48)	-9.0 (± 48.05)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change in ECLAM from Baseline to week 28

End point title | Percent Change in ECLAM from Baseline to week 28

End point description:

Mean percent change from baseline in ECLAM scores at week 28

End point type | Secondary

End point timeframe:

From baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	12	
Units: percent changed score point				
arithmetic mean (standard deviation)	-1.5 (± 46.46)	-42.1 (± 41.25)	-15.9 (± 48.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Classified Disease Activity in Physician's Global Assessment at week 14

End point title	Classified Disease Activity in Physician's Global Assessment at week 14
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End point description:

The proportion of subjects with no or mild or moderate or severe disease activity at week 14. The Physician's Global Assessment of disease activity is based on a 100 mm visual analogue scale (VAS) with the following range and increments:

Score Definition

- 0 No disease activity
- 1 Mild disease activity
- 2 Moderate disease activity
- 3 Severe disease activity

End point type	Secondary
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End point timeframe:

From baseline (week 0) to End of Treatment Visit (week 14)

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: Subjects				
No disease activity	2	3	1	
Mild disease activity	5	3	5	
Moderate disease activity	4	6	6	
Severe disease activity	0	0	0	
Missing	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Classified Disease Activity in Physician's Global Assessment at Weeks 28

End point title	Classified Disease Activity in Physician's Global Assessment at Weeks 28
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End point description:

The proportion of subjects with no or mild or moderate or severe disease activity at week 28.
The Physician's Global Assessment of disease activity is based on a 100 mm visual analogue scale (VAS) with the following range and increments:

Score Definition

0	No disease activity
1	Mild disease activity
2	Moderate disease activity
3	Severe disease activity

End point type	Secondary
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End point timeframe:

From baseline (week 0) to week 28

End point values	BT063 Placebo	BT063 50mg	BT063 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	12	12	
Units: Subjects				
No disease activity	1	3	0	
Mild disease activity	6	5	8	
Moderate disease activity	3	3	3	
Severe disease activity	0	0	1	
Missing	2	1	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline (week 0) to week 28

Adverse event reporting additional description:

An AE can be any unfavourable or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. An AE, that occurs from the first dose of study drug until week 28, is defined as a TEAE.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	BT063 Placebo
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Reporting group description:

End formulation buffer without BT063 drug product

Reporting group title	BT063 50mg
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Reporting group description:

BT063 provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)

Reporting group title	BT063 100mg
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Reporting group description:

BT063 will be provided as a sterile solution containing the IL-10 binding monoclonal antibody (mAb)

Serious adverse events	BT063 Placebo	BT063 50mg	BT063 100mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Overdose	Additional description: Post-treatment event; Baseline Date: 01-Mar-2017; Date of Last Administration: 24-May-2017; AE Onset/Resolution Date: 17-Aug-2017/ 30-Aug-2017 Severity: moderate Relationship: not related to study drug Outcome: resolved		
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Synovitis	Additional description: Post-treatment event; Baseline Date: 24-Feb-2016; Date of Last Administration: 18-May-2016; AE Onset/Resolution Date: 12-Jun-2016/20-Jun-2016 Severity: mild Relationship: not related to study drug Outcome: resolved		

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (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
Infections and infestations			
Bronchopneumonia	Additional description: Post-treatment event; Baseline Date: 01-Mar-2017; Date of Last Administration: 24-May-2017; AE Onset/Resolution Date: 27-Jul-2017/ 30-Aug-2017 Severity: moderate Relationship: not related to study drug Outcome: resolved		
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	BT063 Placebo	BT063 50mg	BT063 100mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)	4 / 12 (33.33%)	7 / 12 (58.33%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Venous occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Fatigue			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Tenderness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Pleurisy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Upper respiratory tract inflammat subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Investigations			
Blood pressure increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Complement factor decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Headache subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Gastrointestinal disorders Anal fissure subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Aphthous stomatitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Haematochezia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Mouth ulceration subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Dermatitis allergic subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Rash			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Myalgia			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Periostitis			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Spinal pain			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Systemic lupus erythematosus			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Infections and infestations			
Bronchitis			
subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0
Demodicidosis			
subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Erysipelas			
subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Influenza			
subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Nasopharyngitis			
subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1
Pharyngitis			

subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported