Clinical trial results:
A 2-Part Phase 2 Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of BIIB059 in Subjects with Systemic Lupus Erythematosus and Active Skin Manifestations and in Subjects with Active Cutaneous Lupus Erythematosus with or without Systemic Manifestations

Summary

EudraCT number	2015-004359-32
Trial protocol	BG PL
Global end of trial date	18 November 2019

Results information

Result version number	v2 (current)
This version publication date	08 November 2023
First version publication date	03 December 2020
Version creation reason	• New data added to full data set • Correction of full data set To align with CT.gov results after resolving QA comments

Trial information

Trial identification

Sponsor protocol code	230LE201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02847598
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Biogen
Sponsor organisation address	225 Binney Street, Cambridge, United Kingdom,
Public contact	Biogen, Biogen Study Medical Director, clinicaltrials@biogen.com
Scientific contact	Biogen Study Medical Director, Biogen, clinicaltrials@biogen.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	18 November 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Part A: The primary objective of the study is to evaluate the efficacy of BIIB059 in reducing disease activity in systemic lupus erythematosus (SLE) subjects with active skin manifestations and joint involvement. Part B: The primary objective of the study is to evaluate the efficacy of BIIB059 in reducing disease activity in subjects with active cutaneous lupus erythematosus (CLE) (subacute cutaneous lupus erythematosus [SCLE] or chronic cutaneous lupus erythematosus [CCLE], including discoid lupus erythematosus [DLE]) with or without systemic manifestations.

Protection of trial subjects:

Written informed consent was obtained from each subject or subject's legally authorised representative (e.g., parent or legal guardian), as applicable, prior to evaluations performed for eligibility. Subjects or the subject's legally authorised representative were given adequate time to review the information in the informed consent/assent and were allowed to ask, and have answered, questions concerning all portions of the conduct of the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 October 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 19
Country: Number of subjects enrolled	Bulgaria: 21
Country: Number of subjects enrolled	Colombia: 15
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Mexico: 23
Country: Number of subjects enrolled	Philippines: 47
Country: Number of subjects enrolled	Poland: 32
Country: Number of subjects enrolled	Serbia: 20
Country: Number of subjects enrolled	Taiwan: 9
Country: Number of subjects enrolled	Thailand: 16
Country: Number of subjects enrolled	United States: 56
Worldwide total number of subjects	264
EEA total number of subjects	53

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)	259
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled at 129 investigative sites in Argentina, Bulgaria, Colombia, Israel, Korea, Mexico, Philippines, Poland, Serbia, Taiwan, Thailand, and the United States from October 20, 2016 to November 18, 2019.

Pre-assignment

Screening details:

A total of 264 subjects were enrolled in the study. The study had two periods, Part A (subjects with SLE with active skin manifestations and joint involvement) and Part B (subjects with active CLE, including DLE, with or without SLE).

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	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Placebo

Arm description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo subcutaneously (SC) every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

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

Dosage and administration details:

BIIB059 matching placebo, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Arm title	Part A: BIIB059 50 mg

Arm description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg (milligrams), SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Litifilimab
Investigational medicinal product code	BIIB059
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Arm title	Part A: BIIB059 150 mg

Arm description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC

every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Litifilimab
Investigational medicinal product code	BIIB059
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm title	Part A: BIIB059 450 mg

Arm description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Litifilimab
Investigational medicinal product code	BIIB059
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm title	Part B: Placebo

Arm description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

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

Dosage and administration details:

BIIB059 matching placebo administered SC, every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm title	Part B: BIIB059 50 mg

Arm description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm type	Experimental
Investigational medicinal product name	Litifilimab
Investigational medicinal product code	BIIB059
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm title	Part B: BIIB059 150 mg

Arm description:

Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4

weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm type	Experimental
Investigational medicinal product name	Litifilimab
Investigational medicinal product code	BIIB059
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm title	Part B: BIIB059 450 mg

Arm description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Arm type	Experimental
Investigational medicinal product name	Litifilimab
Investigational medicinal product code	BIIB059
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Number of subjects in period 1	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg
Started	56	6	6
Completed	51	6	6
Not completed	5	0	0
Adverse Event	-	-	-
Death	3	-	-
Lost to follow-up	-	-	-
Consent withdrawn	2	-	-

Number of subjects in period 1	Part A: BIIB059 450 mg	Part B: Placebo	Part B: BIIB059 50 mg
Started	64	33	26
Completed	60	30	23
Not completed	4	3	3
Adverse Event	-	-	-
Death	-	-	-
Lost to follow-up	-	-	1
Consent withdrawn	4	3	2

Number of subjects in period 1	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Started	25	48

Completed	23	44
Not completed	2	4
Adverse Event	-	1
Death	-	-
Lost to follow-up	1	-
Consent withdrawn	1	3

Baseline characteristics

Reporting groups	
Reporting group title	Part A: Placebo
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo subcutaneously (SC) every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part A: BIIB059 50 mg
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg (milligrams), SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part A: BIIB059 150 mg
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part A: BIIB059 450 mg
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part B: Placebo
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Reporting group title	Part B: BIIB059 50 mg
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Reporting group title	Part B: BIIB059 150 mg
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Reporting group title	Part B: BIIB059 450 mg
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	

Reporting group values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg
Number of subjects	56	6	6
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	41.4	35.0	40.8
standard deviation	± 12.2	± 14.4	± 13.4
Sex: Female, Male Units: subjects			
Female	49	6	5
Male	7	0	1

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	25	1	2
Not Hispanic or Latino	16	4	3
Unknown or Not Reported	15	1	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	8	0	0
Asian	13	4	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	16	1	1
Unknown or Not Reported	15	1	1
Other	4	0	2

Reporting group values	Part A: BIIB059 450 mg	Part B: Placebo	Part B: BIIB059 50 mg
Number of subjects	64	33	26
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	40.3	43.4	43.3
standard deviation	± 11.4	± 11.6	± 15.3
Sex: Female, Male Units: subjects			
Female	63	30	20
Male	1	3	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	24	3	5
Not Hispanic or Latino	20	22	14
Unknown or Not Reported	20	8	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	5	0	0
Asian	12	14	7
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	2	5
White	17	9	4
Unknown or Not Reported	20	8	7
Other	4	0	3

Reporting group values	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg	Total
Number of subjects	25	48	264
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	43.6	44.0	
standard deviation	± 12.1	± 12.6	-
Sex: Female, Male Units: subjects			
Female	20	36	229
Male	5	12	35
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	4	65
Not Hispanic or Latino	13	34	126
Unknown or Not Reported	11	10	73
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	13
Asian	6	17	75
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	5	20
White	6	13	67
Unknown or Not Reported	11	10	73
Other	0	3	16

End points

End points reporting groups

Reporting group title	Part A: Placebo
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo subcutaneously (SC) every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part A: BIIB059 50 mg
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg (milligrams), SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part A: BIIB059 150 mg
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part A: BIIB059 450 mg
Reporting group description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Reporting group title	Part B: Placebo
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Reporting group title	Part B: BIIB059 50 mg
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Reporting group title	Part B: BIIB059 150 mg
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Reporting group title	Part B: BIIB059 450 mg
Reporting group description:	
Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.	
Subject analysis set title	Part A: Placebo
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.	
Subject analysis set title	Part A: BIIB059 50 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.	
Subject analysis set title	Part A: BIIB059 150 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.	

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part B: Placebo
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 50 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 150 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 450 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 50 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 150 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 150 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 150 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 50 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 150 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo SC every 4 weeks, starting at Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part A: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20.

Subject analysis set title	Part B: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 50 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 150 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 50 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 150 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 50 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 50 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 150 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	Part B: BIIB059 450 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Subject analysis set title	BIIB059
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part A: Subjects with SLE with active skin manifestations and joint involvement received BIIB059 50 mg, 150 mg, 450 mg, and matching placebo SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 7 doses up to Week 20. Part B: Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, 150 mg, 450 mg, and matching placebo SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Primary: Part A: Change from Baseline in Active Joint Count (28-joint Assessment) to Week 24

End point title	Part A: Change from Baseline in Active Joint Count (28-joint Assessment) to Week 24

End point description:

An active joint is defined as a joint with pain and signs of inflammation (e.g., tenderness, swelling or effusion). The 28 Joint Count includes assessment of swelling and tenderness in the shoulders, elbows, wrists, metacarpophalangeal joints, proximal interphalangeal joints and knees. The investigator counts how many of the 28 joints are swollen or tender at the given week. Modified intent-to-treat (MITT) population included all randomised subjects in Part A who had received at least 1 dose of study treatment (whether or not the subjects adhered to the protocol). Here, '99999' signifies since only 1 subject was analysed, standard deviation (SD) was not evaluated.

End point type	Primary

End point timeframe:

Baseline to Week 24

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41[1]	2[2]	1[3]	52[4]
Units: joints				
arithmetic mean (standard deviation)	-12.7 (± 10.3)	-9.0 (± 5.7)	-13.0 (± 99999)	-14.5 (± 8.7)

Notes:

[1] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[2] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[3] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[4] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

Statistical analyses

Statistical analysis title	Placebo vs BIIB059 450 mg

Statistical analysis description:

A Mixed Effect Model Repeat Measurement (MMRM) model is performed, using treatment group, study visit, baseline corticosteroid usage level (<=10 mg, >10 mg), region, study visit-by-treatment interaction, baseline value of the endpoint, and baseline-by-visit interaction as fixed effect covariates. Statistical analysis for placebo and BIIB059 450 mg was planned and reported.

Comparison groups	Part A: Placebo v Part A: BIIB059 450 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037
Method	MMRM
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	-0.2

Primary: Part B: Percent Change from Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score to Week 16

End point title	Part B: Percent Change from Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score to Week 16

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale(CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. MITT population included all randomised subjects in Part B who had received at least 1 dose of study treatment(whether or not the subjects adhered to the protocol).

End point type	Primary

End point timeframe:

Baseline to Week 16

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	31[5]	23[6]	24[7]	42[8]
Units: percent change				
arithmetic mean (standard deviation)	-15.03 (± 37.23)	-35.52 (± 33.35)	-47.11 (± 34.10)	-41.66 (± 37.33)

Notes:

[5] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[6] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[7] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[8] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

Statistical analyses

Statistical analysis title	Placebo vs BIIB059 50 mg

Statistical analysis description:

An MMRM model is performed, using treatment group, study visit, study visit-by-treatment interaction, DLE (Yes/No), CLASI-A score (<=10 vs. >10) as fixed effect covariates.

Comparison groups	Part B: Placebo v Part B: BIIB059 50 mg
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.015
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-24.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.7
upper limit	-4.88

Statistical analysis title	Placebo vs BIIB059 150 mg

Statistical analysis description:

An MMRM model is performed, using treatment group, study visit, study visit-by-treatment interaction, DLE (Yes/No), CLASI-A score (<=10 vs. >10) as fixed effect covariates.

Comparison groups	Part B: Placebo v Part B: BIIB059 150 mg
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-33.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.71
upper limit	-14.12

Statistical analysis title	Placebo vs BIIB059 450 mg
Statistical analysis description:	
An MMRM model is performed, using treatment group, study visit, study visit-by-treatment interaction, DLE (Yes/No), CLASI-A score (<=10 vs. >10) as fixed effect covariates.	
Comparison groups	Part B: Placebo v Part B: BIIB059 450 mg
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-27.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.55
upper limit	-11.42

Secondary: Part A: Percentage of Subjects with Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity- 50 (CLASI-50) Response at Week 24

End point title	Part A: Percentage of Subjects with Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity- 50 (CLASI-50) Response at Week 24
End point description:	
CLASI-50 Response is defined as a 50% improvement from baseline in CLASI-A score at Week 24. The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. MITT population. "Number of subjects analyzed" signifies those with baseline CLASI-A >=8 following protocol amendment.	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	6	6	39
Units: percentage of subjects				
number (not applicable)	42.11	50.00	16.67	64.10

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percentage of Subjects with Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity- 50 (CLASI-50) Response at Week 12 and 16

End point title	Part B: Percentage of Subjects with Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity- 50 (CLASI-50) Response at Week 12 and 16

End point description:

CLASI-50 Response is defined as a 50% improvement from baseline in CLASI-A score at Weeks 12 and 16. The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. MITT population. Here, "n" signifies number of subjects analysed at specific timepoint.

End point type	Secondary

End point timeframe:

Week 12, Week 16

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: percentage of subjects				
number (not applicable)				
Week 12 (n= 33, 26, 25, 48)	12.12	38.46	48.00	37.50
Week 16 (n= 32, 26, 25, 43)	21.88	38.46	44.00	46.51

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percent Change from Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12, 16 and 24

End point title	Part A: Percent Change from Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12, 16 and 24

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. MITT population included all randomised subjects who had received at least 1 dose of study treatment (whether or not the subjects adhered to the protocol). Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Baseline, Week 12, 16 and 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg	Part A: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6[9]	6[10]	39[11]	38[12]
Units: percent change				
arithmetic mean (standard deviation)				
Change at Week 12 (n= 6, 6, 38, 37)	-29.32 (± 14.66)	-8.39 (± 34.48)	-44.36 (± 39.69)	-36.63 (± 28.23)
Change at Week 16 (n= 6, 6, 38, 35)	-41.76 (± 19.72)	-6.19 (± 21.31)	-50.20 (± 38.32)	-42.55 (± 32.46)
Change at Week 24 (n= 6, 6, 35, 35)	-58.61 (± 35.16)	-17.92 (± 31.16)	-60.59 (± 37.36)	-45.40 (± 34.38)

Notes:

[9] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[10] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[11] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[12] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

Statistical analyses

Statistical analysis title	Placebo vs BIIB059 450 mg

Statistical analysis description:

Week 12: An MMRM model is performed, using treatment group study visit, baseline corticosteroid usage level (<=10 mg, >10 mg), region, study visit-by-treatment interaction, baseline value of the endpoint, and baseline-by-visit interaction as fixed effect covariates. Statistical analysis for placebo and BIIB059 450 mg was planned and reported.

Comparison groups	Part A: Placebo v Part A: BIIB059 450 mg
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-9.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.94
upper limit	6.08

Statistical analysis title	Placebo vs BIIB059 450 mg

Statistical analysis description:

Week 16: An MMRM model is performed, using treatment group study visit, baseline corticosteroid usage level (<=10 mg, >10 mg), region, study visit-by-treatment interaction, baseline value of the endpoint, and baseline-by-visit interaction as fixed effect covariates. Statistical analysis for placebo and BIIB059 450 mg was planned and reported.

Comparison groups	Part A: Placebo v Part A: BIIB059 450 mg
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.293
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-8.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.82
upper limit	7.9

Statistical analysis title	Placebo vs BIIB059 450 mg

Statistical analysis description:

Week 24: An MMRM model is performed, using treatment group study visit, baseline corticosteroid usage level (<=10 mg, >10 mg), region, study visit-by-treatment interaction, baseline value of the endpoint, and baseline-by-visit interaction as fixed effect covariates. Statistical analysis for placebo and BIIB059 450 mg was planned and reported.

Comparison groups	Part A: Placebo v Part A: BIIB059 450 mg
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.062
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-15.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.28
upper limit	0.79

Secondary: Part B: Percent Change from Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12

End point title	Part B: Percent Change from Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. MITT population included all randomised subjects in Part B who had received at least 1 dose of study treatment (whether or not the subjects adhered to the protocol).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32[13]	23[14]	24[15]	44[16]
Units: percent change				
arithmetic mean (standard deviation)	-10.73 (± 34.41)	-38.72 (± 32.99)	-47.82 (± 31.80)	-35.25 (± 35.77)

Notes:

[13] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[14] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[15] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[16] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

Statistical analyses

Statistical analysis title	Placebo vs BIIB059 50 mg

Statistical analysis description:

An MMRM model is performed, using treatment group, study visit, study visit-by-treatment interaction, DLE (Yes/No), CLASI-A score (<=10 vs. >10) as fixed effect covariates.

Comparison groups	Part B: Placebo v Part B: BIIB059 50 mg
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-30.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.75
upper limit	-11.97

Statistical analysis title	Placebo vs BIIB059 450 mg
Statistical analysis description: An MMRM model is performed, using treatment group, study visit, study visit-by-treatment interaction, DLE (Yes/No), CLASI-A score (<=10 vs. >10) as fixed effect covariates.	
Comparison groups	Part B: Placebo v Part B: BIIB059 450 mg
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-26.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.71
upper limit	-10.4

Statistical analysis title	Placebo vs BIIB059 150 mg
Statistical analysis description: An MMRM model is performed, using treatment group, study visit, study visit-by-treatment interaction, DLE (Yes/No), CLASI-A score (<=10 vs. >10) as fixed effect covariates.	
Comparison groups	Part B: Placebo v Part B: BIIB059 150 mg
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-37.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.46
upper limit	-18.87

Secondary: Part A: Percentage of Subjects with a >=4-point Reduction From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 24

End point title	Part A: Percentage of Subjects with a >=4-point Reduction From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 24

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each

part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. The percentage of subjects with a >=4-point reduction from baseline in CLASI-A score are reported here.MITT population included all randomised subjects who had received at least 1 dose of study treatment(whether or not the subjects adhered to the protocol).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38[17]	6[18]	6[19]	39[20]
Units: percentage of subjects				
number (not applicable)	57.89	83.66	16.67	71.79

Notes:

[17] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[18] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[19] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[20] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percentage of Subjects with a >=4-point Change From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12 and 16

End point title	Part B: Percentage of Subjects with a >=4-point Change From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12 and 16

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. The percentage of subjects with a >=4-point reduction from baseline in CLASI-A score are reported here. MITT population. Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Week 12, Week 16

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: percentage of subjects				
number (not applicable)				
Week 12 (n= 33, 26, 25, 48)	33.33	50.00	76.00	47.92
Week 16 (n= 32, 26, 25, 43)	37.50	46.15	72.00	55.81

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percentage of Subjects with a >=7-point Change From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 24

End point title	Part A: Percentage of Subjects with a >=7-point Change From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 24

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. The percentage of subjects with a >=7-point reduction from baseline in CLASI-A score are reported here.MITT population included all randomised subjects who had received at least 1 dose of study treatment(whether or not the subjects adhered to the protocol).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg	Part A: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6[21]	6[22]	39[23]	38[24]
Units: percentage of subjects				
number (not applicable)	66.67	16.67	56.41	34.21

Notes:

[21] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[22] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[23] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

[24] - "Number of subjects analyzed" signifies number of subject analysed in this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percentage of Subjects with a >=7-point Change From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12 and 16

End point title	Part B: Percentage of Subjects with a >=7-point Change From Baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 12 and 16

End point description:

The CLASI is a clinical tool that quantifies disease activity and damage in CLE. The activity scale (CLASI-A) includes measurements of erythema, scale and hypertrophy, and mucous membrane disease. Each part of the body is listed separately, from the scalp to the feet, in addition to sections focusing on mucous membrane involvement and alopecia. Points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. Composite scores are calculated by summing the individual component scores. CLASI-A scores of 0-9, 10-20, and 21-70 represent disease severity of mild, moderate, and severe, respectively. Higher scores indicate more disease activity. The percentage of subjects with a >=7-point reduction from baseline in CLASI-A score are reported here. MITT population. Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Week 12, Week 16

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: percentage of subjects				
number (not applicable)				
Week 12 (n= 33, 26, 25, 48)	18.18	38.46	40.00	33.33
Week 16 (n= 32, 26, 25, 43)	21.88	30.77	48.00	41.86

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percentage of Subjects Achieving a Systemic Lupus Erythematosus (SLE) Responder Index (SRI) of >=4 at Week 24

End point title	Part A: Percentage of Subjects Achieving a Systemic Lupus Erythematosus (SLE) Responder Index (SRI) of >=4 at Week 24

End point description:

An SRI-4 at Week 24 was a categorical response variable(Yes/No) incorporating the following criteria for achievement of responder status (all criteria must have been met to achieve responder status):A reduction from baseline of >=4 points in SLEDAI-2K,No new organ system affected, as defined by no new BILAG-2004 Grade A and no more than 1 new BILAG-2004 Grade B,No worsening from baseline in subject's lupus disease activity, defined by a <1-point increase in the PGA(VAS) [on a scale of 0 to 10],No changes to protocol-specified medication rules,as follows(all criteria were required to be met):No initiation or increase of SLE standard of care therapy or other disallowed concomitant therapy;Concomitant corticosteroid dosage at Week 24 to be ≤10 mg/day;Concomitant corticosteroid dosage at Week 24 was no more than at Day 1;No increase in corticosteroid dose between Weeks 17 and 24.The percentage of subjects who had responded to each of the 4 criteria was reported. MITT

End point type	Secondary

End point timeframe:

Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: percentage of subjects				
number (not applicable)	33.33	16.67	28.57	56.25

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) Score at Week 24

End point title	Part A: Change from Baseline in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) Score at Week 24[25]

End point description:

The SLEDAI-2K is a reliable, valid, simple, 1-page activity index that measures disease activity and records features of active lupus as present or not. It uses a weighted checklist to assign a numeric score based on the presence or absence of 24 symptoms at the time of assessment or during the previous 28 days. Each symptom present is assigned between 1 and up to 8 points based on its usual clinical importance, yielding a total score that ranges from 0 points (no symptoms) to 105 points (presence of all defined symptoms). MITT population included all randomised subjects in Part A who had received at least 1 dose of study treatment (whether or not the subjects adhered to the protocol).

End point type	Secondary

End point timeframe:

Baseline to Week 24

Notes:

[25] - 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: This endpoint was analysed for Part A arm groups only.

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50[26]	6[27]	3[28]	59[29]
Units: score on a scale				
arithmetic mean (standard deviation)	-2.1 (± 3.3)	-3.0 (± 4.7)	-1.3 (± 2.4)	-4.4 (± 4.2)

Notes:

[26] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[27] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[28] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[29] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

Statistical analyses

Statistical analysis title	Placebo vs BIIB059 450 mg

Statistical analysis description:

An MMRM model is performed, using treatment group, study visit, baseline corticosteroid usage level (<=10 mg, >10 mg), region, study visit-by-treatment interaction, baseline value of the endpoint, and baseline-by-visit interaction as fixed effect covariates. Statistical analysis for placebo and BIIB059 450 mg was planned and reported.

Comparison groups	Part A: Placebo v Part A: BIIB059 450 mg
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-0.5

Secondary: Part A: Percentage of Subjects with No New Organ System Affected at Week 24

End point title	Part A: Percentage of Subjects with No New Organ System Affected at Week 24

End point description:

No new organ system affected, as defined by no new British Isles Lupus Activity Group (BILAG)-2004 A and no more than one new BILAG-2004 B. The BILAG-2004 index categorizes disease activity in each organ system into five different levels from A to E. Grade A represents very active disease, Grade B represents moderate disease activity, Grade C indicates mild stable disease, and grade D implies no disease activity, but suggests the organ system had previously been affected. Grade E indicates no current or previous disease activity. A score is applied to each grade of each organ system using coding scheme of A=12, B=8, C=1, and D/E=0 and is summarized as a total score ranging 0-108. Higher scores indicate more severe disease activity. MITT population included all randomised subjects in Part A who had received at least 1 dose of study treatment (whether or not the subjects adhered to the protocol).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: percentage of subjects				
number (not applicable)	100.00	50.00	82.14	85.94

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from baseline in Physician's Global Assessment (PGA) Visual Analog Scale (VAS) Score at Week 24

End point title	Part A: Change from baseline in Physician's Global Assessment (PGA) Visual Analog Scale (VAS) Score at Week 24

End point description:

The PGA is used to quantify disease activity and is measured using an anchored VAS. The PGA asks the Investigator to assess the subject's current disease activity from a score of 0 (none) to 3 (severe), where higher score means severe SLE disease activity. MITT population included all randomised subjects in Part A who had received at least 1 dose of study treatment (whether or not the subjects adhered to the protocol).

End point type	Secondary

End point timeframe:

Baseline to Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6[30]	6[31]	49[32]	57[33]
Units: score on a scale				
arithmetic mean (standard deviation)	-2.05 (± 1.18)	-0.12 (± 1.48)	-2.46 (± 2.13)	-2.45 (± 2.33)

Notes:

[30] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[31] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[32] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

[33] - "Number of Subjects Analysed" signifies number of subjects analysed in this endpoint.

Statistical analyses

Statistical analysis title	Placebo vs BIIB059 450 mg

Statistical analysis description:

An MMRM model is performed, using treatment group (BIIB059 450 mg vs. placebo), study visit, baseline corticosteroid usage level (<=10 mg, >10 mg), region, study visit-by-treatment interaction, baseline value of the endpoint, and baseline-by-visit interaction as fixed effect covariates. Statistical analysis for placebo and BIIB059 450 mg was planned and reported.

Comparison groups	Part A: Placebo v Part A: BIIB059 450 mg

Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.667
Method	MMRM
Parameter estimate	LS Mean Difference
Point estimate	-0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	0.58

Secondary: Part A: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Part A: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point description:

An AE is any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An SAE is any untoward medical occurrence that at any dose: Results in death; in the view of the Investigator, places the subject at immediate risk of death (a life-threatening event); however, this does not include an event that, had it occurred in a more severe form, might have caused death; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; results in a congenital anomaly/birth defect. Safety population included all randomised subjects in Part A who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 36

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: subjects				
AEs	3	6	38	36
SAEs	0	1	6	3

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Subjects with Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Part B: Number of Subjects with Treatment Emergent Adverse

	Events (AEs) and Serious Adverse Events (SAEs)

End point description:

An AE is any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An SAE is any untoward medical occurrence that at any dose: Results in death; in the view of the Investigator, places the subject at immediate risk of death (a life-threatening event); however, this does not include an event that, had it occurred in a more severe form, might have caused death; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; results in a congenital anomaly/birth defect. Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 28

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: subjects				
AEs	22	18	15	38
SAEs	3	1	3	3

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Subjects With Clinically Significant Laboratory Assessment Abnormalities

End point title	Part A: Number of Subjects With Clinically Significant Laboratory Assessment Abnormalities

End point description:

Safety population included all randomised subjects in Part A who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 36

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Subjects with Clinically Significant Laboratory Assessment Abnormalities

End point title	Part B: Number of Subjects with Clinically Significant Laboratory Assessment Abnormalities

End point description:

Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 28

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Subjects With Clinically Significant Vital Sign Abnormalities

End point title	Part A: Number of Subjects With Clinically Significant Vital Sign Abnormalities

End point description:

Safety population included all randomised subjects in Part A who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 36

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Subjects with Clinically Significant Vital Sign Abnormalities

End point title	Part B: Number of Subjects with Clinically Significant Vital Sign Abnormalities

End point description:

Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 28

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Subjects With Clinically Significant 12-Lead Electrocardiograms (ECGs) Abnormalities

End point title	Part A: Number of Subjects With Clinically Significant 12-Lead Electrocardiograms (ECGs) Abnormalities

End point description:

Safety population included all randomised subjects in Part A who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 36

End point values	Part A: BIIB059 50 mg	Part A: Placebo	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	56	5	64
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Subjects with Clinically Significant 12-Lead Electrocardiograms (ECGs) Abnormalities

End point title	Part B: Number of Subjects with Clinically Significant 12-Lead Electrocardiograms (ECGs) Abnormalities

End point description:

Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 28

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Subjects With Positive BIIB059 Antibodies

End point title	Part A: Number of Subjects With Positive BIIB059 Antibodies

End point description:

Safety population included all randomised subjects in Part A who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	63
Units: subjects	0	0	1	5

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Subjects with Positive BIIB059 Antibodies

End point title	Part B: Number of Subjects with Positive BIIB059 Antibodies

End point description:

Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received.

End point type	Secondary

End point timeframe:

Baseline up to Week 16

End point values	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg	Part B: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	26	25	48	32
Units: subjects	5	4	5	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Absolute Change From Baseline Over Time in Immunoglobulin Levels

End point title	Part A: Absolute Change From Baseline Over Time in Immunoglobulin Levels

End point description:

Safety population included all randomised subjects in Part A who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, ‘n’ signifies number of subjects analysed at specific time point and '99999' signifies no mean and SD were calculated due to 0 subjects in that particular arm at specific time point.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: grams per litre (g/L)				
arithmetic mean (standard deviation)				
Immunoglobulin A (IgA): Baseline (n= 6, 6, 56, 64)	3.610 (± 0.730)	4.080 (± 1.537)	3.350 (± 1.862)	3.116 (± 1.682)
IgA: Change at Week 16 (n= 0, 0, 45, 54)	99999 (± 99999)	99999 (± 99999)	0.033 (± 0.529)	-0.006 (± 0.305)
IgA: Change at Week 24 (n= 6, 6, 52, 59)	-0.433 (± 1.188)	-0.057 (± 0.966)	-0.093 (± 0.704)	0.012 (± 0.505)
Immunoglobulin G (IgG): Baseline (n= 6, 6, 56, 64)	15.723 (± 1.584)	17.620 (± 5.502)	14.423 (± 4.927)	14.792 (± 6.778)
IgG: Change at Week 16 (n= 0, 0, 45, 54)	99999 (± 99999)	99999 (± 99999)	1.057 (± 2.832)	0.233 (± 2.478)
IgG: Change at Week 24 (n= 6, 6, 52, 59)	-0.468 (± 1.333)	-0.790 (± 4.967)	0.874 (± 3.376)	0.758 (± 2.599)
Immunoglobulin M (IgM): Baseline (n= 6, 6, 56, 64)	1.065 (± 0.507)	1.242 (± 0.718)	1.046 (± 0.657)	1.106 (± 0.953)
IgM: Change at Week 16 (n= 0, 0, 45, 54)	99999 (± 99999)	99999 (± 99999)	0.004 (± 0.137)	-0.065 (± 0.294)
IgM: Change at Week 24 (n= 6, 6, 52, 59)	-0.050 (± 0.113)	-0.150 (± 0.160)	-0.003 (± 0.191)	-0.072 (± 0.409)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Absolute Change From Baseline Over Time in Immunoglobulin Levels

End point title	Part B: Absolute Change From Baseline Over Time in Immunoglobulin Levels

End point description:

Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point and '99999' signifies no mean and SD were calculated due to 0 subjects in that particular arm at specific time point.

End point type	Secondary

End point timeframe:

Baseline up to Week 16

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	26	25	48
Units: g/L				
arithmetic mean (standard deviation)				
IgA: Baseline (n= 33, 26, 25, 48)	3.341 (± 1.113)	3.873 (± 1.663)	2.900 (± 1.705)	3.061 (± 1.413)

IgA: Change at Week 12 (n= 7, 0, 0, 14)	-0.029 (± 0.249)	99999 (± 99999)	99999 (± 99999)	-0.304 (± 0.711)
IgA: Change at Week 16 (n= 25, 25, 25, 30)	-0.045 (± 0.432)	-0.117 (± 0.356)	-0.016 (± 0.376)	-0.076 (± 0.254)
IgG: Baseline (n= 33, 26, 25, 48)	13.480 (± 4.193)	14.087 (± 4.285)	13.700 (± 5.397)	14.874 (± 5.904)
IgG: Change at Week 12 (n= 7, 0, 0, 14)	0.120 (± 0.662)	99999 (± 99999)	99999 (± 99999)	-1.961 (± 4.312)
IgG: Change at Week 16 (n= 25, 25, 25, 30)	0.450 (± 3.366)	-0.776 (± 1.405)	-0.084 (± 3.975)	-0.064 (± 1.375)
IgM: Baseline (n= 33, 26, 25, 48	0.978 (± 0.553)	0.880 (± 0.563)	1.095 (± 0.656)	0.993 (± 0.757)
IgM: Change at Week 12 (n= 7, 0, 0, 14)	-0.009 (± 0.061)	99999 (± 99999)	99999 (± 99999)	-0.028 (± 0.096)
IgM: Change at Week 16 (n= 25, 25, 25, 30)	-0.016 (± 0.125)	-0.072 (± 0.119)	-0.045 (± 0.217)	-0.035 (± 0.150)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Absolute Change From Baseline in Vaccine Titres - Streptococcus pneumoniae (S. pneumoniae) at Week 24

End point title	Part A: Absolute Change From Baseline in Vaccine Titres - Streptococcus pneumoniae (S. pneumoniae) at Week 24

End point description:

Vaccine-related immunoglobulin (Ig) titres for Pneumococcus (S. pneumoniae) were analysed, including 23 types of serotypes (sero). AB = Antibody. Safety population included all randomised subjects who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Baseline to Week 24

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	6	6	63
Units: milligrams per litre (mg/L)				
arithmetic mean (standard deviation)				
Sero 1 IgG AB: Baseline (n= 54, 6, 6, 63)	2.017 (± 4.9787)	3.873 (± 3.8400)	2.705 (± 5.3558)	1.495 (± 3.3589)
Sero 1 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	0.445 (± 1.9595)	0.055 (± 2.9840)	-0.565 (± 1.4395)	0.475 (± 3.5101)
Sero 2 IgG AB: Baseline (n= 54, 6, 6, 63)	1.562 (± 2.4661)	5.715 (± 6.9239)	4.202 (± 4.8105)	1.626 (± 2.6861)
Sero 2 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	0.014 (± 0.8316)	-1.648 (± 7.1790)	-1.975 (± 3.2500)	-0.011 (± 1.2676)
Sero 3 IgG AB: Baseline (n= 54, 6, 6, 63)	1.2607 (± 1.77918)	2.1450 (± 2.39861)	1.2733 (± 0.96790)	1.6579 (± 3.35454)
Sero 3 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	-0.0886 (± 0.75890)	-0.2017 (± 2.43817)	-0.2067 (± 1.39370)	0.8122 (± 3.62090)

Sero 4 IgG AB: Baseline (n= 54, 6, 6, 63)	0.734 (± 1.2954)	2.602 (± 4.4908)	1.317 (± 1.5754)	0.429 (± 0.5696)
Sero 4 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	-0.025 (± 0.5104)	-1.510 (± 4.9524)	-0.795 (± 1.6009)	0.060 (± 0.6525)
Sero 5 IgG AB: Baseline (n= 54, 6, 6, 63)	4.921 (± 4.2218)	10.693 (± 17.4616)	13.507 (± 17.7231)	4.442 (± 3.9255)
Sero 5 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	0.813 (± 3.9116)	-4.692 (± 19.3477)	-7.322 (± 16.4934)	0.329 (± 2.3390)
Sero 6B IgG AB: Baseline (n= 54, 6, 6, 63)	3.348 (± 6.4940)	4.462 (± 4.1178)	4.458 (± 6.1968)	1.957 (± 2.7845)
Sero 6B IgG AB: Change at Week 24 (n=51, 6, 6, 59)	-0.448 (± 2.4975)	-2.168 (± 5.1775)	-3.083 (± 5.3923)	0.070 (± 2.4772)
Sero 7F IgG AB: Baseline (n= 54, 6, 6, 63)	6.4300 (± 10.99806)	8.5333 (± 7.97928)	7.0033 (± 8.53321)	3.0983 (± 6.90958)
Sero 7F IgG AB: Change at Week 24 (n=51, 6, 6, 59)	-1.0336 (± 5.35192)	-1.3283 (± 7.23188)	-2.8917 (± 5.30027)	0.3053 (± 3.13517)
Sero 8 IgG AB: Baseline (n= 54, 6, 6, 63)	3.1978 (± 7.08938)	3.1933 (± 3.01698)	2.6183 (± 3.21210)	1.5890 (± 4.46616)
Sero 8 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	0.0925 (± 1.10700)	-1.3300 (± 3.85666)	-1.5483 (± 3.27227)	0.1281 (± 0.84548)
Sero 9N IgG AB: Baseline (n= 54, 6, 6, 63)	1.781 (± 2.9291)	2.710 (± 3.7028)	2.810 (± 4.4518)	2.337 (± 4.6658)
Sero 9N IgG AB: Change at Week 24 (n=51, 6, 6, 59)	0.217 (± 1.7957)	-1.327 (± 3.8703)	-0.907 (± 2.8144)	0.499 (± 4.0782)
Sero 9V IgG AB: Baseline (n= 54, 6, 6, 63)	1.0274 (± 1.44706)	1.8300 (± 3.00647)	1.5900 (± 1.79117)	2.2696 (± 4.71508)
Sero 9V IgG AB: Change at Week 24 (n=51, 6, 6, 59)	0.3963 (± 1.70256)	-0.0767 (± 0.64252)	-0.5750 (± 1.02039)	0.6701 (± 4.70300)
Sero 10A IgG AB: Baseline (n= 54, 6, 6, 63)	6.443 (± 5.8006)	17.847 (± 32.7160)	14.040 (± 14.0133)	7.631 (± 8.2417)
Sero 10A IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.502 (± 7.1412)	-8.062 (± 36.3708)	0.100 (± 9.5476)	-0.384 (± 5.8464)
Sero 11A IgG AB: Baseline (n= 54, 6, 6, 63)	1.768 (± 1.9872)	3.203 (± 3.6280)	4.095 (± 4.7768)	2.308 (± 3.0647)
Sero 11A IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.241 (± 1.1929)	-1.615 (± 4.5191)	-0.782 (± 5.3918)	-0.276 (± 1.6589)
Sero 12F IgG AB: Baseline (n= 54, 6, 6, 63)	0.852 (± 2.5002)	2.355 (± 3.5388)	2.077 (± 2.0373)	0.262 (± 0.3381)
Sero 12F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.060 (± 0.8496)	-1.648 (± 3.7849)	-1.220 (± 1.7397)	-0.072 (± 0.1772)
Sero 14 IgG AB: Baseline (n= 54, 6, 6, 63)	7.910 (± 11.3177)	13.982 (± 16.1988)	8.167 (± 9.5488)	5.183 (± 6.5611)
Sero 14 IgG AB: Change at Week 24 (n=51, 6, 6, 59)	-0.635 (± 6.6892)	-7.027 (± 19.5245)	-0.798 (± 7.1605)	0.597 (± 3.6401)
Sero 15B IgG AB: Baseline (n= 54, 6, 6, 63)	3.926 (± 5.7931)	6.287 (± 7.4576)	4.332 (± 4.0216)	3.690 (± 5.3754)
Sero 15B IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.603 (± 5.1284)	-2.262 (± 9.1738)	-1.607 (± 4.1148)	-0.341 (± 2.2893)
Sero 17F IgG AB: Baseline (n= 54, 6, 6, 63)	4.817 (± 5.7702)	11.422 (± 16.0156)	11.952 (± 10.2915)	4.277 (± 4.8458)
Sero 17F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.427 (± 4.6695)	-6.123 (± 17.3744)	-5.898 (± 9.5001)	1.330 (± 4.8122)
Sero 18C IgG AB: Baseline (n= 54, 6, 6, 63)	3.229 (± 4.8212)	3.475 (± 2.2460)	2.980 (± 1.8997)	2.485 (± 3.8363)
Sero 18C IgG AB:Change at Week 24 (n=51, 6, 6, 59)	-0.096 (± 2.8194)	-1.172 (± 2.2061)	-0.915 (± 1.0038)	0.054 (± 2.2468)
Sero 19A IgG AB: Baseline (n= 54, 6, 6, 63)	15.2372 (± 11.46102)	35.2000 (± 58.79083)	50.3175 (± 56.06189)	14.9554 (± 11.40262)
Sero 19A IgG AB:Change at Week 24 (n=51, 6, 6, 59)	2.2418 (± 6.97357)	-18.0750 (± 61.75995)	-29.3558 (± 44.83082)	4.0988 (± 9.00464)
Sero 19F IgG AB: Baseline (n= 54, 6, 6, 63)	4.203 (± 6.4231)	10.857 (± 14.6665)	8.353 (± 8.4621)	2.609 (± 3.1856)

Sero 19F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.651 (± 3.5642)	-6.447 (± 16.0973)	-3.673 (± 8.5727)	1.136 (± 3.2837)
Sero 20 IgG AB: Baseline (n= 54, 6, 6, 63)	5.4506 (± 6.82628)	26.7958 (± 45.54328)	21.8742 (± 22.32961)	4.0902 (± 4.01659)
Sero 20 IgG AB: Change at Week 24 (n=51, 6, 6, 59)	0.0455 (± 4.96426)	-21.4475 (± 46.04992)	-13.0942 (± 16.16771)	1.2437 (± 2.42526)
Sero 22F IgG AB: Baseline (n= 54, 6, 6, 63)	1.563 (± 2.0162)	5.743 (± 10.5586)	5.525 (± 6.4123)	1.138 (± 1.6187)
Sero 22F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.244 (± 1.8324)	-4.000 (± 11.1710)	-3.657 (± 6.6997)	0.087 (± 0.9350)
Sero 23F IgG AB: Baseline (n= 54, 6, 6, 63)	1.401 (± 2.0138)	1.897 (± 1.3080)	0.685 (± 0.3293)	1.797 (± 2.7461)
Sero 23F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.078 (± 1.0468)	-0.150 (± 1.3425)	0.190 (± 0.4725)	0.125 (± 1.8192)
Sero 33F IgG AB: Baseline (n= 54, 6, 6, 63)	2.610 (± 4.4802)	6.600 (± 12.2931)	5.630 (± 5.3371)	1.800 (± 2.2552)
Sero 33F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	-0.392 (± 1.7998)	-5.042 (± 12.7997)	-3.740 (± 4.4122)	0.066 (± 1.1380)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Absolute Change From Baseline in Vaccine Titres - Streptococcus pneumoniae (S. pneumoniae) at Week 12

End point title	Part B: Absolute Change From Baseline in Vaccine Titres - Streptococcus pneumoniae (S. pneumoniae) at Week 12

End point description:

Vaccine-related immunoglobulin (Ig) titres for Pneumococcus (S. pneumoniae) were analysed, including 23 types of serotypes (sero). AB = Antibody. Safety population included all randomised subjects who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point, '9999' signifies since only 1 subject was analysed, SD was not evaluated and '99999' signifies no mean and SD were calculated due to 0 subjects in that particular arm at specific time point.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	1	0[34]	21
Units: mg/L				
arithmetic mean (standard deviation)				
Sero 1 IgG AB: Baseline (n= 10, 1, 0, 21)	3.538 (± 6.0374)	0.210 (± 9999)	()	1.930 (± 2.6639)
Sero 1 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	4.193 (± 9.8131)	99999 (± 99999)	()	0.116 (± 0.4689)
Sero 2 IgG AB: Baseline (n= 10, 1, 0, 21)	4.7775 (± 10.24616)	0.9900 (± 9999)	()	3.9669 (± 8.68701)
Sero 2 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	-0.4586 (± 0.72158)	99999 (± 99999)	()	-0.4734 (± 4.04649)

Sero 3 IgG AB: Baseline (n= 10, 1, 0, 21)	3.881 (± 7.0122)	0.400 (± 9999)	()	1.133 (± 1.0457)
Sero 3 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	-1.886 (± 5.4670)	99999 (± 99999)	()	0.307 (± 0.7307)
Sero 4 IgG AB: Baseline (n= 10, 1, 0, 21)	3.6185 (± 8.92846)	0.1000 (± 9999)	()	1.2376 (± 1.90643)
Sero 4 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	0.0571 (± 0.20934)	99999 (± 99999)	()	0.0450 (± 0.63581)
Sero 5 IgG AB: Baseline (n= 10, 1, 0, 21)	7.2845 (± 10.00019)	3.3500 (± 9999)	()	5.0124 (± 5.83330)
Sero 5 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	4.4443 (± 7.54015)	99999 (± 99999)	()	3.4794 (± 5.30014)
Sero 6B IgG AB: Baseline (n= 10, 1, 0, 21)	10.7965 (± 29.02953)	0.3600 (± 9999)	()	2.9210 (± 4.10508)
Sero 6B IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	0.2943 (± 0.63629)	99999 (± 99999)	()	0.2738 (± 1.49780)
Sero 7F IgG AB: Baseline (n= 10, 1, 0, 21)	2.482 (± 3.0844)	0.660 (± 9999)	()	3.030 (± 2.6854)
Sero 7F IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	4.399 (± 10.6094)	99999 (± 99999)	()	0.796 (± 1.8650)
Sero 8 IgG AB: Baseline (n= 10, 1, 0, 21)	3.6820 (± 3.59284)	0.2300 (± 9999)	()	2.6629 (± 3.61369)
Sero 8 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	1.5329 (± 4.51498)	99999 (± 99999)	()	0.5931 (± 1.32472)
Sero 9N IgG AB: Baseline (n= 10, 1, 0, 21)	4.1090 (± 6.77642)	0.1300 (± 9999)	()	2.0848 (± 2.59536)
Sero 9N IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	3.3407 (± 8.56070)	99999 (± 99999)	()	0.5875 (± 1.62657)
Sero 9V IgG AB: Baseline (n= 10, 1, 0, 21)	1.104 (± 1.2697)	0.070 (± 9999)	()	1.520 (± 2.4346)
Sero 9V IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	-0.001 (± 0.3491)	99999 (± 99999)	()	-0.181 (± 0.9893)
Sero 10A IgG AB: Baseline (n= 10, 1, 0, 21)	6.760 (± 10.6571)	2.140 (± 9999)	()	6.600 (± 9.0014)
Sero 10A IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	1.833 (± 3.0611)	99999 (± 99999)	()	4.696 (± 13.8354)
Sero 11A IgG AB: Baseline (n= 10, 1, 0, 21)	2.1860 (± 2.85529)	0.3500 (± 9999)	()	3.5831 (± 4.19998)
Sero 11A IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	0.6293 (± 3.04077)	99999 (± 99999)	()	0.6431 (± 1.74757)
Sero 12F IgG AB: Baseline (n= 10, 1, 0, 21)	2.1680 (± 4.29056)	0.2700 (± 9999)	()	1.2424 (± 1.21257)
Sero 12F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	1.1429 (± 2.54387)	99999 (± 99999)	()	0.3638 (± 0.72331)
Sero 14 IgG AB: Baseline (n= 10, 1, 0, 21)	5.6435 (± 7.09870)	8.9000 (± 9999)	()	11.0210 (± 12.99039)
Sero 14 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	1.3686 (± 5.66545)	99999 (± 99999)	()	-1.0319 (± 3.43469)
Sero 15B IgG AB: Baseline (n= 10, 1, 0, 21)	4.717 (± 9.7429)	1.430 (± 9999)	()	3.410 (± 3.5117)
Sero 15B IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	0.209 (± 0.2118)	99999 (± 99999)	()	0.624 (± 1.4874)
Sero 17F IgG AB: Baseline (n= 10, 1, 0, 21)	16.0005 (± 15.82427)	17.4500 (± 9999)	()	6.8752 (± 9.02378)
Sero 17F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	-2.0357 (± 4.29278)	99999 (± 99999)	()	1.4531 (± 1.4531)
Sero 18C IgG AB: Baseline (n= 10, 1, 0, 21)	4.083 (± 6.6047)	0.140 (± 9999)	()	5.630 (± 7.8627)
Sero 18C IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	8.439 (± 21.2741)	99999 (± 99999)	()	0.077 (± 1.0131)
Sero 19A IgG AB: Baseline (n= 10, 1, 0, 21)	24.5485 (± 44.24043)	13.7700 (± 9999)	()	16.5624 (± 15.27894)

Sero 19A IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	3.4457 (± 6.31401)	99999 (± 99999)	()	5.3575 (± 8.84223)
Sero 19F IgG AB: Baseline (n= 10, 1, 0, 21)	4.1040 (± 5.50276)	2.0500 (± 9999)	()	3.3800 (± 3.26583)
Sero 19F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	2.3893 (± 4.24918)	99999 (± 99999)	()	1.2275 (± 2.05550)
Sero 20 IgG AB: Baseline (n= 10, 1, 0, 21)	11.5305 (± 18.12761)	0.7900 (± 9999)	()	8.2971 (± 8.28676)
Sero 20 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	-0.2271 (± 5.08362)	99999 (± 99999)	()	-1.6638 (± 6.48421)
Sero 22F IgG AB: Baseline (n= 10, 1, 0, 21)	5.9930 (± 10.47744)	0.6700 (± 9999)	()	3.8002 (± 6.40547)
Sero 22F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	-1.8500 (± 4.69494)	99999 (± 99999)	()	1.8431 (± 5.04651)
Sero 23F IgG AB: Baseline (n= 10, 1, 0, 21)	1.6980 (± 2.81930)	0.5600 (± 9999)	()	1.9957 (± 2.72717)
Sero 23F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	1.9964 (± 5.10312)	99999 (± 99999)	()	0.2775 (± 0.60481)
Sero 33F IgG AB: Baseline (n= 10, 1, 0, 21)	5.500 (± 8.3404)	0.220 (± 9999)	()	4.245 (± 4.6106)
Sero 33F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	-0.281 (± 0.4481)	99999 (± 99999)	()	0.203 (± 1.4614)

Notes:

[34] - 0 participants were available for analysis in this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Absolute Change From Baseline in Vaccine Titres - Clostridium tetani (C. tetani) and Diphtheria at Week 24

End point title	Part A: Absolute Change From Baseline in Vaccine Titres - Clostridium tetani (C. tetani) and Diphtheria at Week 24

End point description:

Vaccine-related immunoglobulin titres for tetanus and diphtheria were analysed. Safety population included all randomised subjects who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point. IU/mL = international units per millilitre.

End point type	Secondary

End point timeframe:

Baseline to Week 24

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	6	6	62
Units: IU/mL				
arithmetic mean (standard deviation)				
C. tetani IgG Antibody: Baseline (n= 54, 6, 6, 62)	2.46 (± 2.532)	1.73 (± 1.660)	2.52 (± 2.219)	3.30 (± 3.674)
C.tetani IgG Antibody:Change atWeek24(n=50,6,6,58)	-0.07 (± 1.975)	0.07 (± 0.437)	1.07 (± 2.890)	-0.70 (± 2.398)
Diphtheria IgG Antibody: Baseline (n=54, 6, 6, 62)	0.33 (± 0.511)	0.10 (± 0.089)	0.17 (± 0.163)	0.33 (± 0.444)

DiphtheriaIgGAntibody:Change atWeek24(n=50,6,6,58)	-0.06 (± 0.266)	-0.03 (± 0.082)	0.07 (± 0.163)	-0.07 (± 0.340)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Absolute Change From Baseline in Vaccine Titres - Clostridium tetani (C. tetani) and Diphtheria at Week 12

End point title	Part B: Absolute Change From Baseline in Vaccine Titres - Clostridium tetani (C. tetani) and Diphtheria at Week 12

End point description:

Vaccine-related immunoglobulin (Ig) titres for tetanus and diphtheria were analysed. Safety population included all randomised subjects who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point, '9999' signifies since only 1 subject was analysed, SD was not evaluated and '99999' signifies no mean and SD were calculated due to 0 subjects in that particular arm at specific time point.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	1	0[35]	21
Units: IU/mL				
arithmetic mean (standard deviation)				
C. tetani IgG Antibody: Baseline (n= 10, 1, 0, 21)	4.41 (± 3.469)	3.00 (± 9999)	()	5.04 (± 2.910)
C.tetani IgG Antibody:Change atWeek24(n=7,0,0,16)	-0.61 (± 1.178)	99999 (± 99999)	()	1.20 (± 6.948)
Diphtheria IgG Antibody: Baseline (n=10, 1, 0, 21)	0.46 (± 0.465)	0.10 (± 9999)	()	0.74 (± 1.027)
DiphtheriaIgGAntibody:Change atWeek24(n=7,0,0,16)	-0.01 (± 0.146)	99999 (± 99999)	()	0.06 (± 0.875)

Notes:

[35] - 0 participants were available for analysis in this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percent Change From Baseline Over Time in Immunoglobulin Levels

End point title	Part A: Percent Change From Baseline Over Time in Immunoglobulin Levels

End point description:

Safety population included all randomised subjects in Part A who had received at least one dose of

randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: Placebo	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	56	64
Units: percent change				
arithmetic mean (standard deviation)				
IgA: Change at Week 16 (n= 0, 0, 45, 54)	99999 (± 99999)	99999 (± 99999)	1.50 (± 11.91)	-0.53 (± 9.22)
IgA: Change at Week 24 (n= 6, 6, 52, 59)	-15.55 (± 41.08)	-0.10 (± 18.22)	-1.51 (± 18.94)	-0.48 (± 12.94)
IgG: Change at Week 16 (n= 0, 0, 45, 54)	99999 (± 99999)	99999 (± 99999)	7.30 (± 16.58)	2.63 (± 15.23)
IgG: Change at Week 24 (n= 6, 6, 52, 59)	-2.53 (± 8.52)	-5.88 (± 23.39)	6.86 (± 19.20)	6.07 (± 16.44)
IgM: Change at Week 16 (n= 0, 0, 45, 54)	99999 (± 99999)	99999 (± 99999)	0.96 (± 11.71)	-0.73 (± 40.24)
IgM: Change at Week 24 (n= 6, 6, 52, 59)	-6.73 (± 12.57)	-14.99 (± 11.74)	1.86 (± 19.22)	0.87 (± 45.16)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percent Change From Baseline Over Time in Immunoglobulin Levels

End point title	Part B: Percent Change From Baseline Over Time in Immunoglobulin Levels

End point description:

Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Baseline up to Week 16

End point values	Part B: BIIB059 150 mg	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	33	26	48
Units: percent change				
arithmetic mean (standard deviation)				
IgA: Change at Week 12 (n= 0, 7, 0, 14)	99999 (± 99999)	-1.45 (± 7.14)	99999 (± 99999)	14.44 (± 14.44)
IgA: Change at Week 16 (n= 25, 25, 25, 30)	0.19 (± 14.22)	12.92 (± 12.92)	-1.48 (± 10.13)	-2.98 (± 7.64)
IgG: Change at Week 12 (n= 0, 7, 0, 14)	99999 (± 99999)	0.63 (± 5.76)	99999 (± 99999)	18.97 (± 18.97)
IgG: Change at Week 16 (n= 25, 25, 25, 30)	1.05 (± 18.28)	2.48 (± 19.59)	-3.84 (± 11.14)	-0.39 (± 9.81)
IgM: Change at Week 12 (n= 0, 7, 0, 14)	99999 (± 99999)	-1.25 (± 4.98)	99999 (± 99999)	18.25 (± 18.25)
IgM: Change at Week 16 (n= 25, 25, 25, 30)	-1.25 (± 22.27)	-3.62 (± 10.84)	-7.60 (± 12.86)	-0.57 (± 11.85)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percent Change From Baseline in Vaccine Titres at Week 24

End point title	Part A: Percent Change From Baseline in Vaccine Titres at Week 24

End point description:

Vaccine-related immunoglobulin (Ig) titres for Pneumococcus (S. pneumoniae) including 23 types of serotypes (sero), tetanus and diphtheria were analysed. AB = Antibody. Safety population included all randomised subjects who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point.

End point type	Secondary

End point timeframe:

Baseline to Week 24

End point values	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	6	6	63
Units: percent change				
arithmetic mean (standard deviation)				
Sero 1 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	53.629 (± 206.5979)	2.996 (± 56.3607)	-10.403 (± 40.9969)	159.298 (± 788.0577)
Sero 2 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	-2.263 (± 52.3214)	17.857 (± 64.1746)	-26.089 (± 35.2991)	2.207 (± 57.5136)
Sero 3 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	-10.854 (± 34.9399)	530.405 (± 1313.1947)	16.282 (± 89.2804)	51.000 (± 205.2211)
Sero 4 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	-8.039 (± 43.2246)	-15.385 (± 70.4542)	-26.435 (± 50.4316)	26.481 (± 143.2057)

Sero 5 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	13.293 (± 54.1115)	81.053 (± 156.0747)	2.937 (± 88.0683)	23.064 (± 57.0094)
Sero 6B IgG AB: Change at Week 24 (n=51, 6, 6, 59)	-8.215 (± 36.4547)	-7.761 (± 68.3190)	-40.573 (± 28.7097)	34.204 (± 179.4443)
Sero 7F IgG AB: Change at Week 24 (n=51, 6, 6, 59)	-7.560 (± 54.4647)	1.928 (± 90.5777)	-27.272 (± 30.2249)	19.827 (± 120.4336)
Sero 8 IgG AB: Change at Week 24 (n= 51, 6, 6, 59)	13.540 (± 64.9487)	-14.917 (± 72.2397)	-19.919 (± 55.3947)	13.552 (± 54.9741)
Sero 9N IgG AB: Change at Week 24 (n=51, 6, 6, 59)	13.302 (± 108.1678)	22.663 (± 111.5069)	2.985 (± 42.6740)	13.703 (± 137.0620)
Sero 9V IgG AB: Change at Week 24 (n=51, 6, 6, 59)	32.983 (± 138.1448)	-3.399 (± 47.7558)	-13.591 (± 34.6936)	56.445 (± 189.5817)
Sero 10A IgG AB:Change at Week 24 (n=51, 6, 6, 59)	19.729 (± 111.4367)	101.031 (± 168.5588)	11.364 (± 51.7417)	24.321 (± 83.4616)
Sero 11A IgG AB:Change at Week 24 (n=51, 6, 6, 59)	51.134 (± 146.8640)	-16.656 (± 93.1140)	14.976 (± 131.8861)	18.956 (± 90.1198)
Sero 12F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	-4.445 (± 72.6724)	-5.463 (± 105.9311)	-41.416 (± 37.8396)	-11.447 (± 58.0173)
Sero 14 IgG AB: Change at Week 24 (n=51, 6, 6, 59)	-3.087 (± 55.1562)	-31.375 (± 69.5715)	2.213 (± 83.1715)	20.278 (± 136.8606)
Sero 15B IgG AB:Change at Week 24 (n=51, 6, 6, 59)	11.206 (± 116.7649)	17.353 (± 66.5358)	-5.380 (± 47.4598)	69.305 (± 570.5864)
Sero 17F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	20.238 (± 90.3348)	1.009 (± 53.3534)	-29.346 (± 51.5854)	51.187 (± 152.3694)
Sero 18C IgG AB:Change at Week 24 (n=51, 6, 6, 59)	14.720 (± 64.9702)	-14.827 (± 57.5927)	-30.608 (± 35.7004)	43.454 (± 218.7604)
Sero 19A IgG AB:Change at Week 24 (n=51, 6, 6, 59)	21.433 (± 55.0044)	44.814 (± 73.1928)	-16.275 (± 73.1979)	32.146 (± 64.1971)
Sero 19F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	54.691 (± 114.1882)	5.412 (± 83.2939)	-20.778 (± 54.8585)	101.397 (± 221.3435)
Sero 20 IgG AB: Change at Week 24 (n=51, 6, 6, 59)	35.202 (± 90.9529)	-37.641 (± 33.1824)	-53.328 (± 21.6352)	75.407 (± 168.3388)
Sero 22F IgG AB:Change at Week 24 (n=51, 6, 6, 57)	11.419 (± 127.0639)	23.828 (± 108.3336)	-27.150 (± 51.7944)	20.048 (± 139.8965)
Sero 23F IgG AB:Change at Week 24 (n=51, 6, 6, 59)	0.215 (± 50.6348)	18.204 (± 57.8187)	35.862 (± 55.9954)	22.329 (± 156.8530)
Sero 33F IgG AB:Change at Week 24 (n=51, 6, 6, 58)	2.245 (± 65.7260)	-3.348 (± 64.8128)	-47.069 (± 32.3779)	23.533 (± 102.5771)
C.tetani IgG Antibody:Change atWeek24(n=50,6,6,58)	19.517 (± 194.1378)	39.032 (± 83.7958)	29.887 (± 80.9696)	-11.895 (± 48.3260)
DiphtheriaIgGAntibody:Change atWeek24(n=37,4,4,44)	15.310 (± 141.4934)	-50.000 (± 70.7107)	77.083 (± 156.8461)	-8.842 (± 52.9312)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percent Change From Baseline in Vaccine Titres at Week 12

End point title	Part B: Percent Change From Baseline in Vaccine Titres at Week 12

End point description:

Vaccine-related immunoglobulin (Ig) titres for Pneumococcus (S. pneumoniae) including 23 types of serotypes (sero), tetanus and diphtheria were analysed. AB = Antibody. Safety population included all randomised subjects in Part B who had received at least one dose of randomised study treatment and was based on the actual treatment received. Here, 'n' signifies number of subjects analysed at specific time point, '9999' signifies since only 1 subject was analysed, SD was not evaluated and '99999' signifies no mean and SD were calculated due to 0 subjects in that particular arm at specific time point.

End point type	Secondary

End point timeframe:
Baseline to Week 12

End point values	Part B: Placebo	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	1	0[36]	21
Units: percent change				
arithmetic mean (standard deviation)				
Sero 1 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	16.835 (± 59.1269)	99999 (± 99999)	()	4.257 (± 67.8533)
Sero 2 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	-20.725 (± 23.3306)	99999 (± 99999)	()	15.437 (± 65.9854)
Sero 3 IgG AB: Change at Week 12 (n= 7, 0, 0, 15)	-3.370 (± 38.0473)	99999 (± 99999)	()	40.604 (± 72.3862)
Sero 4 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	6.349 (± 31.2778)	99999 (± 99999)	()	32.033 (± 125.5527)
Sero 5 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	39.578 (± 34.1628)	99999 (± 99999)	()	68.850 (± 127.9989)
Sero 6B IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	11.800 (± 36.9732)	99999 (± 99999)	()	43.759 (± 97.2095)
Sero 7F IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	67.784 (± 90.5075)	99999 (± 99999)	()	25.297 (± 48.3430)
Sero 8 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	28.981 (± 76.3568)	99999 (± 99999)	()	41.622 (± 84.8290)
Sero 9N IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	18.274 (± 61.3305)	99999 (± 99999)	()	19.616 (± 74.2945)
Sero 9V IgG AB: Change at Week 12 (n= 7, 0, 0, 15)	-7.707 (± 27.1098)	99999 (± 99999)	()	-0.573 (± 35.9671)
Sero 10A IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	62.824 (± 94.6871)	99999 (± 99999)	()	60.437 (± 145.3385)
Sero 11A IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	12.392 (± 69.6069)	99999 (± 99999)	()	29.295 (± 118.2639)
Sero 12F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	21.768 (± 44.1688)	99999 (± 99999)	()	62.768 (± 118.4103)
Sero 14 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	77.551 (± 191.9769)	99999 (± 99999)	()	18.059 (± 75.7757)
Sero 15B IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	14.160 (± 16.8040)	99999 (± 99999)	()	27.188 (± 56.4211)
Sero 17F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	-14.128 (± 20.3094)	99999 (± 99999)	()	19.712 (± 69.9092)
Sero 18C IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	36.970 (± 99.7771)	99999 (± 99999)	()	8.882 (± 41.3781)
Sero 19A IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	15.179 (± 28.0371)	99999 (± 99999)	()	44.140 (± 113.5780)
Sero 19F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	54.773 (± 49.4505)	99999 (± 99999)	()	46.995 (± 90.7514)
Sero 20 IgG AB: Change at Week 12 (n= 7, 0, 0, 16)	1.131 (± 51.4091)	99999 (± 99999)	()	0.714 (± 49.6361)
Sero 22F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	-14.748 (± 45.9399)	99999 (± 99999)	()	38.974 (± 83.4963)
Sero 23F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	52.210 (± 75.6486)	99999 (± 99999)	()	16.859 (± 40.1773)
Sero 33F IgG AB:Change at Week 12 (n= 7, 0, 0, 16)	0.600 (± 31.4400)	99999 (± 99999)	()	26.241 (± 66.5051)

C.tetani IgG Antibody:Change atWeek12(n=7,0,0,16)	-6.387 (± 18.2069)	99999 (± 99999)	()	27.872 (± 128.3927)
DiphtheriaIgGAntibody:Change atWeek12(n=6,0,0,14)	0.000 (± 34.0588)	99999 (± 99999)	()	28.845 (± 132.2208)

Notes:

[36] - 0 participants were available for analysis in this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Serum Concentration of BIIB059

End point title	Part A: Serum Concentration of BIIB059[37]

End point description:

The PK population included the safety subjects who had at least 1 PK concentration measurement. The number analyzed is the number of subjects with data available for analysis at the specified time point. The number analyzed is the number of subjects with data available for analysis at the specified time point. Here '9999' signifies standard deviation was not estimable as only 1 subject was evaluated. Here '99999' signifies no mean and SD were calculated due to 0 subjects in that particular arm at specific time point.

End point type	Secondary

End point timeframe:

Part A: pre-dose on Days 1, 29, 85 and 113 and post-dose on Days 1, 8, 29, 85, 169, 197 and 253

Notes:

[37] - 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: This endpoint was analysed for Part A BIIB059 arm groups.

End point values	Part A: BIIB059 50 mg	Part A: BIIB059 150 mg	Part A: BIIB059 450 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	64	
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
Day 1: Pre-dose (n= 6, 6, 64)	0.0 (± 0.0)	0.0 (± 0.0)	0.0 (± 0.0)	
Day 1: Post-dose (n= 6, 5, 51)	0.7 (± 0.6)	2.1 (± 1.3)	1.9 (± 2.1)	
Day 8 (n= 6, 6, 62)	5.5 (± 2.0)	17.1 (± 4.1)	45.5 (± 16.5)	
Day 29: Pre-dose (n= 6, 6, 61)	7.0 (± 3.3)	23.7 (± 7.2)	53.6 (± 19.7)	
Day 29: Post-dose (n= 6, 5, 60)	7.9 (± 4.2)	25.9 (± 5.6)	52.5 (± 20.5)	
Day 85: Pre-dose (n= 6, 6, 59)	3.9 (± 1.6)	12.7 (± 3.7)	34.7 (± 19.1)	
Day 85: Post-dose (n= 0, 0, 52)	99999 (± 99999)	99999 (± 99999)	36.1 (± 20.8)	
Day 113: Pre-dose (n= 6, 6, 59)	3.4 (± 1.5)	11.3 (± 5.2)	34.6 (± 20.8)	
Day 169 (n= 6, 4, 59)	3.7 (± 1.5)	12.8 (± 4.8)	32.0 (± 18.6)	
Day 197 (n= 4, 4, 56)	0.9 (± 0.6)	4.1 (± 2.3)	12.6 (± 10.3)	
Day 253 (n= 0, 1, 38)	99999 (± 99999)	0.4 (± 9999)	2.8 (± 2.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Serum Concentration of BIIB059

End point title	Part B: Serum Concentration of BIIB059[38]

End point description:

The PK population included the safety subjects who had at least 1 PK concentration measurement. Number analyzed is the number of subjects with data available for analysis at the specified time point.

End point type	Secondary

End point timeframe:

Part B: pre-dose on Days 1, 29, 85 and post-dose on Days 1, 29, 85, 113, 141, 169 and 197

Notes:

[38] - 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: This endpoint was analysed for Part B BIIB059 arm groups.

End point values	Part B: BIIB059 50 mg	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	26	25	48	
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1: Pre-dose (n= 26, 25, 47)	0.0 (± 0.1)	0.1 (± 0.2)	0.0 (± 0.1)	
Day 1: Post-dose (n= 11, 17, 41)	0.4 (± 0.3)	1.1 (± 1.1)	2.9 (± 3.7)	
Day 8 (n= 26, 24, 27)	6.8 (± 6.6)	13.3 (± 6.1)	47.8 (± 16.9)	
Day 29: Pre-dose (n= 26, 24, 47)	8.3 (± 7.1)	16.9 (± 9.1)	60.2 (± 23.3)	
Day 29: Post-dose (n= 23, 24, 44)	8.7 (± 6.6)	17.6 (± 10.2)	61.0 (± 24.2)	
Day 85: Pre-dose (n= 22, 24, 29)	3.8 (± 3.4)	11.0 (± 6.5)	42.0 (± 17.1)	
Day 85: Post-dose (n= 21, 24, 29)	4.1 (± 3.6)	11.6 (± 5.8)	42.0 (± 17.0)	
Day 113 (n= 22, 25, 30)	4.6 (± 5.9)	12.1 (± 6.5)	43.2 (± 14.3)	
Day 141 (n= 14, 22, 44)	2.5 (± 3.3)	4.6 (± 3.7)	19.3 (± 9.6)	
Day 169 (n= 4, 12, 39)	2.4 (± 2.0)	2.2 (± 1.1)	7.4 (± 5.0)	
Day 197 (n= 2, 8, 35)	0.8 (± 0.7)	1.1 (± 0.4)	3.4 (± 2.3)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part A: up to Week 36, Part B: up to Week 28

Adverse event reporting additional description:

Safety population included all the randomised subjects in Part A and B who had received at least one dose of randomised study treatment and was based on the actual treatment received. Data for safety was reported together for Parts A and B, by dose.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Part A: Placebo

Reporting group description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 matching placebo, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Reporting group title	Part A: BIIB059 50 mg

Reporting group description:

Subjects with SLE with active skin manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Reporting group title	Part A: BIIB059 450 mg

Reporting group description:

Subjects with SLE with active skin manifestations and joint involvement received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Reporting group title	Part A: BIIB059 150 mg

Reporting group description:

Subjects with SLE with active skin manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional dose at Week 2 for a total of 7 doses up to Week 20.

Reporting group title	Part B: Placebo

Reporting group description:

Subjects with active CLE with or without systemic manifestations received BIIB059 matching placebo administered SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Reporting group title	Part B: BIIB059 50 mg

Reporting group description:

Subjects with active CLE with or without systemic manifestations received BIIB059 50 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Reporting group title	Part B: BIIB059 150 mg

Reporting group description:

Subjects with active CLE with or without systemic manifestations received BIIB059 150 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Reporting group title	Part B: BIIB059 450 mg

Reporting group description:

Subjects with active CLE with or without systemic manifestations received BIIB059 450 mg, SC every 4 weeks, starting Week 0 with an additional loading dose at Week 2 for a total of 5 doses up to Week 12.

Serious adverse events	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 450 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 56 (10.71%)	0 / 6 (0.00%)	3 / 64 (4.69%)
number of deaths (all causes)	3	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin angiosarcoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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 leiomyoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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			
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	1 / 64 (1.56%)
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			
Ankle fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cervical vertebral fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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			
Ataxia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Migraine			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (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
Paraesthesia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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
Eye disorders			
Retinal artery thrombosis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (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
Visual impairment			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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			
Ileus			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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
Intestinal obstruction			

subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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
Intestinal perforation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (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
Systemic lupus erythematosus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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
Infections and infestations			
Gastroenteritis bacterial			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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
Parasitic gastroenteritis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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

Urosepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (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
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: BIIB059 150 mg	Part B: Placebo	Part B: BIIB059 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	3 / 33 (9.09%)	1 / 26 (3.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin angiosarcoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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 leiomyoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	0 / 26 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Cervical vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Road traffic accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Cerebrovascular disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Epilepsy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Eye disorders			
Retinal artery thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (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
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Intestinal perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	0 / 26 (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			
Gastroenteritis bacterial			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	0 / 26 (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
Parasitic gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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

Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (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	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 25 (12.00%)	3 / 48 (6.25%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin angiosarcoma			
subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 25 (4.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			

subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Retinal artery thrombosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ileus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 25 (4.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	2 / 25 (8.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Gastroenteritis bacterial			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parasitic gastroenteritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic viral infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part A: Placebo	Part A: BIIB059 50 mg	Part A: BIIB059 450 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 56 (39.29%)	3 / 6 (50.00%)	22 / 64 (34.38%)
Investigations			

Neutrophil count increased			
subjects affected / exposed	0 / 56 (0.00%)	1 / 6 (16.67%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	4 / 64 (6.25%)
occurrences (all)	2	0	4
Repetitive strain injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 56 (14.29%)	1 / 6 (16.67%)	1 / 64 (1.56%)
occurrences (all)	9	1	1
Tension headache			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 56 (3.57%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences (all)	2	0	1
Fatigue			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences (all)	1	0	1
Injection site erythema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	5
Injection site warmth			

subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 6 (16.67%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 56 (5.36%)	1 / 6 (16.67%)	3 / 64 (4.69%)
occurrences (all)	3	1	3
Nausea			
subjects affected / exposed	0 / 56 (0.00%)	1 / 6 (16.67%)	1 / 64 (1.56%)
occurrences (all)	0	1	1
Spigelian hernia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Pruritus			
subjects affected / exposed	2 / 56 (3.57%)	1 / 6 (16.67%)	2 / 64 (3.13%)
occurrences (all)	2	1	2
Ecchymosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Urticaria			
subjects affected / exposed	0 / 56 (0.00%)	1 / 6 (16.67%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Cutaneous lupus erythematosus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 56 (3.57%)	0 / 6 (0.00%)	2 / 64 (3.13%)
occurrences (all)	2	0	2
Back pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Systemic lupus erythematosus			
subjects affected / exposed	1 / 56 (1.79%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	3	0	0
Myalgia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Influenza			
subjects affected / exposed	2 / 56 (3.57%)	0 / 6 (0.00%)	1 / 64 (1.56%)
occurrences (all)	2	0	1
Nasopharyngitis			

subjects affected / exposed	2 / 56 (3.57%)	1 / 6 (16.67%)	3 / 64 (4.69%)
occurrences (all)	2	4	4
Sinusitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	6 / 56 (10.71%)	0 / 6 (0.00%)	2 / 64 (3.13%)
occurrences (all)	6	0	2
Urinary tract infection			
subjects affected / exposed	4 / 56 (7.14%)	0 / 6 (0.00%)	4 / 64 (6.25%)
occurrences (all)	5	0	5
Cystitis			
subjects affected / exposed	2 / 56 (3.57%)	1 / 6 (16.67%)	0 / 64 (0.00%)
occurrences (all)	3	1	0
Rhinitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 6 (16.67%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 6 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: BIIB059 150 mg	Part B: Placebo	Part B: BIIB059 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	19 / 33 (57.58%)	16 / 26 (61.54%)
Investigations			
Neutrophil count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 33 (6.06%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Repetitive strain injury			

subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 6 (16.67%)	3 / 33 (9.09%)	6 / 26 (23.08%)
occurrences (all)	4	4	6
Tension headache			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Injection site erythema			
subjects affected / exposed	1 / 6 (16.67%)	1 / 33 (3.03%)	3 / 26 (11.54%)
occurrences (all)	2	1	5
Injection site warmth			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 33 (6.06%)	0 / 26 (0.00%)
occurrences (all)	0	5	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Neutrophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 33 (6.06%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	4	0	0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	3 / 33 (9.09%)	1 / 26 (3.85%)
occurrences (all)	0	3	1
Spigelian hernia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	2 / 26 (7.69%)
occurrences (all)	0	2	2
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Ecchymosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Purpura			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Cutaneous lupus erythematosus			
subjects affected / exposed	0 / 6 (0.00%)	4 / 33 (12.12%)	1 / 26 (3.85%)
occurrences (all)	0	4	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 33 (6.06%)	1 / 26 (3.85%)
occurrences (all)	1	2	1
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	3 / 26 (11.54%)
occurrences (all)	0	0	3
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Systemic lupus erythematosus			
subjects affected / exposed	1 / 6 (16.67%)	3 / 33 (9.09%)	2 / 26 (7.69%)
occurrences (all)	2	3	2
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 33 (6.06%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
Infections and infestations			
Influenza			
subjects affected / exposed	2 / 6 (33.33%)	0 / 33 (0.00%)	2 / 26 (7.69%)
occurrences (all)	2	0	2
Nasopharyngitis			
subjects affected / exposed	1 / 6 (16.67%)	2 / 33 (6.06%)	2 / 26 (7.69%)
occurrences (all)	1	2	2
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 33 (3.03%)	2 / 26 (7.69%)
occurrences (all)	1	1	2
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Cystitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 33 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 33 (6.06%)	1 / 26 (3.85%)
occurrences (all)	0	2	1

Non-serious adverse events	Part B: BIIB059 150 mg	Part B: BIIB059 450 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 25 (40.00%)	28 / 48 (58.33%)	
Investigations			
Neutrophil count increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Transaminases increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Repetitive strain injury			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 25 (4.00%)	3 / 48 (6.25%)	
occurrences (all)	1	3	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 25 (0.00%)	2 / 48 (4.17%)	
occurrences (all)	0	3	
Tension headache			

subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 25 (0.00%)	2 / 48 (4.17%)	
occurrences (all)	0	2	
Injection site erythema			
subjects affected / exposed	2 / 25 (8.00%)	4 / 48 (8.33%)	
occurrences (all)	2	6	
Injection site warmth			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Injection site pruritus			
subjects affected / exposed	0 / 25 (0.00%)	3 / 48 (6.25%)	
occurrences (all)	0	4	
Injection site rash			
subjects affected / exposed	0 / 25 (0.00%)	3 / 48 (6.25%)	
occurrences (all)	0	3	
Pyrexia			
subjects affected / exposed	1 / 25 (4.00%)	2 / 48 (4.17%)	
occurrences (all)	2	4	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Neutrophilia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences (all)	0	1	
Spigelian hernia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 25 (4.00%)	2 / 48 (4.17%)	
occurrences (all)	1	2	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 25 (12.00%)	1 / 48 (2.08%)	
occurrences (all)	3	1	
Ecchymosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Purpura			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Cutaneous lupus erythematosus			
subjects affected / exposed	1 / 25 (4.00%)	2 / 48 (4.17%)	
occurrences (all)	1	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 25 (8.00%)	3 / 48 (6.25%)	
occurrences (all)	2	4	
Back pain			
subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences (all)	0	1	

Pain in extremity			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Systemic lupus erythematosus			
subjects affected / exposed	2 / 25 (8.00%)	2 / 48 (4.17%)	
occurrences (all)	2	2	
Myalgia			
subjects affected / exposed	1 / 25 (4.00%)	2 / 48 (4.17%)	
occurrences (all)	1	2	
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 25 (4.00%)	2 / 48 (4.17%)	
occurrences (all)	1	2	
Nasopharyngitis			
subjects affected / exposed	5 / 25 (20.00%)	3 / 48 (6.25%)	
occurrences (all)	5	3	
Sinusitis			
subjects affected / exposed	2 / 25 (8.00%)	1 / 48 (2.08%)	
occurrences (all)	2	1	
Upper respiratory tract infection			
subjects affected / exposed	2 / 25 (8.00%)	2 / 48 (4.17%)	
occurrences (all)	2	2	
Urinary tract infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 48 (2.08%)	
occurrences (all)	0	1	
Cystitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 48 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 25 (0.00%)	2 / 48 (4.17%)	
occurrences (all)	0	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 May 2017	Part A was modified to evaluate the effects of a single dosing regimen of BIIB059 on the joint and skin manifestations of SLE. Joint symptoms are a common systemic component of SLE that have been shown to improve in the first 6 months of treatment, based on Phase 2 comparator data. With this change, Part A became a proof-of-concept study to evaluate whether BIIB059 works beyond the skin in SLE. Part B was modified to be a dose-ranging study of BIIB059 in CLE. The sample size for Part B was increased from 30 to 130 subjects to allow for a more thorough evaluation of the activity of BIIB059 in CLE observed in the Phase 1 study (2013-005361-39) and to identify an efficacious dose for CLE.
11 December 2017	Amended to inform the sites of the correct type of screening biopsy to be performed (i.e., punch biopsy, not shave biopsy). Note, Version 3 was retired due to errors in the text and was never distributed to the study sites.
08 February 2018	Errors was corrected that were inadvertently made in Table 1 (Schedule of Activities for Part A): • Erroneous footnotes (footnote 10 and footnote 12, Version 3 numbering) and corresponding footnote indicators were deleted from Table 1. The remaining footnotes were renumbered accordingly. • Footnote 13 (Version 3 numbering) was corrected to accurately reflect the instructions for Part A.
15 March 2019	To add an IA of efficacy and safety after the last subjects completed the double-blind treatment periods for Part A (at Week 24) and Part B (at Week 16).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported