Clinical trial results:
A Phase 3, Multicenter, Double-Blind, Placebo-Controlled Study with an Initial Treatment Period
Followed by a Randomized-Withdrawal Period to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects with Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2016-003426-16
Trial protocol	GB DE HU
Global end of trial date	07 January 2020

Results information

Result version number	v2 (current)
This version publication date	09 June 2022
First version publication date	09 January 2021
Version creation reason	• Correction of full data set Alignment with final posting on ClinicalTrials.gov after NIH review.

Trial information

Trial identification

Sponsor protocol code	PS0013

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03410992
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	05 March 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Compare the efficacy of bimekizumab versus placebo in the treatment of participants with moderate to severe plaque psoriasis (PSO)

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Not Applicable

Evidence for comparator:

Not Applicable

Actual start date of recruitment	05 February 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 10
Country: Number of subjects enrolled	Canada: 89
Country: Number of subjects enrolled	Germany: 38
Country: Number of subjects enrolled	Hungary: 31
Country: Number of subjects enrolled	Poland: 150
Country: Number of subjects enrolled	Russian Federation: 19
Country: Number of subjects enrolled	Korea, Republic of: 7
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	United States: 85
Worldwide total number of subjects	435
EEA total number of subjects	219

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	410
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in February 2018 and concluded in January 2020.

Pre-assignment

Screening details:

Study has a 2-5 weeks Screening Period, a 16 weeks Initial Period, a 40 weeks Randomized-Withdrawal Period (RWP) and a SFU Period (20 weeks after final dose). Participants who did not achieve a PASI90 response at Wk16 or who relapsed at Wk20/later during the RWP, entered 12 weeks of escape treatment. Participant Flow refers to the Randomized Set.

Period 1

Period 1 title	Initial Treatment Period: up to Wk16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W

Arm description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Number of subjects in period 1	Placebo	Bimekizumab 320 mg Q4W
Started	86	349
Completed	82	340
Not completed	4	9
Consent withdrawn by subject	1	-
Adverse event, non-fatal	-	5
Lost to follow-up	1	3
Lack of efficacy	2	1

Period 2	
Period 2 title	Week 16 assessment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W

Arm description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Number of subjects in period 2	Placebo	Bimekizumab 320 mg Q4W
Started	82	340
Received escape treatment	81	23 [1]
Completed	1	311
Not completed	81	29
PASI90 Non-Response at Week 16	81	23
Incorrect escapers	-	6

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who did not achieve a PASI90 response at Week 16 of the Initial Treatment Period and received open-label bimekizumab 320 mg Q4W for 12 weeks (ie, escape treatment).

Period 3

Period 3 title	Randomized-Withdrawal Period: up to Wk56
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/Placebo

Arm description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive placebo during the Randomized-Withdrawal Period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W/Placebo

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period.

Arm type	Placebo
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W/Q8W

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W/Q4W

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Number of subjects in period 3	Placebo/Placebo	Bimekizumab 320 mg Q4W/Placebo	Bimekizumab 320 mg Q4W/Q8W
Started	1	105	100
Received escape treatment	0 [2]	67	4 [3]
Completed	1	33	93
Not completed	0	72	7
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	3	2
Lost to follow-up	-	2	1
Relapse at Week 20 or later	-	67	4

Number of subjects in period 3	Bimekizumab 320 mg Q4W/Q4W
Started	106
Received escape treatment	7 [4]
Completed	94
Not completed	12
Consent withdrawn by subject	3
Adverse event, non-fatal	-
Lost to follow-up	2
Relapse at Week 20 or later	7

Notes:

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of participants at the milestones reflects those who relapse at Week 20 or later during the Randomized-Withdrawal Period (up to Week 56) and received open-label bimekizumab 320 mg Q4W for 12 weeks (ie, escape treatment).

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of participants at the milestones reflects those who relapse at Week 20 or later during the Randomized-Withdrawal Period (up to Week 56) and received open-label bimekizumab 320 mg Q4W for 12 weeks (ie, escape treatment).

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of participants at the milestones reflects those who relapse at Week 20 or later during the Randomized-Withdrawal Period (up to Week 56) and received open-label bimekizumab 320 mg Q4W for 12 weeks (ie, escape treatment).

Period 4

Period 4 title	Escape Treatment: 12 Weeks
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Placebo Escape

Arm description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W Escape

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Arm title	Bimekizumab 320 mg Q4W/ Placebo Escape

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Arm title	Bimekizumab 320 mg Q4W/Q8W Escape

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo, administered subcutaneously (sc) at pre-specified time points.

Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Arm title	Bimekizumab 320 mg Q4W/Q4W Escape

Arm description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	BKZ
Other name	UCB4940
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study participants received bimekizumab 320 mg administered sc at pre-specified time intervals.

Number of subjects in period 4[5]	Placebo Escape	Bimekizumab 320 mg Q4W Escape	Bimekizumab 320 mg Q4W/ Placebo Escape
Started	81	23	67
Completed	81	22	66
Not completed	0	1	1
Consent withdrawn by subject	-	-	1

Adverse event, non-fatal	-	1	-

Number of subjects in period 4[5]	Bimekizumab 320 mg Q4W/Q8W Escape	Bimekizumab 320 mg Q4W/Q4W Escape
Started	4	7
Completed	4	7
Not completed	0	0
Consent withdrawn by subject	-	-
Adverse event, non-fatal	-	-

Notes:

[5] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The Escape Treatment is not a subsequent period to the Randomized-Withdrawal period, but rather a separate period. It gives an overview of the participants who did not achieve a PASI90 response at Week 16 of the Initial Treatment Period and all participants who relapsed at Week 20 or later during the Randomized-Withdrawal Period (up to Week 56).

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.	
Reporting group title	Bimekizumab 320 mg Q4W
Reporting group description:	
Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.	

Reporting group values	Placebo	Bimekizumab 320 mg Q4W	Total
Number of subjects	86	349	435
Age Categorical Units: Participants			
<=18 years	2	1	3
Between 18 and 65 years	80	327	407
>=65 years	4	21	25
Age Continuous Units: years			
arithmetic mean	43.5	44.5	
standard deviation	± 13.1	± 12.9	-
Sex: Female, Male Units: Participants			
Female	28	94	122
Male	58	255	313

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Bimekizumab 320 mg Q4W

Reporting group description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Bimekizumab 320 mg Q4W

Reporting group description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Placebo/Placebo

Reporting group description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive placebo during the Randomized-Withdrawal Period.

Reporting group title	Bimekizumab 320 mg Q4W/Placebo

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period.

Reporting group title	Bimekizumab 320 mg Q4W/Q8W

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Reporting group title	Bimekizumab 320 mg Q4W/Q4W

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period.

Reporting group title	Placebo Escape

Reporting group description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Bimekizumab 320 mg Q4W Escape

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment

Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Bimekizumab 320 mg Q4W/ Placebo Escape

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Reporting group title	Bimekizumab 320 mg Q4W/Q8W Escape

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Reporting group title	Bimekizumab 320 mg Q4W/Q4W Escape

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks.

Subject analysis set title	Placebo (RS)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the Randomized Set (RS).

Subject analysis set title	Bimekizumab 320 mg Q4W (RS)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the RS.

Subject analysis set title	Placebo (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the Safety Set (SS).

Subject analysis set title	Bimekizumab 320 mg Q4W (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the SS.

Subject analysis set title	Placebo/Placebo (WK16ResS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive placebo during the Randomized-Withdrawal Period. Participants formed the Week 16 Responder Set (WK16ResS).

Subject analysis set title	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period. Participants formed the WK16ResS.

Subject analysis set title	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants formed the WK16ResS. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Subject analysis set title	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period. Participants formed the WK16ResS.

Subject analysis set title	Placebo Escape (ESS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the Escape Study Participant Set (ESS).

Subject analysis set title	Bimekizumab 320 mg Q4W Escape (ESS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS.

Subject analysis set title	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS.

Subject analysis set title	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Subject analysis set title	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS.

Subject analysis set title	Bimekizumab 320 mg Q4W/Q8W+Q4W/Q4W (WK16ResS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This arm consists of participants who were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period and those who were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants formed the

WK16ResS. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Primary: Percentage of participants with a Psoriasis Area and Severity Index 90 (PASI90) response at Week 16

End point title	Percentage of participants with a Psoriasis Area and Severity Index 90 (PASI90) response at Week 16

End point description:

A PASI90 responder was defined as a participant that achieved 90% reduction from Baseline in the PASI score. Body divided into 4 areas: head/arms/trunk to groin/legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear)-4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0-6 scale. Final PASI=average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The min possible PASI score is 0=no disease, the max score is 72=maximal disease. Study participants with missing score at Week 16 were counted as nonresponders (NRI). The Randomized Set (RS) consisted of all randomized study participants.

End point type	Primary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: percentage of participants				
number (not applicable)	1.2	90.8		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	496.318
Confidence interval	
level	95 %
sides	2-sided
lower limit	82.798
upper limit	2975.086

Notes:

[1] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Primary: Percentage of participants with an Investigator's Global Assessment (IGA) response at Week 16

End point title	Percentage of participants with an Investigator's Global Assessment (IGA) response at Week 16

End point description:

The Investigator's Global Assessment (IGA) measures the overall psoriasis severity following a 5-point scale (0-4), where scale 0= clear, no signs of psoriasis; presence of post-Inflammatory hyperpigmentation, scale 1= almost clear, no thickening; normal to pink coloration; no to minimal focal scaling, scale 2= mild thickening, pink to light red coloration and predominately fine scaling, 3= moderate, clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling and 4= severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. IGA response was defined as Clear or Almost Clear with at least a 2-category improvement relative to Baseline. Study participants with missing score at Week 16 were counted as nonresponders (NRI). The Randomized Set (RS) consisted of all randomized study participants.

End point type	Primary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: percentage of participants				
number (not applicable)	1.2	92.6		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	657.255
Confidence interval	
level	95 %
sides	2-sided
lower limit	105.792
upper limit	4083.333

Notes:

[2] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a PASI100 response at Week 16

End point title	Percentage of participants with a PASI100 response at Week 16

End point description:

A PASI100 responder was defined as a participant that achieved 100% reduction from Baseline in the PASI score. Body divided into 4 areas: head/arms/trunk to groin/legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear)-4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0-6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The min possible PASI score is 0=no disease, the max score is 72=maximal disease. Study participants with missing score at Week 16 were counted as nonresponders (NRI). The Randomized Set (RS) consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: percentage of participants				
number (not applicable)	1.2	68.2		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	220.038
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.757
upper limit	1683.639

Notes:

[3] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a IGA Clear response at Week 16

End point title	Percentage of participants with a IGA Clear response at Week 16

End point description:

The Investigator's Global Assessment (IGA) measures the overall psoriasis severity following a 5-point scale (0-4), where scale 0= clear, no signs of psoriasis; presence of post-inflammatory hyperpigmentation, scale 1= almost clear, no thickening; normal to pink coloration; no to minimal focal scaling, scale 2= mild thickening, pink to light red coloration and predominately fine scaling, 3= moderate, clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling and 4= severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. IGA response was defined as Clear with at least >= 2 category improvement relative to Baseline. Study participants with missing score at Week 16 were counted as nonresponders (NRI). The Randomized Set (RS) consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: percentage of participants				
number (not applicable)	1.2	69.6		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	224.744
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.13
upper limit	1676.425

Notes:

[4] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a PASI75 response at Week 4

End point title	Percentage of participants with a PASI75 response at Week 4

End point description:

A PASI75 responder was defined as a participant that achieved 75% reduction from Baseline in the PASI score. Body divided into 4 areas: head/arms/trunk to groin/legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear)-4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0-6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The min possible PASI score is 0=no disease, the max score is 72=maximal disease. Study participants with missing score at a given week were counted as nonresponders. The Randomized Set (RS) consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

At Week 4

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: percentage of participants				
number (not applicable)	1.2	75.9		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	316.641
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.423
upper limit	2543.254

Notes:

[5] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a Patient Symptom Diary response for pain at Week 16

End point title	Percentage of participants with a Patient Symptom Diary response for pain at Week 16

End point description:

As PRO measure, the PSD (further published as P-SIM) was used to assess key symptoms relevant to patients with moderate to severe plaque psoriasis. Site staff trained participants on the use of the electronic device used to collect ePRO diary data at Screening, device was then dispensed to the participant for home use until Week 16 Visit. The ePRO diary was completed on daily basis from Screening to Week 16 Visit.
PSD pain item was assessed daily on a numeric rating scale (NRS) from 0 (no pain) to 10 (very severe pain). PSD score for pain at a given visit was an average of daily values over the week prior to the visit. The response was defined as an improvement (decrease) in pain score higher than the prespecified 1.98 response threshold at Week 16. The endpoint was characterized as percentage of participants with PSD pain response.
The RS consisted of all randomized participants. Number of participants analyzed reflect those with Baseline score at or above 1.98 response threshold.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	67	255		
Units: percentage of participants				
number (not applicable)	9.0	78.8		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	322
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	34.325

Confidence interval	
level	95 %
sides	2-sided
lower limit	14.22
upper limit	82.856

Notes:

[6] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a Patient Symptom Diary response for itch at Week 16

End point title	Percentage of participants with a Patient Symptom Diary response for itch at Week 16

End point description:

A PRO measure, the PSD (further published as P-SIM) was used to assess key symptoms relevant to patients with moderate to severe plaque psoriasis. Site staff trained participants on the use of the electronic device used to collect ePRO diary data at Screening, device was then dispensed to participant for home use until Week 16 Visit. The ePRO diary was completed on daily basis from Screening to Week 16 Visit.
PSD itch item was assessed daily on a NRS from 0 (no itch) to 10 (very severe itch). PSD score for itch was an average of daily values over the week prior to the visit. The response was defined as an improvement (decrease) in itch score higher than the prespecified 2.39 response threshold at Week 16. The endpoint was characterized as percentage of participants with a PSD itch response.
The RS consisted of all randomized participants. Number of participants analyzed reflect those with a Baseline score at or above the 2.39 response threshold.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	72	278		
Units: percentage of participants				
number (not applicable)	5.6	75.5		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	43.497

Confidence interval	
level	95 %
sides	2-sided
lower limit	15.728
upper limit	120.295

Notes:

[7] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a Patient Symptom Diary response for scaling at Week 16

End point title	Percentage of participants with a Patient Symptom Diary response for scaling at Week 16

End point description:

As PRO measure, the PSD (further published as P-SIM) was used to assess key symptoms relevant to patients with moderate to severe plaque psoriasis. Site staff trained participants on the use of the electronic device used to collect ePRO diary data at Screening, device was then dispensed to the participant for home use until Week 16 Visit. The ePRO diary was completed on daily basis from Screening to Week 16 Visit. PSD scaling item was assessed daily on a NRS from 0 (no scaling) to 10 (very severe scaling). PSD score for scaling was an average of daily values over the week prior to the visit. The response was defined as an improvement (decrease) in scaling score higher than the prespecified 2.86 response threshold at Week 16. The endpoint was characterized as percentage of participants with a PSD scaling response.
The RS consisted of all randomized participants. Number of participants analyzed reflect those with a Baseline score at or above the 2.86 response threshold.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	70	286		
Units: percentage of participants				
number (not applicable)	5.7	78.0		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haensze (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	60.946

Confidence interval	
level	95 %
sides	2-sided
lower limit	20.56
upper limit	180.669

Notes:

[8] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with Scalp IGA Response (Clear or Almost Clear) at Week 16 for participants with scalp psoriasis (PSO) at Baseline

End point title	Percentage of participants with Scalp IGA Response (Clear or Almost Clear) at Week 16 for participants with scalp psoriasis (PSO) at Baseline

End point description:

Only participants with scalp involvement at Baseline completed the scalp IGA. Participants with scalp involvement at Baseline were defined as those with a scalp IGA score >0 at Baseline. Scalp lesions were assessed in terms of clinical signs of redness, thickness, and scaliness using a 5-point scale (0=Clear, 1=Almost Clear, 2=Mild, 3=Moderate, 4= Severe). Scalp IGA 0/1 response at Week 16 was defined as clear (0) or almost clear (1) with at least a 2-category improvement from Baseline to Week 16. The Randomized Set (RS) consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Placebo (RS)	Bimekizumab 320 mg Q4W (RS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	74	310		
Units: percentage of participants				
number (not applicable)	6.8	92.3		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables.

Comparison groups	Placebo (RS) v Bimekizumab 320 mg Q4W (RS)
Number of subjects included in analysis	384
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	158

Confidence interval	
level	95 %
sides	2-sided
lower limit	49.263
upper limit	506.745

Notes:

[9] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Percentage of participants with a PASI90 response at Week 56 among Week 16 PASI90 responders

End point title	Percentage of participants with a PASI90 response at Week 56 among Week 16 PASI90 responders

End point description:

A PASI90 responder was defined as a participant that achieved 90% reduction from Baseline in the PASI score. Study participants with missing score at Week 56 or who met the criterion for relapse were counted as nonresponders (NRI). The Week 16 Responder Set (WK16ResS) consisted of all study participants who achieved a PASI90 response at Week 16 and received at least 1 dose of IMP during Randomized-Withdrawal Period at Week 16 or later. The hypothesis test for PASI90 at Week 56, based on Wk16ResS, compared pooled BKZ regimens (BKZ 320mg Q4W/Q8W + 320mg Q4W/Q4W) versus placebo.

End point type	Secondary

End point timeframe:

At Week 56

End point values	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)	Bimekizumab 320 mg Q4W/Q8W+Q4W/Q4W (WK16ResS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	105	100	106	206
Units: percentage of participants				
number (not applicable)	16.2	91.0	86.8	88.8

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables. This statistical analysis is not controlled for multiplicity and is only nominal.

Comparison groups	Bimekizumab 320 mg Q4W/Placebo (WK16ResS) v Bimekizumab 320 mg Q4W/Q8W (WK16ResS)
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	45.192

Confidence interval	
level	95 %
sides	2-sided
lower limit	18.622
upper limit	109.672

Notes:

[10] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables. This statistical analysis is not controlled for multiplicity and is only nominal.

Comparison groups	Bimekizumab 320 mg Q4W/Placebo (WK16ResS) v Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [11]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	49.297
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.887
upper limit	128.673

Notes:

[11] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Odds ratio: Bimekizumab/Placebo calculated using stratified Cochran-Mantel-Haenszel (CMH) test with region and prior biologic exposure as stratification variables. This statistical analysis is not controlled for multiplicity and is only nominal.

Comparison groups	Bimekizumab 320 mg Q4W/Placebo (WK16ResS) v Bimekizumab 320 mg Q4W/Q8W+Q4W/Q4W (WK16ResS)
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [12]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	47.406
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.087
upper limit	101.75

Notes:

[12] - P-values for the comparison of treatment groups were based on the CMH test from the general association.

Secondary: Number of treatment-emergent adverse events (TEAEs) adjusted by duration of participant exposure to study treatment during the Initial Treatment Period

End point title	Number of treatment-emergent adverse events (TEAEs) adjusted by duration of participant exposure to study treatment during the Initial Treatment Period

End point description:

The number of TEAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the adverse event (AE) being considered. If a participant had no events, the total time at risk was used. The Safety Set (SS) consisted of all study participants who received at least 1 dose of the IMP.

End point type	Secondary

End point timeframe:

From Baseline to end of Initial Treatment Period (up to Week 16)

End point values	Placebo (SS)	Bimekizumab 320 mg Q4W (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	177.38 (123.55 to 246.69)	323.61 (281.60 to 370.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of serious adverse events (SAEs) adjusted by duration of participant exposure to study treatment during the Initial Treatment Period

End point title	Number of serious adverse events (SAEs) adjusted by duration of participant exposure to study treatment during the Initial Treatment Period

End point description:

The number of SAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. The Safety Set (SS) consisted of all study participants who received at least 1 dose of the IMP.

End point type	Secondary

End point timeframe:

From Baseline to end of Initial Treatment Period (up to Week 16)

End point values	Placebo (SS)	Bimekizumab 320 mg Q4W (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	7.66 (0.93 to 27.68)	5.59 (2.05 to 12.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of TEAEs leading to withdrawal adjusted by duration of participant exposure to study treatment during the Initial Treatment Period

End point title	Number of TEAEs leading to withdrawal adjusted by duration of participant exposure to study treatment during the Initial Treatment Period

End point description:

The number of TEAEs leading to discontinuation adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. The Safety Set (SS) consisted of all study participants who received at least 1 dose of the IMP. Here, '999' signifies that 95% CI could not be calculated for this outcome measure because number of TEAEs leading to withdrawal were 0.

End point type	Secondary

End point timeframe:

From Baseline to end of Initial Treatment Period (up to Week 16)

End point values	Placebo (SS)	Bimekizumab 320 mg Q4W (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	86	349		
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0 (-999 to 999)	2.78 (0.57 to 8.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of treatment-emergent adverse events (TEAEs) adjusted by duration of participant exposure to study treatment during the Randomized-Withdrawal Period

End point title	Number of treatment-emergent adverse events (TEAEs) adjusted by duration of participant exposure to study

	treatment during the Randomized-Withdrawal Period

End point description:

The number of TEAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the adverse event (AE) being considered. If a participant had no events, the total time at risk was used. The Week 16 Responder Set (WK16ResS) consisted of all study participants who achieved a PASI90 response at Week 16 and received at least 1 dose of the IMP during the Randomized-Withdrawal Period at Week 16 or later.

End point type	Secondary

End point timeframe:

From end of Initial Treatment Period (Week 16) until the Safety Follow-Up (up to 56 weeks duration)

End point values	Placebo/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	105	100	106
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	144.37 (3.66 to 804.36)	242.11 (189.44 to 304.90)	224.87 (177.46 to 281.05)	208.88 (165.11 to 260.69)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of serious adverse events (SAEs) adjusted by duration of participant exposure to study treatment during the Randomized-Withdrawal Period

End point title	Number of serious adverse events (SAEs) adjusted by duration of participant exposure to study treatment during the Randomized-Withdrawal Period

End point description:

The number of SAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. The Week 16 Responder Set (WK16ResS) consisted of all study participants who achieved a PASI90 response at Week 16 and received at least 1 dose of the IMP during the Randomized-Withdrawal Period at Week 16 or later. Here, '999' signifies that 95% CI could not be calculated for this outcome measure because number of serious adverse events were 0.

End point type	Secondary

End point timeframe:

From end of Initial Treatment Period (Week 16) until the Safety Follow-Up (up to 56 weeks duration)

End point values	Placebo/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	105	100	106
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0 (-999 to 999)	7.20 (1.96 to 18.43)	4.04 (0.83 to 11.80)	6.64 (2.16 to 15.50)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of TEAEs leading to withdrawal adjusted by duration of participant exposure to study treatment during the Randomized-Withdrawal Period

End point title	Number of TEAEs leading to withdrawal adjusted by duration of participant exposure to study treatment during the Randomized-Withdrawal Period

End point description:

The number of TEAEs leading to discontinuation adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. The Week 16 Responder Set (WK16ResS) consisted of all study participants who achieved a PASI90 response at Week 16 and received at least 1 dose of the IMP during the Randomized-Withdrawal Period at Week 16 or later. Here, '999' signifies that 95% CI could not be calculated for this outcome measure because number of TEAEs leading to withdrawal were 0.

End point type	Secondary

End point timeframe:

From end of Initial Treatment Period (Week 16) until the Safety Follow-Up (up to 56 weeks duration)

End point values	Placebo/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	105	100	106
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0 (-999 to 999)	5.33 (1.10 to 15.58)	2.69 (0.33 to 9.71)	0 (-999 to 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of treatment-emergent adverse events (TEAEs) adjusted by duration of participant exposure to study treatment during the Escape Treatment

End point title	Number of treatment-emergent adverse events (TEAEs) adjusted by duration of participant exposure to study treatment during the Escape Treatment

End point description:

The number of TEAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the adverse event (AE) being considered. If a participant had no events, the total time at risk was used. The Escape Study Participant Set (ESS) consisted of all study participants who received at least 1 dose of escape bimekizumab treatment either due to not achieving a PASI90 response at Week 16 or experiencing a relapse after entering the Randomized-Withdrawal Period.

End point type	Secondary

End point timeframe:

From Escape Baseline (Week 0) until Safety Follow-Up (up to 28 weeks duration)

End point values	Placebo Escape (ESS)	Bimekizumab 320 mg Q4W Escape (ESS)	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	81	23	67	4
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	235.86 (164.29 to 328.03)	287.19 (143.36 to 513.86)	180.89 (115.90 to 269.15)	491.37 (101.33 to 1435.98)

End point values	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	349.52 (95.23 to 894.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of serious adverse events (SAEs) adjusted by duration of participant exposure to study treatment during the Escape Treatment

End point title	Number of serious adverse events (SAEs) adjusted by duration of participant exposure to study treatment during the Escape Treatment

End point description:

The number of SAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no

events, the total time at risk was used. The ESS consisted of all study participants who received at least 1 dose of escape bimekizumab treatment either due to not achieving a PASI90 response at Week 16 or experiencing a relapse after entering the Randomized-Withdrawal Period. Here, '999' signifies that 95% CI could not be calculated for this outcome measure because number of serious adverse events were 0.

End point type	Secondary

End point timeframe:

From Escape Baseline (Week 0) until Safety Follow-Up (up to 28 weeks duration)

End point values	Placebo Escape (ESS)	Bimekizumab 320 mg Q4W Escape (ESS)	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	81	23	67	4
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	5.24 (0.13 to 29.22)	0 (-999 to 999)	0 (-999 to 999)	0 (-999 to 999)

End point values	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0 (-999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of TEAEs leading to withdrawal adjusted by duration of participant exposure to study treatment during the Escape Treatment

End point title	Number of TEAEs leading to withdrawal adjusted by duration of participant exposure to study treatment during the Escape Treatment

End point description:

The number of TEAEs leading to discontinuation adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. The ESS consisted of all study participants who received at least 1 dose of escape bimekizumab treatment either due to not achieving a PASI90 response at Week 16 or experiencing a relapse after entering the Randomized-Withdrawal Period. Here, '999' signifies that 95% CI could not be calculated for this outcome measure because number of TEAEs leading to withdrawal were 0.

End point type	Secondary

End point timeframe:

From Escape Baseline (Week 0) until Safety Follow-Up (up to 28 weeks duration)

End point values	Placebo Escape (ESS)	Bimekizumab 320 mg Q4W Escape (ESS)	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	81	23	67	4
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0 (-999 to 999)	18.77 (0.48 to 104.58)	0 (-999 to 999)	0 (-999 to 999)

End point values	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0 (-999 to 999)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from Baseline (Week 0) until Safety Follow-Up Visit (up to 80 weeks duration)

Adverse event reporting additional description:

Treatment-emergent AEs were defined as those AEs that had a start date on or following the first dose of study treatment through the final dose of study treatment + 140 days (covering the 20-week Safety Follow-Up Period).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Placebo/Placebo (WK16ResS)

Reporting group description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive placebo during the Randomized-Withdrawal Period. Participants formed the Week 16 Responder Set (WK16ResS).

Reporting group title	Bimekizumab 320 mg Q4W (SS)

Reporting group description:

Participants received bimekizumab 320 mg Q4W for 16 weeks. Participants who achieved a PASI90 response criteria were re-randomized to either receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W or placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the SS.

Reporting group title	Placebo (SS)

Reporting group description:

Participants received placebo for 16 weeks. Participants who achieved a Psoriasis Area Severity Index (PASI) 90 response criteria proceeded with placebo until Week 56. Participants who did not achieve a PASI90 response criteria at Week 16 or who relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the Safety Set (SS).

Reporting group title	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants formed the WK16ResS. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Reporting group title	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period. Participants formed the WK16ResS.

Reporting group title	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period. Participants formed the WK16ResS.

Reporting group title	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive placebo during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS.

Reporting group title	Placebo Escape (ESS)

Reporting group description:

Participants in this arm were randomized to placebo during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the Escape Study Participant Set (ESS).

Reporting group title	Bimekizumab 320 mg Q4W Escape (ESS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, did not achieve a PASI90 response at Week 16, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS.

Reporting group title	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and were re-randomized to receive bimekizumab 320 mg Q8W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS. Participants receiving 320 mg Q8W received placebo at pre-specified time points to maintain the blinding.

Reporting group title	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)

Reporting group description:

Participants in this arm were randomized to bimekizumab 320 mg Q4W during the Initial Treatment Period, achieved a PASI90 response at Week 16 and continued to receive bimekizumab 320 mg Q4W during the Randomized-Withdrawal Period. Participants relapsed at Week 20 or later, entered the escape arm and received open-label bimekizumab 320 mg Q4W for 12 weeks. Participants formed the ESS.

Serious adverse events	Placebo/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W (SS)	Placebo (SS)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	6 / 349 (1.72%)	2 / 86 (2.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian adenoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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
Prostate cancer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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			
Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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

Injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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 / 1 (0.00%)	0 / 349 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve prolapse			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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
Coronary artery disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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			
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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 detachment			

subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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			
Gastrointestinal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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
Diverticular perforation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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			
Psoriatic arthropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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			
Enterovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (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
Otitis media chronic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (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	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 100 (3.00%)	4 / 105 (3.81%)	5 / 106 (4.72%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian adenoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 100 (0.00%)	1 / 105 (0.95%)	0 / 106 (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
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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
Mitral valve prolapse			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 100 (1.00%)	0 / 105 (0.00%)	0 / 106 (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
Ischaemic cardiomyopathy			

subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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
Coronary artery disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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			
Syncope			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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 detachment			
subjects affected / exposed	0 / 100 (0.00%)	1 / 105 (0.95%)	0 / 106 (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
Cataract			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
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			
Gastrointestinal inflammation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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
Diverticular perforation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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
Diarrhoea			
subjects affected / exposed	2 / 100 (2.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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 hypertension			
subjects affected / exposed	0 / 100 (0.00%)	1 / 105 (0.95%)	0 / 106 (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
Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 105 (0.95%)	0 / 106 (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
Musculoskeletal and connective tissue disorders			
Psoriatic arthropathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Enterovirus infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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
Otitis media chronic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (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	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)	Placebo Escape (ESS)	Bimekizumab 320 mg Q4W Escape (ESS)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 67 (0.00%)	1 / 81 (1.23%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian adenoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Prostate cancer			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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			
Humerus fracture			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Mitral valve prolapse			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 81 (1.23%)	0 / 23 (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
Coronary artery disease			
subjects affected / exposed	0 / 67 (0.00%)	1 / 81 (1.23%)	0 / 23 (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
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 67 (0.00%)	1 / 81 (1.23%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Cataract			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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			

Gastrointestinal inflammation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Diverticular perforation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Diarrhoea			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	1 / 81 (1.23%)	0 / 23 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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 hypertension			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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			
Psoriatic arthropathy			

subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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			
Enterovirus infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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
Otitis media chronic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 67 (0.00%)	1 / 81 (1.23%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian adenoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (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			
Humerus fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (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	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve prolapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (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			
Psoriatic arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Enterovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (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	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (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	Placebo/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W (SS)	Placebo (SS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	66 / 349 (18.91%)	15 / 86 (17.44%)
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 349 (0.57%)	0 / 86 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	1 / 86 (1.16%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	4 / 86 (4.65%)
occurrences (all)	0	1	5
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	23 / 349 (6.59%)	4 / 86 (4.65%)
occurrences (all)	0	27	4
Oral candidiasis			

subjects affected / exposed	0 / 1 (0.00%)	21 / 349 (6.02%)	0 / 86 (0.00%)
occurrences (all)	0	23	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 1 (100.00%)	14 / 349 (4.01%)	7 / 86 (8.14%)
occurrences (all)	1	14	7
Tinea pedis			
subjects affected / exposed	0 / 1 (0.00%)	4 / 349 (1.15%)	0 / 86 (0.00%)
occurrences (all)	0	4	0
Impetigo			
subjects affected / exposed	0 / 1 (0.00%)	2 / 349 (0.57%)	1 / 86 (1.16%)
occurrences (all)	0	2	1
Body tinea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 349 (0.29%)	0 / 86 (0.00%)
occurrences (all)	0	1	0
Tinea capitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 349 (0.00%)	0 / 86 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Bimekizumab 320 mg Q4W/Q8W (WK16ResS)	Bimekizumab 320 mg Q4W/Placebo (WK16ResS)	Bimekizumab 320 mg Q4W/Q4W (WK16ResS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 100 (40.00%)	34 / 105 (32.38%)	34 / 106 (32.08%)
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			

subjects affected / exposed	0 / 100 (0.00%)	3 / 105 (2.86%)	1 / 106 (0.94%)
occurrences (all)	0	3	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 100 (0.00%)	3 / 105 (2.86%)	3 / 106 (2.83%)
occurrences (all)	0	4	4
Rash papular			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	23 / 100 (23.00%)	20 / 105 (19.05%)	11 / 106 (10.38%)
occurrences (all)	31	28	12
Oral candidiasis			
subjects affected / exposed	9 / 100 (9.00%)	6 / 105 (5.71%)	12 / 106 (11.32%)
occurrences (all)	18	6	20
Upper respiratory tract infection			
subjects affected / exposed	8 / 100 (8.00%)	5 / 105 (4.76%)	12 / 106 (11.32%)
occurrences (all)	9	6	17
Tinea pedis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	1 / 106 (0.94%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	0 / 100 (0.00%)	1 / 105 (0.95%)	1 / 106 (0.94%)
occurrences (all)	0	1	1
Body tinea			
subjects affected / exposed	1 / 100 (1.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences (all)	1	0	0
Tinea capitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 105 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Bimekizumab 320 mg Q4W/ Placebo Escape (ESS)	Placebo Escape (ESS)	Bimekizumab 320 mg Q4W Escape (ESS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 67 (16.42%)	8 / 81 (9.88%)	5 / 23 (21.74%)
Injury, poisoning and procedural complications			

Rib fracture			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 67 (2.99%)	1 / 81 (1.23%)	1 / 23 (4.35%)
occurrences (all)	2	1	1
Oral candidiasis			
subjects affected / exposed	7 / 67 (10.45%)	4 / 81 (4.94%)	1 / 23 (4.35%)
occurrences (all)	8	5	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 67 (2.99%)	3 / 81 (3.70%)	1 / 23 (4.35%)
occurrences (all)	2	3	1
Tinea pedis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Body tinea			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tinea capitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 81 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Bimekizumab 320 mg Q4W/Q8W Escape (ESS)	Bimekizumab 320 mg Q4W/Q4W Escape (ESS)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	4 / 7 (57.14%)	
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Tinea pedis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Impetigo			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Body tinea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Tinea capitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 April 2018	Protocol Amendment 2 (dated 06 Apr 2018) was implemented to incorporate the following key changes: • Updated name and contact information for Clinical Project Manager (CPM) • Extended the duration of the Screening Period, and therefore the overall study duration, by 1 week • Updated list of current treatment for psoriasis (PSO) to reflect changes in labeling and approved countries • Updated list of completed and ongoing bimekizumab studies to reflect completion of UP0042 • Clarified calculation of Psoriasis Area and Severity Index (PASI) response rates • Removed references to pharmacodynamic (PD) assessments as they were not conducted in this study • Updated Table 5-1 Schedule of study assessments to modify the visits at which the physical examination, tuberculosis (TB) questionnaire, body weight, electrocardiogram (ECG), and the Patient Symptom Diary (PSD) (daily) were assessed • Clarified that all visits from first dose through Week 24 would have a ±3 day visit window, while all visits from Week 28 through end of study would have a ±7 day window • Clarified the dosing window • Modified exclusion criterion to clarify exclusion of study participants who participated in other studies of bimekizumab, other medications (systemic or topical), or devices • Modified exclusion criteria pertaining to history of malignancy, systemic disease, and major depression • Added new withdrawal criteria for study participants with newly diagnosed inflammatory bowel disease (IBD) • Clarified withdrawal criteria for study participants with depression or suicidal ideation or behavior • Updated prohibited concomitant medications to include tildrakizumab and risankizumab • Corrected discrepancies between Section 8 Study procedures by visit and Table 5-1 Schedule of study assessments • Revised Psoriatic Arthritis Screening and Evaluation (PASE) questionnaire scoring • Clarified definition of abortion • Updated laboratory measurements to be performed
06 April 2018	Continuation of Protocol Amendment 2: • Provided additional details for requirements for investigational medicinal product (IMP) rechallenge in the event of potential drug-induced liver injury (PDILI) • Updated the definition of the Full Analysis Set (FAS) • Clarified regions for analyses In addition, minor spelling, editorial, and formatting changes were made, and the List of abbreviations was updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported