



Clinical trial results:

A Multicenter, Randomized, Double-Blind, Secukinumab-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2017-003784-35
Trial protocol	DE GB BE NL PL ES
Global end of trial date	09 August 2023

Results information

Result version number	v1 (current)
This version publication date	23 August 2024
First version publication date	23 August 2024

Trial information

Trial identification

Sponsor protocol code	PS0015
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03536884
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	11 September 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 September 2019
Global end of trial reached?	Yes
Global end of trial date	09 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Compare the efficacy of bimekizumab versus secukinumab at achieving complete clearance (PASI100) in subjects with moderate to severe chronic plaque psoriasis (PSO).

Protection of trial subjects:

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

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Bimekizumab is a humanized, full-length monoclonal antibody (mAb) of the immunoglobulin G1 subclass with 2 identical antigen binding regions that potently and selectively bind and neutralize IL-17A, IL-17F, and IL-17AF cytokines. This property makes bimekizumab distinct from other IL17-targeting agents, like secukinumab and ixekizumab (selective anti IL17A cytokine-targeting mAbs). Antibodies targeting IL-17A cytokines have demonstrated efficacy in patients with PSO, psoriatic arthritis (PsA), and ankylosing spondylitis. As shown in human in vitro immune mediated disease models, dual neutralization of both IL-17A and IL-17F like with bimekizumab was superior to neutralization of IL-17A alone (Glatt et al, 2018). In a Phase 3 study in patients with PSO, inhibition of both IL-17A and IL-17F with bimekizumab was shown to be therapeutically superior to inhibition of IL-17A alone (Reich et al, 2021). The primary objective of this study was to compare the efficacy of bimekizumab administered sc for 16 weeks versus secukinumab at achieving complete clearance (100% improvement in the PASI score [PASI100]) in study participants with moderate to severe chronic plaque PSO.

Actual start date of recruitment	13 June 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 99
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Poland: 255
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	Türkiye: 18
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	United States: 203
Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Canada: 88
Country: Number of subjects enrolled	France: 11

Worldwide total number of subjects	743
EEA total number of subjects	399

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	666
From 65 to 84 years	76
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in June 2018 and concluded in August 2023. Study has Screening Period (2-5 weeks (wk)), DB Treatment Period 48 wks (ITP-Wk 0-16 and MTP- Wk 16-Wk 48), an optional OLE Period (96 wks) followed by SFU Visit (20 wks after final dose) and an optional OLE2 Period followed by SFU2 Visit (20 wks after final dose).

Pre-assignment

Screening details:

Participant flow refers to the Randomized Set (RS), Maintenance Set (MS), Open-Label Set (OLS), and Open-Label Set 2 (OLS2).

Period 1

Period 1 title	Double-Blind (DB) Period: ITP Wk 0-16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	ITP: Bimekizumab (BKZ) 320 milligrams (mg) Q4W

Arm description:

Participants randomized to this arm received BKZ 320 mg subcutaneously (sc) every 4 weeks (Q4W) for 16 weeks in the Initial Treatment Period (ITP). Placebo was administered at pre-specified time-points to maintain the blinding.

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

Dosage and administration details:

Participants received placebo at pre-specified time-points to maintain the blinding.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	ITP: Secukinumab 300 mg Q4W
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Arm description:

Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 16 in the Initial Treatment Period.

Arm type	Active comparator
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	COSENTYX®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received secukinumab 300 mg at pre-specified time-points.

Number of subjects in period 1	ITP: Bimekizumab (BKZ) 320 milligrams (mg) Q4W	ITP: Secukinumab 300 mg Q4W
Started	373	370
Completed	362	354
Not completed	11	16
Unable to attend visits	-	1
Consent withdrawn by subject	3	4
Adverse event, non-fatal	8	6
Withdrawn by Investigator for abnormal lab values	-	1
Unblinding was reason for dropout	-	1
Lost to follow-up	-	3

Period 2

Period 2 title	Double-Blind Period: MTP Wk 16-48
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	MTP: BKZ 320 mg Q4W/Q8W

Arm description:

Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period. At Week 16, participants were re-randomized to receive bimekizumab 320 mg sc Q8W until Week 48 in the Maintenance Treatment Period (MTP). Placebo was administered at pre-specified time-points to maintain the blinding.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

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

Dosage and administration details:

Participants received placebo at pre-specified time-points to maintain the blinding.

Arm title	MTP: BKZ 320 mg Q4W/Q4W
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Arm description:

Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period. At Week 16, participants continued to receive BKZ 320 mg sc every 4 Weeks (Q4W/Q4W) until Week 48 in the Maintenance Treatment Period.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	MTP: Secukinumab 300 mg Q4W/Q4W
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Arm description:

Participants in secukinumab arm continued to receive secukinumab 300 mg sc Q4W until Week 48 in the Maintenance Treatment Period.

Arm type	Active comparator
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	
Other name	COSENTYX®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received secukinumab 300 mg at pre-specified time-points.

Number of subjects in period 2	MTP: BKZ 320 mg Q4W/Q8W	MTP: BKZ 320 mg Q4W/Q4W	MTP: Secukinumab 300 mg Q4W/Q4W
Started	215	147	354
Completed	205	138	325
Not completed	10	9	29
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	7	3	12
Adverse event, non-fatal	1	3	3
Lost to follow-up	1	2	9
Lack of efficacy	-	1	4

Period 3

Period 3 title	OLE Period: Wk48-Wk144
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	OLE Period: BKZ Week 0-48/BKZ Q8W 320 mg

Arm description:

Participants randomized to this arm received BKZ 320 mg sc Q4W for the first 16 weeks and then re-randomized to receive BKZ 320 mg sc Q4W or Q8W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response and the dose the participant was receiving at Week 48, participants were randomized to receive BKZ 320 mg sc Q8W until Week 136 in the Open-Label Extension (OLE) Period.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	OLE Period: BKZ Week 0-48/ BKZ Q4W 320 mg
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Arm description:

Participants randomized to this arm received BKZ 320 mg sc Q4W for the first 16 weeks and then re-randomized to receive BKZ 320 mg sc Q4W or Q8W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response and the dose the participant was receiving at Week 48, participants were randomized to receive BKZ 320 mg sc Q4W starting in OLE Period. The participant's dosing interval was changed from BKZ 320mg Q4W to BKZ 320mg Q8W at Week 64, or at the next scheduled clinic visit if the participant has already completed the Week 64 after protocol amendment 5.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	OLE Period: Secukinumab Week 0-48/ BKZ Q8W 320 mg
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Arm description:

Participants randomized to this arm received Secukinumab 300 mg sc Q4W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response in double-blind Treatment Period, participants randomized to receive BKZ 320 mg sc Q8W until Week 136 of the OLE Period.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	OLE Period: Secukinumab Week 0-48/ BKZ Q4W 320 mg
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Arm description:

Participants randomized to this arm received Secukinumab 300 mg sc Q4W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response in double-blind Treatment Period, participants randomized to receive BKZ 320 mg sc Q4W starting in OLE Period. The participant's dosing interval was changed from BKZ 320mg Q4W to BKZ 320mg Q8W at Week 64, or at the next scheduled clinic visit if the participant has already completed the Week 64 after protocol amendment 5.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Number of subjects in period 3 ^[1]	OLE Period: BKZ Week 0-48/BKZ Q8W 320 mg	OLE Period: BKZ Week 0-48/ BKZ Q4W 320 mg	OLE Period: Secukinumab Week 0-48/ BKZ Q8W 320 mg
	Started	238	98
Completed	205	80	106
Not completed	33	18	16
Consent withdrawn by subject	12	7	6
She wants to be pregnant	-	-	-
Adverse event, non-fatal	10	8	6
Not dosing for over 6 Months while out of country	1	-	-
Non-compliance	1	-	-
Went to jail, unable to continue study visits	-	1	-
Patient held IP due to pandemic, not restarted	-	1	-
Lost to follow-up	7	-	1
Lack of efficacy	1	1	1
Protocol deviation	1	-	2

Number of subjects in period 3 ^[1]	OLE Period: Secukinumab Week 0-48/ BKZ Q4W 320 mg
Started	196
Completed	167
Not completed	29

Consent withdrawn by subject	6
She wants to be pregnant	1
Adverse event, non-fatal	13
Not dosing for over 6 Months while out of country	-
Non-compliance	-
Went to jail, unable to continue study visits	-
Patient held IP due to pandemic, not restarted	-
Lost to follow-up	5
Lack of efficacy	4
Protocol deviation	-

Notes:

[1] - 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: Participants who provided consent to continue in OLE Period.

Period 4

Period 4 title	OLE2 Period: Wk 144/OLE2 BL- OLE2 Wk 48
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	OLE2 Period - Group A: BKZ 320 mg Q8W

Arm description:

Participants who were still receiving treatment in the OLE Period and attended the Week 144 visit were directly rolled over to the OLE2 Period. In OLE2 Period, participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	OLE2 Period - Group B: BKZ 320 mg Q8W
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Arm description:

Participants who completed the Week 144 and were participating in the Safety Follow-Up (SFU) or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score less than (<) 3 at the Week 144/OLE2 Baseline Visit continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48 in OLE2 Period.

Arm type	Experimental
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Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details:	
Participants received BKZ 320 mg at pre-specified time-points.	
Arm title	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W

Arm description:

Participants who completed the Week 144 visit and were participating in the SFU or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score greater than or equal to (\geq) 3 at the Week 144/OLE2 Baseline Visit received BKZ 320 mg sc Q4W for the first 16 weeks, and then switched to BKZ 320 mg sc Q8W for 24 weeks until OLE2 Week 48 in OLE2 Period.

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

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Number of subjects in period 4 ^[2]	OLE2 Period - Group A: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q8W	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W
	Started	9	66
Completed	6	61	52
Not completed	3	5	7
Adverse event, non-fatal	1	2	1
Subject had threatening behavior to site staff	-	-	1
Lost to follow-up	2	2	2
Site's business is closing on 30 september 2022	-	1	-
Site closure	-	-	3

Notes:

[2] - 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: Participants who provided consent to continue in OLE2 Period.

Baseline characteristics

Reporting groups

Reporting group title	ITP: Bimekizumab (BKZ) 320 milligrams (mg) Q4W
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Reporting group description:

Participants randomized to this arm received BKZ 320 mg subcutaneously (sc) every 4 weeks (Q4W) for 16 weeks in the Initial Treatment Period (ITP). Placebo was administered at pre-specified time-points to maintain the blinding.

Reporting group title	ITP: Secukinumab 300 mg Q4W
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Reporting group description:

Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 16 in the Initial Treatment Period.

Reporting group values	ITP: Bimekizumab (BKZ) 320 milligrams (mg) Q4W	ITP: Secukinumab 300 mg Q4W	Total
Number of subjects	373	370	743
Age Categorical Units: Participants			
<=18 years	3	7	10
Between 18 and 65 years	332	324	656
>=65 years	38	39	77
Age Continuous Units: years			
arithmetic mean	45.9	44.0	
standard deviation	± 14.2	± 14.7	-
Sex: Female, Male Units: Participants			
Female	122	135	257
Male	251	235	486

End points

End points reporting groups

Reporting group title	ITP: Bimekizumab (BKZ) 320 milligrams (mg) Q4W
Reporting group description: Participants randomized to this arm received BKZ 320 mg subcutaneously (sc) every 4 weeks (Q4W) for 16 weeks in the Initial Treatment Period (ITP). Placebo was administered at pre-specified time-points to maintain the blinding.	
Reporting group title	ITP: Secukinumab 300 mg Q4W
Reporting group description: Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 16 in the Initial Treatment Period.	
Reporting group title	MTP: BKZ 320 mg Q4W/Q8W
Reporting group description: Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period. At Week 16, participants were re-randomized to receive bimekizumab 320 mg sc Q8W until Week 48 in the Maintenance Treatment Period (MTP). Placebo was administered at pre-specified time-points to maintain the blinding.	
Reporting group title	MTP: BKZ 320 mg Q4W/Q4W
Reporting group description: Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period. At Week 16, participants continued to receive BKZ 320 mg sc every 4 Weeks (Q4W/Q4W) until Week 48 in the Maintenance Treatment Period.	
Reporting group title	MTP: Secukinumab 300 mg Q4W/Q4W
Reporting group description: Participants in secukinumab arm continued to receive secukinumab 300 mg sc Q4W until Week 48 in the Maintenance Treatment Period.	
Reporting group title	OLE Period: BKZ Week 0-48/BKZ Q8W 320 mg
Reporting group description: Participants randomized to this arm received BKZ 320 mg sc Q4W for the first 16 weeks and then re-randomized to receive BKZ 320 mg sc Q4W or Q8W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response and the dose the participant was receiving at Week 48, participants were randomized to receive BKZ 320 mg sc Q8W until Week 136 in the Open-Label Extension (OLE) Period.	
Reporting group title	OLE Period: BKZ Week 0-48/ BKZ Q4W 320 mg
Reporting group description: Participants randomized to this arm received BKZ 320 mg sc Q4W for the first 16 weeks and then re-randomized to receive BKZ 320 mg sc Q4W or Q8W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response and the dose the participant was receiving at Week 48, participants were randomized to receive BKZ 320 mg sc Q4W starting in OLE Period. The participant's dosing interval was changed from BKZ 320mg Q4W to BKZ 320mg Q8W at Week 64, or at the next scheduled clinic visit if the participant has already completed the Week 64 after protocol amendment 5.	
Reporting group title	OLE Period: Secukinumab Week 0-48/ BKZ Q8W 320 mg
Reporting group description: Participants randomized to this arm received Secukinumab 300 mg sc Q4W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response in double-blind Treatment Period, participants randomized to receive BKZ 320 mg sc Q8W until Week 136 of the OLE Period.	
Reporting group title	OLE Period: Secukinumab Week 0-48/ BKZ Q4W 320 mg
Reporting group description: Participants randomized to this arm received Secukinumab 300 mg sc Q4W until Week 48 of the double-blind Treatment Period. Based on the PASI90 response in double-blind Treatment Period, participants randomized to receive BKZ 320 mg sc Q4W starting in OLE Period. The participant's dosing interval was changed from BKZ 320mg Q4W to BKZ 320mg Q8W at Week 64, or at the next scheduled clinic visit if the participant has already completed the Week 64 after protocol amendment 5.	
Reporting group title	OLE2 Period - Group A: BKZ 320 mg Q8W
Reporting group description: Participants who were still receiving treatment in the OLE Period and attended the Week 144 visit were directly rolled over to the OLE2 Period. In OLE2 Period, participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48.	

Reporting group title	OLE2 Period - Group B: BKZ 320 mg Q8W
Reporting group description: Participants who completed the Week 144 and were participating in the Safety Follow-Up (SFU) or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score less than (<) 3 at the Week 144/OLE2 Baseline Visit continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48 in OLE2 Period.	
Reporting group title	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W
Reporting group description: Participants who completed the Week 144 visit and were participating in the SFU or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score greater than or equal to (>=) 3 at the Week 144/OLE2 Baseline Visit received BKZ 320 mg sc Q4W for the first 16 weeks, and then switched to BKZ 320 mg sc Q8W for 24 weeks until OLE2 Week 48 in OLE2 Period.	
Subject analysis set title	ITP: Bimekizumab (BKZ) 320 mg Q4W
Subject analysis set type	Full analysis
Subject analysis set description: Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period (ITP). Placebo was administered at pre-specified time-points to maintain the blinding.	
Subject analysis set title	ITP: Secukinumab 300 mg Q4W
Subject analysis set type	Full analysis
Subject analysis set description: Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 16 in the Initial Treatment Period.	
Subject analysis set title	ITP+MTP: BKZ Q4W/Q4W +BKZ Q4W/Q8W
Subject analysis set type	Full analysis
Subject analysis set description: Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the ITP. At Week 16, participants either continued to receive BKZ 320 mg sc every 4 Weeks (Q4W/Q4W) or re-randomized to receive BKZ 320 mg sc Q8W until Week 48 in the MTP. Placebo was administered at pre-specified time-points to maintain the blinding.	
Subject analysis set title	ITP+MTP: Secukinumab 300 mg Q4W/Q4W
Subject analysis set type	Full analysis
Subject analysis set description: Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 16 in the ITP. Participants continued to receive secukinumab 300 mg sc Q4W until Week 48 in the MTP.	
Subject analysis set title	MTP: BKZ 320 mg Q4W/Q8W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period. At Week 16, participants were re-randomized to receive BKZ 320 mg sc Q8W until Week 48 in the Maintenance Treatment Period (MTP). Placebo was administered at pre-specified time-points to maintain the blinding.	
Subject analysis set title	MTP: BKZ 320 mg Q4W/Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period. At Week 16, participants continued to receive BKZ 320 mg sc every 4 Weeks (Q4W/Q4W) until Week 48 in the Maintenance Treatment Period.	
Subject analysis set title	MTP: Secukinumab 300 mg Q4W/Q4W
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants in secukinumab arm continued to receive secukinumab 300 mg sc Q4W until Week 48 in the Maintenance Treatment Period.	
Subject analysis set title	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received at least one dose of BKZ 320 mg sc Q8W from Week 16 until Week 48.

Subject analysis set title	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who received at least one dose of BKZ 320 mg sc Q4W until Week 48.

Subject analysis set title	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 48.

Subject analysis set title	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received BKZ 320 mg sc Q8W from Week 48 until Week 136 during OLE Period. For participants that received both BKZ 320 mg Q4W and Q8W, events are counted in the dose group most recently received prior to the date of the event or assessment.

Subject analysis set title	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received BKZ 320 mg sc Q4W from Week 48 until Week 136 during OLE Period. The participant's dosing interval was changed from BKZ 320 mg Q4W to BKZ 320 mg Q8W at Week 64, or at the next scheduled clinic visit if the participant has already completed the Week 64.

Subject analysis set title	OLE2 Period - Group A: BKZ 320 mg Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who were still receiving treatment in the OLE Period and attended the Week 144 visit were directly rolled over to the OLE2 Period. In OLE2 Period, participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48.

Subject analysis set title	OLE2 Period - Group B: BKZ 320 mg Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who completed the Week 144 and were participating in the Safety Follow-Up (SFU) or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score less than (<) 3 at the Week 144/OLE2 Baseline Visit continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48 in OLE2 Period.

Subject analysis set title	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who completed the Week 144 visit and were participating in the SFU or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score greater than or equal to (>=) 3 at the Week 144/OLE2 Baseline Visit received BKZ 320 mg sc Q4W for the first 16 weeks, and then switched to BKZ 320 mg sc Q8W for 24 weeks until OLE2 Week 48 in OLE2 Period.

Primary: Percentage of Participants with a Psoriasis Area and Severity Index 100 (PASI100) Response at Week 16

End point title	Percentage of Participants with a Psoriasis Area and Severity Index 100 (PASI100) Response at Week 16
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End point description:

The PASI100 response assessments are based on 100% improvement in PASI score from Baseline. Body divided into 4 areas: head, arms, trunk to groin, and 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) to 4 (very marked). Determining the percentage of skin covered with PSO for each of body areas and converting to a 0 to 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 minimum possible PASI score is

0= no disease, the maximum score is 72= maximal disease. The Randomized Set (RS) consisted of all randomized study participants.

End point type	Primary
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End point timeframe:

Week 16

End point values	ITP: Bimekizumab (BKZ) 320 mg Q4W	ITP: Secukinumab 300 mg Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	373	370		
Units: percentage of participants				
number (not applicable)	61.7	48.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

Odds ratio calculated using stratified CMH test with region and prior biologic exposure as stratification variables.

Comparison groups	ITP: Bimekizumab (BKZ) 320 mg Q4W v ITP: Secukinumab 300 mg Q4W
Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.714
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.271
upper limit	2.31

Notes:

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

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

Risk Difference: BKZ-Secukinumab calculated using stratified Cochran-Mantel-Haenszel (CMH).

Comparison groups	ITP: Bimekizumab (BKZ) 320 mg Q4W v ITP: Secukinumab 300 mg Q4W
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Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
Parameter estimate	Risk difference (RD)
Point estimate	12.682
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.771
upper limit	19.592

Notes:

[2] - The evaluation of noninferiority is tested at a 1-sided alpha level of 0.025 and based on a 1-sided 97.5% CI and a noninferiority margin of 10%.

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:	
<p>The PASI75 response assessments are based on at least 75% improvement in PASI score from Baseline. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for redness, thickness, and scaling for each of the 4 body areas with score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of body areas and converting to 0 to 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 minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease. The Randomized Set (RS) consisted of all randomized study participants.</p>	
End point type	Secondary
End point timeframe:	
Week 4	

End point values	ITP: Bimekizumab (BKZ) 320 mg Q4W	ITP: Secukinumab 300 mg Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	373	370		
Units: percentage of participants				
number (not applicable)	71.0	47.3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Odds ratio calculated using stratified CMH test with region and prior biologic exposure as stratification variables.	
Comparison groups	ITP: Bimekizumab (BKZ) 320 mg Q4W v ITP: Secukinumab 300 mg Q4W

Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.817
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.068
upper limit	3.836

Notes:

[3] - P-values for the comparison of treatment groups are based on the CMH test from the general association. P-values are not controlled for multiplicity and should only be considered descriptively.

Secondary: Percentage of Participants with a PASI90 Response at Week 16

End point title	Percentage of Participants with a PASI90 Response at Week 16
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End point description:

The PASI90 response assessments are based on at least 90% improvement in PASI score from Baseline. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for redness, thickness, and scaling for each of the 4 body areas with score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 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 respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease. The Randomized Set (RS) consisted of all randomized study participants.

End point type	Secondary
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End point timeframe:

Week 16

End point values	ITP: Bimekizumab (BKZ) 320 mg Q4W	ITP: Secukinumab 300 mg Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	373	370		
Units: percentage of participants				
number (not applicable)	85.5	74.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a PASI100 Response at Week 48

End point title	Percentage of Participants with a PASI100 Response at Week 48
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End point description:

PASI100 response assessments are based on 100% improvement in PASI score from Baseline. Body

divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very marked). Determining percentage of skin covered with PSO for each of body areas and converting to a 0 to 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 minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease. The RS consisted of all randomized study participants. The MS consisted of all study participants that received at least 1 dose of IMP at Week 16 or later in the Double-Blind Treatment Period (including the Week 16 dose).

End point type	Secondary
End point timeframe:	
Week 48	

End point values	ITP+MTP: BKZ Q4W/Q4W +BKZ Q4W/Q8W	ITP+MTP: Secukinumab 300 mg Q4W/Q4W	MTP: BKZ 320 mg Q4W/Q8W	MTP: BKZ 320 mg Q4W/Q4W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	373	370	215	147
Units: percentage of participants				
number (not applicable)	67.3	46.2	66.5	73.5

End point values	MTP: Secukinumab 300 mg Q4W/Q4W			
Subject group type	Subject analysis set			
Number of subjects analysed	354			
Units: percentage of participants				
number (not applicable)	48.3			

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Odds ratio calculated using stratified CMH test with region and prior biologic exposure as stratification variables.	
Comparison groups	ITP+MTP: BKZ Q4W/Q4W +BKZ Q4W/Q8W v ITP+MTP: Secukinumab 300 mg Q4W/Q4W
Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.49

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.835
upper limit	3.377

Notes:

[4] - P-values for the comparison of treatment groups are based on the CMH test from the general association. P-values are not controlled for multiplicity and should only be considered descriptively.

Statistical analysis title	Statistical Analysis 3
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Statistical analysis description:

Odds ratio calculated using stratified CMH test with region and prior biologic exposure as stratification variables.

Comparison groups	MTP: BKZ 320 mg Q4W/Q4W v MTP: Secukinumab 300 mg Q4W/Q4W
Number of subjects included in analysis	501
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.243
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.103
upper limit	5

Notes:

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

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

Odds ratio calculated using stratified CMH test with region and prior biologic exposure as stratification variables.

Comparison groups	MTP: BKZ 320 mg Q4W/Q8W v MTP: Secukinumab 300 mg Q4W/Q4W
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.168
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.511
upper limit	3.11

Notes:

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

Secondary: Percentage of Participants with a Investigator ´s Global Assessment

(IGA) Response (0/1) at Week 16

End point title	Percentage of Participants with a Investigator 's Global Assessment (IGA) Response (0/1) at Week 16
End point description: The 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 (0) or Almost Clear (1) with at least a two-category improvement from Baseline at Week 16. The Randomized Set (RS) consisted of all randomized study participants.	
End point type	Secondary
End point timeframe: Week 16	

End point values	ITP: Bimekizumab (BKZ) 320 mg Q4W	ITP: Secukinumab 300 mg Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	373	370		
Units: percentage of participants				
number (not applicable)	85.5	78.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treatment-emergent Adverse Events (TEAEs) Adjusted by Duration of Participant Exposure to Investigational Medicinal Product (IMP) from Baseline up to Week 225

End point title	Number of Treatment-emergent Adverse Events (TEAEs) Adjusted by Duration of Participant Exposure to Investigational Medicinal Product (IMP) from Baseline up to Week 225
End point description: The number of TEAEs adjusted by duration of exposure to study treatment was scaled such that provided 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 that received at least 1 dose of IMP. The Open-Label Set (OLS) consisted of all study participants who received at least 1 dose of BKZ at Week 48 or later in the OLE Period (including the Week 48 dose). The Open-Label Set 2 (OLS2) consisted of all study participants who received at least 1 dose of BKZ at the Week 144/OLE2 Baseline Visit or later in the OLE2 Period (including the Week 144/OLE2 Baseline dose).	
End point type	Secondary
End point timeframe: From Baseline up to Week 225	

End point values	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	215	373	370	626
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	250.13 (213.09 to 291.75)	331.26 (293.40 to 372.66)	234.88 (209.22 to 262.83)	115.35 (105.27 to 126.14)

End point values	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)	OLE2 Period - Group A: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q4W/Q8W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	294	9	66	59
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	165.22 (143.73 to 189.02)	164.95 (66.32 to 339.86)	74.25 (51.72 to 103.26)	94.18 (65.97 to 130.39)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Serious Adverse Events (SAEs) Adjusted by Duration of Participant Exposure to IMP from Baseline up to Week 225

End point title	Number of Serious Adverse Events (SAEs) Adjusted by Duration of Participant Exposure to IMP from Baseline up to Week 225
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End point description:

The number of SAEs adjusted by duration of exposure to study treatment was scaled such that it provided 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 SS consisted of all study participants that received at least 1 dose of IMP. The OLS consisted of all study participants who received at least 1 dose of BKZ at Week 48 or later in the OLE Period (including the Week 48 dose). The OLS2 consisted of all study participants who received at least 1 dose of BKZ at the Week 144/OLE2 Baseline Visit or later in the OLE2 Period (including the Week 144/OLE2 Baseline dose).

End point type	Secondary
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End point timeframe:

From Baseline up to Week 225

End point values	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	215	373	370	626
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	6.94 (3.17 to 13.17)	7.33 (4.10 to 12.09)	6.75 (4.23 to 10.22)	5.93 (4.48 to 7.70)

End point values	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)	OLE2 Period - Group A: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q4W/Q8W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	294	9	66	59
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	4.34 (2.16 to 7.76)	12.28 (0.31 to 68.43)	1.38 (0.03 to 7.66)	6.39 (1.74 to 16.37)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of TEAEs Leading to Withdrawal Adjusted by Duration of Participant Exposure to IMP from Baseline up to Week 225

End point title	Number of TEAEs Leading to Withdrawal Adjusted by Duration of Participant Exposure to IMP from Baseline up to Week 225
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End point description:

The number of TEAEs leading to discontinuation adjusted by duration of exposure to study treatment was scaled such that it provided 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 SS consisted of all study participants that received at least 1 dose of IMP. The OLS consisted of all study participants who received at least 1 dose of BKZ at Week 48 or later in the OLE Period (including the Week 48 dose). The OLS2 consisted of all study participants who received at least 1 dose of BKZ at the Week 144/OLE2 Baseline Visit or later in the OLE2 Period (including the Week 144/OLE2 Baseline dose).

End point type	Secondary
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End point timeframe:

From Baseline up to Week 225

End point values	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	215	373	370	626
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	1.51 (0.18 to 5.45)	5.85 (3.02 to 10.22)	3.33 (1.66 to 5.96)	2.56 (1.65 to 3.77)

End point values	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)	OLE2 Period - Group A: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q4W/Q8W
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	294	9	66	59
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	3.52 (1.61 to 6.69)	11.33 (0.29 to 63.10)	2.76 (0.33 to 9.99)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline up to 165 weeks for each study participant not entering the OLE2 Period and up to 225 weeks for participants entering OLE2 Period

Adverse event reporting additional description:

TEAEs were defined as those AEs that have a start date on or following the first dose of study treatment through final dose of study treatment + 140 days (covering 20-week SFU period). For participants that switched from BKZ 320 mg Q4W to Q8W, events prior to switch are counted in Q4W group and events after switch are counted in Q8W group.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)
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Reporting group description:

Participants who received at least one dose of BKZ 320 mg sc Q8W from Week 16 until Week 48.

Reporting group title	ITP: Secukinumab 300 mg Q4W (up to Week 16)
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Reporting group description:

Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 16 in the Initial Treatment Period.

Reporting group title	ITP: BKZ 320 mg Q4W (up to Week 16)
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Reporting group description:

Participants randomized to this arm received BKZ 320 mg sc Q4W for 16 weeks in the Initial Treatment Period (ITP). Placebo was administered at pre-specified time-points to maintain the blinding.

Reporting group title	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)
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Reporting group description:

Participants received BKZ 320 mg sc Q4W from Week 48 until Week 136 during OLE Period. The participant's dosing interval was changed from BKZ 320 mg Q4W to BKZ 320 mg Q8W at Week 64, or at the next scheduled clinic visit if the participant has already completed the Week 64.

Reporting group title	OLE2 Period - Group A: BKZ 320 mg Q8W
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Reporting group description:

Participants who were still receiving treatment in the OLE Period and attended the Week 144 visit were directly rolled over to the OLE2 Period. In OLE2 Period, participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48. Due to small number of participants, each event met the 5% threshold frequency criteria.

Reporting group title	OLE2 Period - Group B: BKZ 320 mg Q8W
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Reporting group description:

Participants who completed the Week 144 and were participating in the Safety Follow-Up (SFU) or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score less than (<) 3 at the Week 144/OLE2 Baseline Visit continued receiving BKZ 320 mg sc Q8W for 40 additional weeks until OLE2 Week 48 in OLE2 Period.

Reporting group title	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)
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Reporting group description:

Participants received BKZ 320 mg sc Q8W from Week 48 until Week 136 during OLE Period. For participants that received both BKZ 320 mg Q4W and Q8W, events are counted in the dose group most recently received prior to the date of the event or assessment.

Reporting group title	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W
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Reporting group description:

Participants who completed the Week 144 visit and were participating in the SFU or had completed the SFU visit reinitiated their treatment in the OLE2 Period after having undergone Screening assessments during a 4-week OLE2 Screening Period. Participants with an IGA score greater than or equal to (>=) 3 at the Week 144/OLE2 Baseline Visit received BKZ 320 mg sc Q4W for the first 16 weeks, and then

switched to BKZ 320 mg sc Q8W for 24 weeks until OLE2 Week 48 in OLE2 Period.

Reporting group title	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)
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Reporting group description:

Participants who received at least one dose of BKZ 320 mg sc Q4W until Week 48.

Reporting group title	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)
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Reporting group description:

Participants received secukinumab 300 mg sc at Baseline and Weeks 1, 2, 3, and 4 followed by dosing Q4W until Week 48.

Serious adverse events	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)	ITP: Secukinumab 300 mg Q4W (up to Week 16)	ITP: BKZ 320 mg Q4W (up to Week 16)
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 215 (4.19%)	6 / 370 (1.62%)	10 / 373 (2.68%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Renal cell carcinoma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Angiofibroma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Bladder cancer stage III			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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

Hodgkin's disease nodular sclerosis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Lentigo maligna			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Parathyroid tumour benign			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Metastases to liver			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Metastatic neoplasm			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Thromboangiitis obliterans			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Surgical and medical procedures			

Abortion induced subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pregnancy on oral contraceptive subjects affected / exposed	0 / 215 (0.00%)	1 / 370 (0.27%)	0 / 373 (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
Pregnancy on contraceptive subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Reproductive system and breast disorders			
Uterine polyp subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Idiopathic pulmonary fibrosis subjects affected / exposed	0 / 215 (0.00%)	1 / 370 (0.27%)	0 / 373 (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
Pleurisy			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Asphyxia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Aspiration			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Pulmonary embolism			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Pneumothorax			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 failure			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Laceration			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Meniscus injury			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Multiple fractures			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Pneumothorax traumatic			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Rib fracture			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Spinal fracture			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 abrasion			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Ankle fracture			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Coronary artery disease			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Atrial fibrillation			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 failure congestive			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 coronary syndrome			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Myocardial infarction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Pericardial effusion			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Atrial flutter			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 arrest			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Transient ischaemic attack			
subjects affected / exposed	0 / 215 (0.00%)	1 / 370 (0.27%)	0 / 373 (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
IIIrd nerve paralysis			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Cerebrovascular accident			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Cerebral infarction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Seizure			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Ear and labyrinth disorders			
Otosclerosis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Inguinal hernia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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

Pancreatitis acute			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Diverticulum oesophageal			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Abdominal pain			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Pancreatic fistula			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Ileus			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Dysphagia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Hiatus hernia			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Bile duct stone			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Cholecystitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Cholecystitis acute			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Hepatic pain			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Psoriasis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Eczema			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Erythrodermic psoriasis			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Nephrolithiasis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 kidney injury			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Obstructive nephropathy			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Endocrine disorders			
Endocrine disorder			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Arthralgia			
subjects affected / exposed	0 / 215 (0.00%)	1 / 370 (0.27%)	0 / 373 (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
Osteoarthritis			
subjects affected / exposed	0 / 215 (0.00%)	1 / 370 (0.27%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral disc protrusion			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Intervertebral disc disorder			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Chondropathy			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Osteonecrosis of jaw			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Atypical pneumonia			
subjects affected / exposed	0 / 215 (0.00%)	1 / 370 (0.27%)	0 / 373 (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
Dengue fever			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Peritoneal abscess			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Gastroenteritis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Appendicitis			
subjects affected / exposed	2 / 215 (0.93%)	0 / 370 (0.00%)	0 / 373 (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
Localised infection			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Tooth abscess			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Respiratory tract infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Soft tissue infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Latent tuberculosis			
subjects affected / exposed	1 / 215 (0.47%)	0 / 370 (0.00%)	0 / 373 (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
Pyelonephritis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Anal abscess			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Rectal abscess			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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 externa			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Postoperative abscess			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Candida sepsis			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Tonsillitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Erysipelas			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Staphylococcal skin infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Urinary tract infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Staphylococcal infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Corona virus infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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			
Diabetic ketoacidosis			

subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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
Dehydration			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (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	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)	OLE2 Period - Group A: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 294 (3.74%)	1 / 9 (11.11%)	1 / 66 (1.52%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Renal cell carcinoma			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Angiofibroma			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Bladder cancer stage III			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Hodgkin's disease nodular sclerosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Lentigo maligna			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Parathyroid tumour benign			
subjects affected / exposed	0 / 294 (0.00%)	1 / 9 (11.11%)	0 / 66 (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
Metastases to liver			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Metastatic neoplasm			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Thromboangiitis obliterans			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pregnancy on oral contraceptive			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy on contraceptive			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Reproductive system and breast disorders			
Uterine polyp			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Endometriosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Idiopathic pulmonary fibrosis			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pleurisy			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Asphyxia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Aspiration			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pulmonary embolism			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pneumothorax			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 failure			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			

Road traffic accident			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Laceration			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Joint dislocation			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Meniscus injury			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Multiple fractures			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pneumothorax traumatic			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Rib fracture			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Spinal fracture			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 abrasion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Ankle fracture			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Coronary artery disease			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Atrial fibrillation			
subjects affected / exposed	2 / 294 (0.68%)	0 / 9 (0.00%)	0 / 66 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Arteriosclerosis coronary artery			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 failure congestive			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 coronary syndrome			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Myocardial infarction			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pericardial effusion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Atrial flutter			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 arrest			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Transient ischaemic attack			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
IIIrd nerve paralysis			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Cerebral infarction			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Seizure			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Ear and labyrinth disorders			
Otosclerosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Inguinal hernia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Colitis ulcerative			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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

Pancreatitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pancreatitis acute			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Diverticulum oesophageal			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Abdominal pain			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pancreatic fistula			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Ileus			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Dysphagia			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Hiatus hernia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Bile duct stone			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Cholecystitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Cholecystitis acute			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Hepatic pain			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Dermal cyst			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Eczema			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Erythrodermic psoriasis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Nephrolithiasis			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Acute kidney injury			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Obstructive nephropathy			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Endocrine disorder			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Arthralgia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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

Osteoarthritis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Intervertebral disc disorder			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Chondropathy			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Osteonecrosis of jaw			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Atypical pneumonia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Dengue fever			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Extradural abscess			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Peritoneal abscess			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Gastroenteritis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Appendicitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Localised infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Tooth abscess			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Soft tissue infection			

subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Urosepsis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Latent tuberculosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Pyelonephritis			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Rectal abscess			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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 externa			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Postoperative abscess			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Candida sepsis			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 294 (0.34%)	0 / 9 (0.00%)	0 / 66 (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
Tonsillitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Erysipelas			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Staphylococcal skin infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Urinary tract infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Staphylococcal infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Corona virus infection			

subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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
Dehydration			
subjects affected / exposed	0 / 294 (0.00%)	0 / 9 (0.00%)	0 / 66 (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	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)
Total subjects affected by serious adverse events			
subjects affected / exposed	56 / 626 (8.95%)	4 / 59 (6.78%)	15 / 373 (4.02%)
number of deaths (all causes)	3	1	0
number of deaths resulting from adverse events	3	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	2 / 626 (0.32%)	0 / 59 (0.00%)	0 / 373 (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
Renal cell carcinoma			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiofibroma			

subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Bladder cancer stage III			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Hodgkin's disease nodular sclerosis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Lentigo maligna			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Uterine leiomyoma			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Parathyroid tumour benign			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Metastases to liver			
subjects affected / exposed	0 / 626 (0.00%)	1 / 59 (1.69%)	0 / 373 (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
Metastatic neoplasm			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			

subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Thromboangiitis obliterans			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Pregnancy, puerperium and perinatal conditions			
Pregnancy on oral contraceptive			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy on contraceptive			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Reproductive system and breast disorders			
Uterine polyp			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			

subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Respiratory, thoracic and mediastinal disorders			
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Pleurisy			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Aspiration			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Pulmonary embolism			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Pneumothorax			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Respiratory failure			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Psychiatric disorders			

Suicide attempt			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Laceration			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Meniscus injury			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Multiple fractures			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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

Pneumothorax traumatic			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Rib fracture			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Spinal fracture			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Skin abrasion			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Ankle fracture			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Atrial fibrillation			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	2 / 626 (0.32%)	0 / 59 (0.00%)	0 / 373 (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
Acute coronary syndrome			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Myocardial infarction			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Pericardial effusion			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Atrial flutter			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Transient ischaemic attack			

subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
IIIrd nerve paralysis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Cerebral infarction			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Seizure			
subjects affected / exposed	0 / 626 (0.00%)	1 / 59 (1.69%)	0 / 373 (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
Ear and labyrinth disorders			
Otosclerosis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ulcerative			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Pancreatitis acute			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Diverticulum oesophageal			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Pancreatic fistula			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Ileus			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Haemorrhoidal haemorrhage			

subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Dysphagia			
subjects affected / exposed	0 / 626 (0.00%)	1 / 59 (1.69%)	0 / 373 (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
Hiatus hernia			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Cholecystitis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Cholecystitis acute			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Hepatic pain			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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			
Psoriasis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			

subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Eczema			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythrodermic psoriasis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	2 / 626 (0.32%)	0 / 59 (0.00%)	0 / 373 (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
Acute kidney injury			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Obstructive nephropathy			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Endocrine disorders			
Endocrine disorder			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Osteoarthritis			
subjects affected / exposed	4 / 626 (0.64%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Intervertebral disc disorder			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Chondropathy			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Osteonecrosis of jaw			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Rotator cuff syndrome			
subjects affected / exposed	2 / 626 (0.32%)	0 / 59 (0.00%)	0 / 373 (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
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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

Dengue fever			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Peritoneal abscess			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Gastroenteritis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Appendicitis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Localised infection			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Tooth abscess			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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	1 / 626 (0.16%)	1 / 59 (1.69%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Latent tuberculosis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Pyelonephritis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Rectal abscess			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Otitis externa			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Postoperative abscess			

subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Candida sepsis			
subjects affected / exposed	0 / 626 (0.00%)	0 / 59 (0.00%)	0 / 373 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Erysipelas			
subjects affected / exposed	2 / 626 (0.32%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Staphylococcal infection			

subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Corona virus infection			
subjects affected / exposed	5 / 626 (0.80%)	1 / 59 (1.69%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (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
Dehydration			
subjects affected / exposed	1 / 626 (0.16%)	0 / 59 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)		
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 370 (5.95%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	2		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angiofibroma			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer stage III			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease nodular sclerosis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lentigo maligna			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid tumour benign			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to liver			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic neoplasm			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thromboangiitis obliterans			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Pregnancy on oral contraceptive			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy on contraceptive			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Uterine polyp			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometriosis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleurisy			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asphyxia			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aspiration			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary embolism			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Multiple fractures			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal fracture			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin abrasion			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	2 / 370 (0.54%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			

subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute coronary syndrome			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
IIIrd nerve paralysis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Otosclerosis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders				
Inguinal hernia				
subjects affected / exposed	0 / 370 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
subjects affected / exposed	0 / 370 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	1 / 370 (0.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	1 / 370 (0.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulum oesophageal				
subjects affected / exposed	0 / 370 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 370 (0.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic fistula				
subjects affected / exposed	1 / 370 (0.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 370 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysphagia			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic pain			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

Psoriasis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermal cyst			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eczema			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erythrodermic psoriasis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructive nephropathy			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			

Endocrine disorder			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chondropathy			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis of jaw			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extradural abscess			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritoneal abscess			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			

subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue infection			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 370 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Latent tuberculosis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis externa			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative abscess			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Candida sepsis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal skin infection			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			

subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Corona virus infection			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 370 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	MTP: BKZ 320 mg Q8W (Week 16 to Week 48)	ITP: Secukinumab 300 mg Q4W (up to Week 16)	ITP: BKZ 320 mg Q4W (up to Week 16)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	87 / 215 (40.47%)	88 / 370 (23.78%)	107 / 373 (28.69%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 215 (0.47%)	1 / 370 (0.27%)	2 / 373 (0.54%)
occurrences (all)	1	5	2
Investigations			
White blood cell count increased			
subjects affected / exposed	0 / 215 (0.00%)	0 / 370 (0.00%)	0 / 373 (0.00%)
occurrences (all)	0	0	0

Psychiatric evaluation abnormal subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	0 / 370 (0.00%) 0	0 / 373 (0.00%) 0
Blood pressure increased subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	1 / 370 (0.27%) 1	5 / 373 (1.34%) 5
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 370 (0.27%) 1	2 / 373 (0.54%) 2
Fall subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 370 (0.27%) 1	3 / 373 (0.80%) 3
Nervous system disorders			
Paraesthesia subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	1 / 370 (0.27%) 1	1 / 373 (0.27%) 1
Blood and lymphatic system disorders			
Macrocytosis subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 370 (0.00%) 0	0 / 373 (0.00%) 0
Polycythaemia subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 370 (0.00%) 0	0 / 373 (0.00%) 0
General disorders and administration site conditions			
Malaise subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 370 (0.27%) 1	0 / 373 (0.00%) 0
Reproductive system and breast disorders			
Prostatomegaly subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 370 (0.27%) 1	0 / 373 (0.00%) 0
Hepatobiliary disorders			
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 370 (0.00%) 0	0 / 373 (0.00%) 0

Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	1 / 370 (0.27%) 1	0 / 373 (0.00%) 0
Skin and subcutaneous tissue disorders Intertrigo subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1 1 / 215 (0.47%) 1	2 / 370 (0.54%) 2 2 / 370 (0.54%) 3	1 / 373 (0.27%) 1 4 / 373 (1.07%) 4
Infections and infestations Corona virus infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0 33 / 215 (15.35%) 40 36 / 215 (16.74%) 47 21 / 215 (9.77%) 25 10 / 215 (4.65%) 14	0 / 370 (0.00%) 0 54 / 370 (14.59%) 61 4 / 370 (1.08%) 4 17 / 370 (4.59%) 17 7 / 370 (1.89%) 8	0 / 373 (0.00%) 0 47 / 373 (12.60%) 54 39 / 373 (10.46%) 41 16 / 373 (4.29%) 16 6 / 373 (1.61%) 7

Non-serious adverse events	OLE Period: BKZ 320 mg Q4W (Week 48 to Week 144)	OLE2 Period - Group A: BKZ 320 mg Q8W	OLE2 Period - Group B: BKZ 320 mg Q8W
Total subjects affected by non-serious adverse events subjects affected / exposed	103 / 294 (35.03%)	7 / 9 (77.78%)	18 / 66 (27.27%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Basal cell carcinoma subjects affected / exposed occurrences (all)	1 / 294 (0.34%) 2	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Investigations			

White blood cell count increased subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Psychiatric evaluation abnormal subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 2	0 / 66 (0.00%) 0
Blood pressure increased subjects affected / exposed occurrences (all)	2 / 294 (0.68%) 2	1 / 9 (11.11%) 1	1 / 66 (1.52%) 1
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	1 / 66 (1.52%) 1
Fall subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	1 / 66 (1.52%) 1
Nervous system disorders			
Paraesthesia subjects affected / exposed occurrences (all)	1 / 294 (0.34%) 2	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Blood and lymphatic system disorders			
Macrocytosis subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Polycythaemia subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
General disorders and administration site conditions			
Malaise subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Reproductive system and breast disorders			
Prostatomegaly subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Hepatobiliary disorders			

Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	1 / 9 (11.11%) 1	0 / 66 (0.00%) 0
Skin and subcutaneous tissue disorders Intertrigo subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	1 / 294 (0.34%) 1 5 / 294 (1.70%) 7	1 / 9 (11.11%) 1 0 / 9 (0.00%) 0	1 / 66 (1.52%) 1 1 / 66 (1.52%) 2
Infections and infestations Corona virus infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	9 / 294 (3.06%) 9 34 / 294 (11.56%) 41 39 / 294 (13.27%) 51 13 / 294 (4.42%) 13 19 / 294 (6.46%) 25	2 / 9 (22.22%) 2 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 1 / 9 (11.11%) 1	7 / 66 (10.61%) 7 3 / 66 (4.55%) 3 4 / 66 (6.06%) 4 0 / 66 (0.00%) 0 1 / 66 (1.52%) 1

Non-serious adverse events	OLE Period: BKZ 320 mg Q8W (Week 48 to Week 144)	OLE2 Period -Group B: BKZ 320 mg Q4W/Q8W	ITP+MTP: BKZ 320 mg Q4W (up to Week 48)
Total subjects affected by non-serious adverse events subjects affected / exposed	233 / 626 (37.22%)	19 / 59 (32.20%)	140 / 373 (37.53%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Basal cell carcinoma subjects affected / exposed occurrences (all)	3 / 626 (0.48%) 4	2 / 59 (3.39%) 2	3 / 373 (0.80%) 3
Investigations			
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 626 (0.00%) 0	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Psychiatric evaluation abnormal subjects affected / exposed occurrences (all)	1 / 626 (0.16%) 1	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Blood pressure increased subjects affected / exposed occurrences (all)	11 / 626 (1.76%) 12	0 / 59 (0.00%) 0	7 / 373 (1.88%) 8
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	1 / 626 (0.16%) 1	0 / 59 (0.00%) 0	3 / 373 (0.80%) 3
Fall subjects affected / exposed occurrences (all)	4 / 626 (0.64%) 4	2 / 59 (3.39%) 2	3 / 373 (0.80%) 3
Nervous system disorders			
Paraesthesia subjects affected / exposed occurrences (all)	0 / 626 (0.00%) 0	0 / 59 (0.00%) 0	1 / 373 (0.27%) 1
Blood and lymphatic system disorders			
Macrocytosis subjects affected / exposed occurrences (all)	0 / 626 (0.00%) 0	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Polycythaemia subjects affected / exposed occurrences (all)	0 / 626 (0.00%) 0	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
General disorders and administration site conditions			
Malaise subjects affected / exposed occurrences (all)	0 / 626 (0.00%) 0	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Reproductive system and breast disorders			

Prostatomegaly subjects affected / exposed occurrences (all)	1 / 626 (0.16%) 1	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	2 / 626 (0.32%) 2	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	3 / 626 (0.48%) 3	0 / 59 (0.00%) 0	0 / 373 (0.00%) 0
Skin and subcutaneous tissue disorders Intertrigo subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	8 / 626 (1.28%) 9 38 / 626 (6.07%) 40	0 / 59 (0.00%) 0 1 / 59 (1.69%) 1	2 / 373 (0.54%) 3 5 / 373 (1.34%) 6
Infections and infestations Corona virus infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	49 / 626 (7.83%) 50 62 / 626 (9.90%) 85 53 / 626 (8.47%) 68 35 / 626 (5.59%) 46 30 / 626 (4.79%) 40	10 / 59 (16.95%) 10 1 / 59 (1.69%) 1 5 / 59 (8.47%) 7 2 / 59 (3.39%) 2 0 / 59 (0.00%) 0	0 / 373 (0.00%) 0 62 / 373 (16.62%) 76 50 / 373 (13.40%) 64 23 / 373 (6.17%) 26 15 / 373 (4.02%) 19

Non-serious adverse events	ITP+MTP: Secukinumab 300 mg Q4W (up to Week 48)		
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Total subjects affected by non-serious adverse events subjects affected / exposed	166 / 370 (44.86%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Basal cell carcinoma subjects affected / exposed occurrences (all)	2 / 370 (0.54%) 12		
Investigations White blood cell count increased subjects affected / exposed occurrences (all) Psychiatric evaluation abnormal subjects affected / exposed occurrences (all) Blood pressure increased subjects affected / exposed occurrences (all)	0 / 370 (0.00%) 0 0 / 370 (0.00%) 0 3 / 370 (0.81%) 3		
Injury, poisoning and procedural complications Arthropod bite subjects affected / exposed occurrences (all) Fall subjects affected / exposed occurrences (all)	2 / 370 (0.54%) 2 1 / 370 (0.27%) 1		
Nervous system disorders Paraesthesia subjects affected / exposed occurrences (all)	1 / 370 (0.27%) 1		
Blood and lymphatic system disorders Macrocytosis subjects affected / exposed occurrences (all) Polycythaemia subjects affected / exposed occurrences (all)	0 / 370 (0.00%) 0 0 / 370 (0.00%) 0		
General disorders and administration site conditions			

Malaise subjects affected / exposed occurrences (all)	1 / 370 (0.27%) 1		
Reproductive system and breast disorders Prostatomegaly subjects affected / exposed occurrences (all)	1 / 370 (0.27%) 1		
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 370 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	2 / 370 (0.54%) 2		
Skin and subcutaneous tissue disorders Intertrigo subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	3 / 370 (0.81%) 4 16 / 370 (4.32%) 17		
Infections and infestations Corona virus infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Urinary tract infection	0 / 370 (0.00%) 0 102 / 370 (27.57%) 141 11 / 370 (2.97%) 16 36 / 370 (9.73%) 39		

subjects affected / exposed	22 / 370 (5.95%)		
occurrences (all)	30		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 October 2018	Protocol Amendment 1 (dated 17 Oct 2018) was implemented to incorporate the following key changes: • Incorporated a rerandomization at Week 16 for study participants in the bimekizumab 320 mg treatment arm (study participants in the bimekizumab 320 mg treatment arm were rerandomized 1:2 to receive bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W). This change was implemented to assess the 2 bimekizumab maintenance regimens used in pivotal Phase 3 PSO studies relative to the active comparator. • Added the number of study participants included in the summary of the completed study UP0042. • Clarified the scalp-specific IGA and palmoplantar Investigator's Global Assessment (pp-IGA) efficacy response criteria. • Moved the Patient Health Questionnaire-9 (PHQ-9) variable from an "other" safety variable to an "other" efficacy variable. • Added percent of study participants achieving at least a 75%, 90%, or 100% reduction from Baseline in the Modified Nail Psoriasis Severity Index (mNAPSI) score (mNAPSI75/90/100) for study participants with nail PSO at Baseline as an "other" efficacy variable. • Clarified that all study assessments should be performed prior to administration of IMP. • Clarified the study visit windows. • Clarified that the Patient's Global Assessment of Disease Activity (PGADA) should be performed on all study participants at Baseline. • Defined mental healthcare professional. • Clarified the assessment and management of tuberculosis (TB) wording. • Clarified the drug accountability wording. • Revised the systemic retinoid washout period.
17 October 2018	Continuation of Protocol Amendment 1: • Clarified that the same assessor should evaluate the study participant at each assessment. • Removed the requirement for a rheumatologist evaluation for study participants with a Psoriatic Arthritis Screening and Evaluation (PASE) ≥ 47 . • Clarified the IMP restart/rechallenge requirements in case of potential drug-induced liver injury (PDILI). • Added the definition of the Enrolled Set (ES) and Maintenance Set (MS). • Revised the statistical analysis based on the addition of rerandomization at Week 16. Minor spelling, editorial, and formatting changes were also made, and the List of Abbreviations was updated.
06 May 2019	Protocol Amendment 2 (dated 06 May 2019) was implemented to incorporate the following key changes: • Extended the study duration for an additional 96 weeks in an OLE Period. Changes included addition of a new schedule of assessments for the additional 96 weeks, additional other objectives and endpoints, and updates to Section 8 (Study procedures by visit). • Added planned rerandomization by treatment regimens and PASI response at Week 48 in the OLE Period. • Clarified secondary efficacy variable for IGA response at Week 16, and added other efficacy variables for the product of Investigator's Global Assessment and body surface area (IGA \times BSA) and PASE score suggestive of PsA. • Modified the text in Section 7 of the Protocol to include guidance for allowing study participants the option to self-inject IMP at home after Week 48. • Updated Section 12.2.1 of the Protocol (Evaluation of PDILI) for improved clarity and consistency with other Phase 3 studies of bimekizumab in study participants with PSO. • Added statistical analyses for the OLE Period. • Minor spelling, editorial, and formatting changes were made throughout the document.

23 May 2019	Protocol Amendment 3 (dated 23 May 2019) was implemented to incorporate the following key changes: • Moved study participant self-injection training into the start of the OLE Period at Week 48. • Added the description of the PGADA, which was inadvertently deleted in global Protocol Amendment 2, back into Section 9 of the Protocol. • Updated the name and contact information of the Clinical Trial Biostatistician. • Minor spelling, editorial, and formatting changes were made throughout the document.
09 June 2020	Protocol Amendment 5 (dated 09 Jun 2020) was implemented to incorporate the following key changes: • Changed the dosing regimen at Week 64 (or at the next scheduled clinic visit after implementation of Protocol Amendment 5 if the study participant already completed the Week 64 Visit) from bimekizumab 320 mg Q4W to bimekizumab 320 mg Q8W. This was based on pooled data from the Phase 3 studies (PS0008, PS0009, and PS0013), which demonstrated that during the Maintenance Treatment Period bimekizumab 320 mg Q8W provided essentially the same efficacy as bimekizumab 320 mg Q4W. • Corrected the visit window for the Week 24 visit from 7 days to 3 days. • Added a provision for collecting a concurrent sample for central laboratory testing if laboratory tests were performed locally. • Minor corrections, including typographical and grammatical errors, were made throughout the document.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported