Clinical trial results:
A Dose-Ranging, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Tezepelumab Alone or Combined With Topical Corticosteroids in Moderate-to-Severe Atopic Dermatitis

Summary

EudraCT number	2018-001997-52
Trial protocol	EE GB LV DE CZ HU PL ES
Global end of trial date	22 December 2020

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022

Trial information

Trial identification

Sponsor protocol code	20170755

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03809663
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States,
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.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	22 December 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 December 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of tezepelumab compared with placebo, assessed using the Investigator’s Global Assessment (IGA) and Eczema Area and Severity Index (EASI).

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 March 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Japan: 35
Country: Number of subjects enrolled	Korea, Republic of: 14
Country: Number of subjects enrolled	Czechia: 16
Country: Number of subjects enrolled	Estonia: 10
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Latvia: 12
Country: Number of subjects enrolled	Poland: 41
Country: Number of subjects enrolled	Ukraine: 18
Country: Number of subjects enrolled	Canada: 23
Country: Number of subjects enrolled	United States: 36
Country: Number of subjects enrolled	Australia: 10
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	United Kingdom: 9
Worldwide total number of subjects	251
EEA total number of subjects	106

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)	237
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in 78 centers in 14 countries including Australia, Canada, Czech Republic, Estonia, Germany, Hungary, Japan, Latvia, Poland, Republic of Korea, Spain, Ukraine, the United Kingdom, and the United States.

Pre-assignment

Screening details:

Part A was stopped as of 27 July 2020 and the study was terminated prior to the enrollment of any participants into Part B.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Matching placebo administered via subcutaneous (SC) injection once every 2 weeks (Q2W) for a maximum of 52 weeks. Participants defined as non-responders (those who did not achieve at least 50% improvement in Eczema Area and Severity Index [EASI] at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.

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

Dosage and administration details:

Matching placebo administered via SC injection.

Arm title	Tezepelumab 210 mg Q4W

Arm description:

Tezepelumab 210 mg administered via SC injection once every 4 weeks (Q4W) from Week 4 for a maximum of 52 weeks. All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received a placebo at Week 2 and every other week to maintain blinding. Participants defined as non-responders (those who did not achieve at least 50% improvement in EASI at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.

Arm type	Experimental
Investigational medicinal product name	Tezepelumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Tezepelumab administered via SC injection.

Arm title	Tezepelumab 280 mg Q2W

Arm description:

Tezepelumab 280 mg administered via SC injection Q2W from Week 2 for a maximum of 52 weeks. All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received their randomized dose of 280 mg Q2W from Week 2. Participants defined as non-responders (those who did not achieve at least 50% improvement in EASI at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.

Arm type	Experimental
Investigational medicinal product name	Tezepelumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Tezepelumab administered via SC injection.

Arm title	Tezepelumab 420 mg Q2W

Arm description:

Tezepelumab 420 mg administered via SC injection Q2W for a maximum of 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Tezepelumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Tezepelumab administered via SC injection.

Number of subjects in period 1	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W
Started	63	62	63
Received investigational product	63	61	63
EASI 50 non-responder at Week 16	40	26	30
Switched after Week 16	39	24	30
Completed	12	18	15
Not completed	51	44	48
Consent withdrawn by subject	26	22	27
Lost to follow-up	1	4	1
Decision by sponsor	24	18	20

Number of subjects in period 1	Tezepelumab 420 mg Q2W
Started	63
Received investigational product	63
EASI 50 non-responder at Week 16	38
Switched after Week 16	38
Completed	16
Not completed	47

Consent withdrawn by subject	26
Lost to follow-up	1
Decision by sponsor	20

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Matching placebo administered via subcutaneous (SC) injection once every 2 weeks (Q2W) for a maximum of 52 weeks. Participants defined as non-responders (those who did not achieve at least 50% improvement in Eczema Area and Severity Index [EASI] at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.	
Reporting group title	Tezepelumab 210 mg Q4W
Reporting group description:	
Tezepelumab 210 mg administered via SC injection once every 4 weeks (Q4W) from Week 4 for a maximum of 52 weeks. All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received a placebo at Week 2 and every other week to maintain blinding. Participants defined as non-responders (those who did not achieve at least 50% improvement in EASI at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.	
Reporting group title	Tezepelumab 280 mg Q2W
Reporting group description:	
Tezepelumab 280 mg administered via SC injection Q2W from Week 2 for a maximum of 52 weeks. All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received their randomized dose of 280 mg Q2W from Week 2. Participants defined as non-responders (those who did not achieve at least 50% improvement in EASI at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.	
Reporting group title	Tezepelumab 420 mg Q2W
Reporting group description:	
Tezepelumab 420 mg administered via SC injection Q2W for a maximum of 52 weeks.	

Reporting group values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W
Number of subjects	63	62	63
Age categorical Units: Subjects			
18 - 35 years	33	33	35
36 - 75 years	30	29	28
Age Continuous Units: Years			
arithmetic mean	35.7	38.5	36.9
standard deviation	± 13.4	± 15.0	± 13.4
Sex: Female, Male Units: Participants			
Female	27	32	23
Male	36	30	40
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	6	4	1
Not Hispanic or Latino	57	58	62
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	1	0

Asian	21	16	16
Black or African-American	1	3	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	41	42	45
Unknown	0	0	0
Other	0	0	1
Investigator's Global Assessment Score			
The IGA allows investigators to assess overall disease severity at 1 given time point and consists of a 5-point severity scale from clear to severe disease * 0 = clear * 1 = almost clear * 2 = mild disease * 3 = moderate disease * 4 = severe disease * 5 = very severe disease The IGA uses clinical characteristics of erythema, infiltration, papulation, oozing, and crusting as guidelines for the overall severity assessment (Breuer et al, 2004).			
Units: Subjects			
IGA Score of 3	26	37	26
IGA Score of 4	32	17	30
IGA Score of 5	5	8	7
Eczema Area and Severity Index (EASI)			
The EASI was designed by modifying the Psoriasis Area and Severity Index (Schmitt et al, 2007). The EASI evaluates 4 natural anatomical regions for severity and extent of key disease signs and focuses on key acute and chronic signs of inflammation (ie, erythema, induration/papulation, excoriation, and lichenification). The maximum score is 72, with higher values indicating more severe disease.			
Units: Score on a scale			
arithmetic mean	32.0	28.4	30.3
standard deviation	± 11.1	± 13.2	± 10.7

Reporting group values	Tezepelumab 420 mg Q2W	Total	
Number of subjects	63	251	
Age categorical Units: Subjects			
18 - 35 years	24	125	
36 - 75 years	39	126	
Age Continuous Units: Years			
arithmetic mean	40.7		
standard deviation	± 14.3	-	
Sex: Female, Male Units: Participants			
Female	27	109	
Male	36	142	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4	15	
Not Hispanic or Latino	59	236	
Unknown or Not Reported	0	0	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	13	66	
Black or African-American	3	8	
Native Hawaiian or Other Pacific Islander	0	0	
White	47	175	
Unknown	0	0	

Other	0	1	
Investigator's Global Assessment Score			
The IGA allows investigators to assess overall disease severity at 1 given time point and consists of a 5-point severity scale from clear to severe disease * 0 = clear * 1 = almost clear * 2 = mild disease * 3 = moderate disease * 4 = severe disease * 5 = very severe disease The IGA uses clinical characteristics of erythema, infiltration, papulation, oozing, and crusting as guidelines for the overall severity assessment (Breuer et al, 2004).			
Units: Subjects			
IGA Score of 3	37	126	
IGA Score of 4	18	97	
IGA Score of 5	8	28	
Eczema Area and Severity Index (EASI)			
The EASI was designed by modifying the Psoriasis Area and Severity Index (Schmitt et al, 2007). The EASI evaluates 4 natural anatomical regions for severity and extent of key disease signs and focuses on key acute and chronic signs of inflammation (ie, erythema, induration/papulation, excoriation, and lichenification). The maximum score is 72, with higher values indicating more severe disease.			
Units: Score on a scale			
arithmetic mean	28.6		
standard deviation	± 12.4	-	

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Matching placebo administered via subcutaneous (SC) injection once every 2 weeks (Q2W) for a maximum of 52 weeks. Participants defined as non-responders (those who did not achieve at least 50% improvement in Eczema Area and Severity Index [EASI] at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.

Reporting group title	Tezepelumab 210 mg Q4W

Reporting group description:

Tezepelumab 210 mg administered via SC injection once every 4 weeks (Q4W) from Week 4 for a maximum of 52 weeks. All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received a placebo at Week 2 and every other week to maintain blinding. Participants defined as non-responders (those who did not achieve at least 50% improvement in EASI at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.

Reporting group title	Tezepelumab 280 mg Q2W

Reporting group description:

Tezepelumab 280 mg administered via SC injection Q2W from Week 2 for a maximum of 52 weeks. All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received their randomized dose of 280 mg Q2W from Week 2. Participants defined as non-responders (those who did not achieve at least 50% improvement in EASI at Week 16 compared to baseline) switched to receive tezepelumab 420 mg SC injection Q2W for the remainder of the study beginning with the Week 18 dose.

Reporting group title	Tezepelumab 420 mg Q2W

Reporting group description:

Tezepelumab 420 mg administered via SC injection Q2W for a maximum of 52 weeks.

Subject analysis set title	Tezepelumab 210 mg Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

Tezepelumab 210 mg administered via SC once every 4 weeks (Q4W) from Week 4 for a maximum of 52 weeks.

All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received a placebo at Week 2 and every other week to maintain blinding.

Subject analysis set title	Tezepelumab 280 mg Q2W
Subject analysis set type	Per protocol

Subject analysis set description:

Tezepelumab 280 mg administered via SC injection Q2W from Week 2 for a maximum of 52 weeks.

All participants randomized to tezepelumab received 420 mg SC injection as their first dose. Participants then received their randomized dose of 280 mg Q2W from Week 2.

Subject analysis set title	Tezepelumab 420 mg Q2W
Subject analysis set type	Per protocol

Subject analysis set description:

Tezepelumab 420 mg administered via SC injection Q2W for a maximum of 52 weeks.

Also includes participants randomized to lower doses of tezepelumab but who only received 420 mg and discontinued before receiving their randomized treatment. In addition, includes participants who were randomized to placebo, tezepelumab 210 mg and 280 mg, but switched to tezepelumab 420 mg in error after Week 16.

Subject analysis set title	Placebo; Tezepelumab 420 mg Switchers
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received the matching placebo Q2W up to Week 16 and were assessed as EASI 50 non-responders and switched to receive tezepelumab 420 mg Q2W up to Week 52 (switchers).

Tezepelumab 420 mg administered via SC injection Q2W from Week 18 to Week 52.

Subject analysis set title	Tezepelumab 210 mg; Tezepelumab 420 mg Switchers
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received tezepelumab 210 mg Q4W up to Week 16 and were assessed as EASI 50 non-responders and switched to receive tezepelumab 420 mg Q2W up to Week 52 (switchers).

Tezepelumab 420 mg administered via SC injection Q2W from Week 18 to Week 52.

Subject analysis set title	Tezepelumab 280 mg; Tezepelumab 420 mg Switchers
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received tezepelumab 280 mg Q2W up to Week 16 and were assessed as EASI 50 non-responders and switched to receive tezepelumab 420 mg Q2W up to Week 52 (switchers).

Tezepelumab 420 mg administered via SC injection Q2W from Week 18 to Week 52.

Subject analysis set title	Tezepelumab 420 mg; Tezepelumab 420 mg Switchers
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received tezepelumab 420 mg Q2W up to Week 16 and were assessed as EASI 50 non-responders and continued to receive tezepelumab 420 mg Q2W up to Week 52 (switchers).

Tezepelumab 420 mg administered via SC injection Q2W from Week 18 to Week 52.

Primary: Number of Participants with Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) (IGA 0/1) at Week 16

End point title	Number of Participants with Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) (IGA 0/1) at Week 16

End point description:

The IGA allows investigators to assess overall disease severity at 1 given time point and consists of a 5-point severity scale from clear to severe disease
* 0 = clear
* 1 = almost clear
* 2 = mild disease
* 3 = moderate disease
* 4 = severe disease
* 5 = very severe disease

The IGA uses clinical characteristics of erythema, infiltration, papulation, oozing, and crusting as guidelines for the overall severity assessment (Breuer et al, 2004).

Participants who took rescue medication between Day 29 to Week 16 were considered non-responders

End point type	Primary

End point timeframe:

Week 16

End point values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	63	63
Units: Participants	2	4	2	5

Statistical analyses

Statistical analysis title	Placebo vs Tezepelumab 210 mg
Comparison groups	Tezepelumab 210 mg Q4W v Placebo
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.56 [1]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.686
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	9.809

Notes:

[1] - Nominal p-value

Statistical analysis title	Placebo vs Tezepelumab 420 mg
Comparison groups	Placebo v Tezepelumab 420 mg Q2W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.38 [2]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.146
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	11.8

Notes:

[2] - Nominal p-value

Statistical analysis title	Placebo vs Tezepelumab 280 mg
Comparison groups	Placebo v Tezepelumab 280 mg Q2W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.99 [3]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.011
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.135
upper limit	7.551

Notes:

[3] - Nominal p-value

Primary: Number of Participants who Experienced a 75% Reduction from Baseline in Eczema Area and Severity Index (EASI 75) at Week 16

End point title	Number of Participants who Experienced a 75% Reduction from Baseline in Eczema Area and Severity Index (EASI 75) at Week 16

End point description:

The EASI evaluates 4 natural anatomical regions for severity and extent of key disease signs and focuses on key acute and chronic signs of inflammation (ie, erythema, induration/papulation, excoriation, and lichenification).

A reduction in the EASI score indicates an improvement in severity. Participants who took rescue medication between Day 29 to Week 16 were considered non-responders.

End point type	Primary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	63	63
Units: Participants	8	9	10	7

Statistical analyses

Statistical analysis title	Placebo vs Tezepelumab 210 mg
Comparison groups	Placebo v Tezepelumab 210 mg Q4W
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.97 [4]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.982
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.344
upper limit	2.803

Notes:

[4] - Nominal p-value

Statistical analysis title	Placebo vs Tezepelumab 420 mg
Comparison groups	Placebo v Tezepelumab 420 mg Q2W

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.58 [5]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.243
upper limit	2.197

Notes:

[5] - Nominal p-value

Statistical analysis title	Placebo vs Tezepelumab 280 mg
Comparison groups	Placebo v Tezepelumab 280 mg Q2W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7 [6]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.217
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.441
upper limit	3.356

Notes:

[6] - Nominal p-value

Secondary: Number of Participants who Experienced a 50% or 90% Reduction from Baseline in Eczema Area and Severity Index (EASI 50/90) at Week 16

End point title	Number of Participants who Experienced a 50% or 90% Reduction from Baseline in Eczema Area and Severity Index (EASI 50/90) at Week 16

End point description:

The EASI evaluates 4 natural anatomical regions for severity and extent of key disease signs and focuses on key acute and chronic signs of inflammation (ie, erythema, induration/papulation, excoriation, and lichenification).

A reduction in the EASI score indicates an improvement in severity. Participants who took rescue medication between Day 29 to Week 16 were considered non-responders.

Rescue medication = topical corticosteroids (TCS)/topical calcineurin inhibitors (TCI).

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56[7]	58[8]	58[9]	56[10]
Units: Participants				
EASI 50	11	21	18	11
EASI 90	3	3	3	3

Notes:

[7] - All participants with non-missing response or who had received rescue medication prior to Week 16

[8] - All participants with non-missing response or who had received rescue medication prior to Week 16

[9] - All participants with non-missing response or who had received rescue medication prior to Week 16

[10] - All participants with non-missing response or who had received rescue medication prior to Week 16

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achievement of 50%, 75% or 90% Reduction from Day 1 in Eczema Area and Severity Index (EASI 50/75/90)

End point title	Time to Achievement of 50%, 75% or 90% Reduction from Day 1 in Eczema Area and Severity Index (EASI 50/75/90)

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to End of Study Visit (Week 70)

End point values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	63	63
Units: Weeks				
median (full range (min-max))				
Time to EASI 50	6.143 (4.14 to 19.57)	8.143 (3.86 to 16.14)	6.286 (3.86 to 22.14)	5.857 (3.86 to 16.14)
Time to EASI 75	6.143 (4.14 to 19.57)	6.286 (4.00 to 16.43)	6.714 (4.14 to 22.14)	6.429 (4.14 to 16.14)
Time to EASI 90	8.286 (4.43 to 19.57)	10.929 (4.00 to 16.14)	10.071 (6.14 to 16.14)	7.286 (4.14 to 16.29)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Scoring of Atopic Dermatitis (SCORAD) at Week 16

End point title	Change from Baseline in Scoring of Atopic Dermatitis (SCORAD) at Week 16

End point description:

The SCORAD is a clinical tool for assessing the severity (ie, extent, intensity) of atopic dermatitis (AD). The tool evaluates the extent and intensity of the AD lesions, along with subjective symptoms (Kunz et al, 1997). The total score ranges from 0 to 103, with higher values indicating more severe disease. A negative change from baseline indicates an improvement in severity of disease.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	63	63
Units: Score on a scale				
least squares mean (standard error)	-8.00 (± 2.55)	-16.75 (± 2.40)	-11.87 (± 2.49)	-9.32 (± 2.48)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pruritus Numeric Rating Scale (NRS) at Week 16

End point title	Change from Baseline in Pruritus Numeric Rating Scale (NRS) at Week 16

End point description:

Pruritus was assessed using an NRS (0-10) with 0 = no itch and 10 = worst imaginable itch. A negative change from baseline indicates an improvement in symptoms.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	63	63
Units: Score on a scale				
least squares mean (standard error)	-0.71 (± 0.30)	-1.40 (± 0.27)	-0.94 (± 0.28)	-0.38 (± 0.28)

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Trough Concentrations of Tezepelumab after Q2W or Q4W

Administration.

End point title	Serum Trough Concentrations of Tezepelumab after Q2W or Q4W Administration.

End point description:

Switchers were included up to Week 16 and were then excluded from the analysis after switching.

All Tezepelumab participants received 420 mg of Tezepelumab on Day 1.

99999 = Not calculated: Insufficient samples to measure standard deviation.

End point type	Secondary

End point timeframe:

Pre-dose on Day 1, Week 2, 4, 12, 16, 24, 32, 40, 48, 50, 52, 58 and 70

End point values	Tezepelumab 210 mg Q4W	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	58	58	66	
Units: µg/mL				
arithmetic mean (standard deviation)				
Day 1 (N=58, 58, 66)	0.00031 (± 0.00236)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 2 (N=51, 49, 60)	34.9 (± 10.9)	36.3 (± 12.9)	34.8 (± 12.9)	
Week 4 (N=56, 48, 53)	23.4 (± 9.03)	48.8 (± 16.0)	58.9 (± 21.4)	
Week 12 (N=49, 48 ,47)	21.7 (± 8.47)	66.7 (± 22.9)	97.0 (± 35.0)	
Week 16 (N=47, 46 ,44)	22.2 (± 9.42)	77.4 (± 33.0)	98.0 (± 37.8)	
Week 24 (N=20, 17 ,11)	23.2 (± 10.6)	83.6 (± 31.2)	107 (± 29.5)	
Week 32 (N=16, 15, 5)	25.4 (± 17.0)	75.1 (± 36.3)	81.4 (± 26.4)	
Week 40 (N=11, 6, 4)	22.9 (± 12.7)	76.8 (± 19.7)	112 (± 63.3)	
Week 48 (N=5, 5, 5)	18.2 (± 6.49)	76.4 (± 26.4)	118 (± 48.3)	
Week 50 (N=5, 4, 4)	29.2 (± 9.11)	86.8 (± 27.7)	113 (± 44.4)	
Week 52 (N=4, 5, 4)	18.3 (± 7.24)	67.2 (± 33.2)	102 (± 31.2)	
Week 58 (N=3, 3, 2)	5.41 (± 2.56)	18.0 (± 7.09)	20.9 (± 99999)	
Week 70 (N=4, 3, 3)	0.699 (± 0.380)	1.87 (± 1.74)	5.36 (± 3.20)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Trough Concentrations of Tezepelumab after Switching to 420 mg Q2W Administration After Week 16

End point title	Serum Trough Concentrations of Tezepelumab after Switching to 420 mg Q2W Administration After Week 16

End point description:

Participants who switched to 420 mg Q2W at Week 16 were included in the analyses (including participants who did not respond to 420 mg Q2W at Week 16 and continued to take 420 mg Q2W).

99999 = Not calculated: Insufficient samples to measure standard deviation.

End point type	Secondary

End point timeframe:

Pre-dose on Week 24, 32, 40, 48, 50, 52, 58 and 70

End point values	Placebo; Tezepelumab 420 mg Switchers	Tezepelumab 210 mg; Tezepelumab 420 mg Switchers	Tezepelumab 280 mg; Tezepelumab 420 mg Switchers	Tezepelumab 420 mg; Tezepelumab 420 mg Switchers
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	30	22	21	25
Units: µg/mL				
arithmetic mean (standard deviation)				
Week 24 (N=30, 22, 21, 25)	70.5 (± 28.3)	87.2 (± 24.0)	96.6 (± 29.2)	100 (± 38.2)
Week 32 (N=23, 15, 17, 24)	91.0 (± 38.7)	104 (± 38.8)	97.8 (± 39.3)	105 (± 39.1)
Week 40 (N=15, 11, 9, 15)	117 (± 42.7)	93.8 (± 35.5)	113 (± 31.1)	101 (± 37.7)
Week 48 (N=9, 6, 5, 9)	134 (± 60.2)	121 (± 29.1)	89.6 (± 35.1)	103 (± 29.9)
Week 50 (N=10, 5, 5, 8)	115 (± 39.0)	125 (± 42.2)	79.1 (± 38.6)	106 (± 27.0)
Week 52 (N=9, 6, 4, 8)	125 (± 30.8)	113 (± 45.0)	88.3 (± 33.0)	105 (± 30.2)
Week 58 (N=4, 1, 1, 4)	26.0 (± 21.6)	52.6 (± 99999)	36.7 (± 99999)	17.6 (± 9.28)
Week 70 (N=9, 5, 4, 7)	5.07 (± 5.10)	4.47 (± 3.39)	2.60 (± 1.72)	3.49 (± 2.42)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to week 16 for Arms 1-4 and after week 16 up to week 70 for Arms 5-12.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants who took placebo from Week 1 to Week 16.

Reporting group title	Tezepelumab 280 mg Q2W

Reporting group description:

Participants who took 280 mg Q2W from Week 1 to Week 16.

Reporting group title	Tezepelumab 420 mg Q2W

Reporting group description:

Participants who took 420 mg Q2W from Week 1 to Week 16.

Includes 7 subjects randomized to the lower doses of Tezepelumab but received only the first dose of Tezepelumab 420 mg SC and early discontinued.

Reporting group title	Placebo - Placebo

Reporting group description:

Non-switching participants who took placebo from Week 16 to Week 52.

Reporting group title	Tezepelumab 210 mg Q4W

Reporting group description:

Participants who took 210 mg Q4W from Week 1 to Week 16.

Reporting group title	Tezepelumab 210 mg Q4W - 210 mg Q4W

Reporting group description:

Non-switching participants who took 210 mg Q4W from Week 16 to Week 52.

Reporting group title	Tezepelumab 280 mg Q2W - 280 mg Q2W

Reporting group description:

Non-switching participants who took 280 mg Q2W from Week 16 to Week 52.

Reporting group title	Tezepelumab 420 mg Q2W - 420 mg Q2W

Reporting group description:

Non-switching participants who continued to take 420 mg Q2W from Week 16 to Week 52.

Includes 6 participants who were randomized to placebo (n=2), 210 mg Q4W (n=3) and 280 mg Q2W (n=1) but switched to Tezepelumab 420 mg SC Q2W in error after Week 16.

Reporting group title	Placebo- Tezepelumab 420 mg Q2W

Reporting group description:

Participants who switched after Week 16 to take 420 mg Q2W.

Reporting group title	Tezepelumab 210 mg Q4W-420 mg Q2W

Reporting group description:

Participants who switched after Week 16 to take 420 mg Q2W.

Reporting group title	Tezepelumab 280 mg Q2W-420 mg Q2W

Reporting group description:

Participants who switched after Week 16 to take 420 mg Q2W.

Reporting group title	Tezepelumab 420 mg Q2W-420 mg Q2W

Reporting group description:

Participants who switched after week 16 who continued to take 420 mg Q2W.

Serious adverse events	Placebo	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	1 / 70 (1.43%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Corneal degeneration			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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			
Hepatic cirrhosis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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			
Dermatitis atopic			

subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis herpetiformis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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 erosion			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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			
Alcohol abuse			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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			
Bronchitis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device failure			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
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	Placebo - Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 210 mg Q4W - 210 mg Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	0 / 25 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events		0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Corneal degeneration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
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			
Hepatic cirrhosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
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			
Dermatitis atopic			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 25 (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

Dermatitis herpetiformis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin erosion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
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			
Alcohol abuse			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
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			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 25 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
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	Tezepelumab 280 mg Q2W - 280 mg Q2W	Tezepelumab 420 mg Q2W - 420 mg Q2W	Placebo-Tezepelumab 420 mg Q2W
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	2 / 39 (5.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Corneal degeneration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
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			
Ascites			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (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
Hepatobiliary disorders			
Hepatic cirrhosis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (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
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis herpetiformis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
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 erosion			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (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			
Alcohol abuse			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
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			
Bronchitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (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
Product issues			
Device failure			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (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	Tezepelumab 210 mg Q4W-420 mg Q2W	Tezepelumab 280 mg Q2W-420 mg Q2W	Tezepelumab 420 mg Q2W-420 mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	1 / 30 (3.33%)	4 / 38 (10.53%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Corneal degeneration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 30 (3.33%)	0 / 38 (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
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
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			
Hepatic cirrhosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
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			
Dermatitis atopic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis herpetiformis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
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 erosion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
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			
Alcohol abuse			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo	Tezepelumab 280 mg Q2W	Tezepelumab 420 mg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 63 (39.68%)	29 / 58 (50.00%)	30 / 70 (42.86%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 63 (1.59%)	3 / 58 (5.17%)	2 / 70 (2.86%)
occurrences (all)	1	3	2
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	1 / 63 (1.59%)	0 / 58 (0.00%)	1 / 70 (1.43%)
occurrences (all)	1	0	1
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 63 (1.59%)	0 / 58 (0.00%)	1 / 70 (1.43%)
occurrences (all)	1	0	1
Investigations			
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			

subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 63 (4.76%)	1 / 58 (1.72%)	4 / 70 (5.71%)
occurrences (all)	3	1	4
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 63 (0.00%)	1 / 58 (1.72%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 63 (0.00%)	1 / 58 (1.72%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 63 (0.00%)	1 / 58 (1.72%)	3 / 70 (4.29%)
occurrences (all)	0	2	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 63 (1.59%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	12 / 63 (19.05%)	13 / 58 (22.41%)	13 / 70 (18.57%)
occurrences (all)	14	17	17
Eczema			
subjects affected / exposed	0 / 63 (0.00%)	2 / 58 (3.45%)	1 / 70 (1.43%)
occurrences (all)	0	2	2
Erythema			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

Intertrigo			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 63 (3.17%)	3 / 58 (5.17%)	0 / 70 (0.00%)
occurrences (all)	2	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 63 (1.59%)	1 / 58 (1.72%)	0 / 70 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
Herpes zoster			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	6 / 63 (9.52%)	10 / 58 (17.24%)	6 / 70 (8.57%)
occurrences (all)	10	11	6
Oral herpes			
subjects affected / exposed	0 / 63 (0.00%)	1 / 58 (1.72%)	1 / 70 (1.43%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	3 / 63 (4.76%)	1 / 58 (1.72%)	2 / 70 (2.86%)
occurrences (all)	4	1	2
Pyoderma			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Respiratory tract infection viral			

subjects affected / exposed	0 / 63 (0.00%)	1 / 58 (1.72%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	1 / 63 (1.59%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 63 (6.35%)	2 / 58 (3.45%)	1 / 70 (1.43%)
occurrences (all)	4	2	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 63 (0.00%)	1 / 58 (1.72%)	1 / 70 (1.43%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 63 (0.00%)	0 / 58 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo - Placebo	Tezepelumab 210 mg Q4W	Tezepelumab 210 mg Q4W - 210 mg Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 12 (50.00%)	20 / 59 (33.90%)	10 / 25 (40.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Seasonal allergy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	3
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	2 / 12 (16.67%)	9 / 59 (15.25%)	5 / 25 (20.00%)
occurrences (all)	2	12	14
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 25 (4.00%)
occurrences (all)	0	2	3
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	0 / 25 (0.00%)
occurrences (all)	0	2	0

Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	2 / 59 (3.39%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	5 / 59 (8.47%)	3 / 25 (12.00%)
occurrences (all)	0	6	4
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Pyoderma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 12 (8.33%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 59 (1.69%)	2 / 25 (8.00%)
occurrences (all)	2	1	2
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	3 / 59 (5.08%)	1 / 25 (4.00%)
occurrences (all)	0	3	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 59 (1.69%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 12 (0.00%)	0 / 59 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Tezepelumab 280 mg Q2W - 280 mg Q2W	Tezepelumab 420 mg Q2W - 420 mg Q2W	Placebo-Tezepelumab 420 mg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 20 (55.00%)	5 / 22 (22.73%)	18 / 39 (46.15%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Rhinitis allergic			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	1 / 39 (2.56%)
occurrences (all)	1	1	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Investigations			
SARS-CoV-2 antibody test positive			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0

Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	4 / 39 (10.26%)
occurrences (all)	0	0	11
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	2 / 20 (10.00%)	3 / 22 (13.64%)	9 / 39 (23.08%)
occurrences (all)	2	6	12
Eczema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Intertrigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	3 / 20 (15.00%)	3 / 22 (13.64%)	3 / 39 (7.69%)
occurrences (all)	3	4	3
Oral herpes			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Pyoderma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			

subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 20 (10.00%)	0 / 22 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Tezepelumab 210 mg Q4W-420 mg Q2W	Tezepelumab 280 mg Q2W-420 mg Q2W	Tezepelumab 420 mg Q2W-420 mg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 24 (37.50%)	10 / 30 (33.33%)	19 / 38 (50.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			

subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 24 (0.00%)	1 / 30 (3.33%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Rhinitis allergic			
subjects affected / exposed	2 / 24 (8.33%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Investigations			
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	2 / 24 (8.33%)	1 / 30 (3.33%)	0 / 38 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	2	0	2
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	4
Conjunctivitis allergic			

subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Dermatitis atopic			
subjects affected / exposed	2 / 24 (8.33%)	4 / 30 (13.33%)	6 / 38 (15.79%)
occurrences (all)	5	6	9
Eczema			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	3 / 38 (7.89%)
occurrences (all)	2	0	7
Erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 30 (3.33%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	5

Conjunctivitis			
subjects affected / exposed	2 / 24 (8.33%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	2	0	2
Herpes zoster			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	3 / 30 (10.00%)	3 / 38 (7.89%)
occurrences (all)	0	3	6
Oral herpes			
subjects affected / exposed	0 / 24 (0.00%)	1 / 30 (3.33%)	1 / 38 (2.63%)
occurrences (all)	0	1	3
Pharyngitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Pyoderma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 30 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 30 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 30 (0.00%) 0	2 / 38 (5.26%) 2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 November 2018	* Extended the safety follow-up period from 12 weeks to 20 weeks after the final dose of investigational product (18 weeks after the EOT visit). * Added additional descriptive statistics for continuous endpoints. * Added PPD or Quantiferon GOLD testing at screening and EOT/ET visits. * Updated inclusion criterion #107 to remove moisturizers containing additives such as ceramide, hyaluronic acid, urea, or filaggrin. * Updated exclusion criterion #215 to include within 5 elimination half-lives for receipt of any approved biologic agent. * Removed language regarding receiving treatment with systemic corticosteroids or nonsteroidal systemic immunosuppressive drugs after week 16. * Updated interim analysis guidelines. * Changed week 64 pregnancy testing to week 70. * Updated contraception guidance to specify female partners of male participants will be required to use a highly effective method of contraception.
04 September 2019	* Addressed Amgen-mandated updates to the collection and reporting of disease-related events. * Aligned male contraception language in the protocol with the updated contraception guidance in the tezepelumab investigator's brochure.
25 August 2020	* Updated safety language to specify female participants and female partners of male participants were required to refrain from becoming pregnant or breastfeeding, and to report pregnancies, for an additional 16 weeks, instead of 14 weeks, after the last dose of tezepelumab.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Enrollment of Part A of this study was completed as of 27 July 2020. The study was terminated prior to the enrollment of any participants into Part B.

Notes: