



Clinical trial results:

A Randomised, Double-Blind, Parallel-Group, Placebo-Controlled 28-week Phase 3 Efficacy and Safety Study of Tezepelumab in Reducing Oral Corticosteroid Use in Adults with Oral Corticosteroid Dependent Asthma (SUNRISE)

Summary

EudraCT number	2021-006691-17
Trial protocol	CZ
Global end of trial date	24 March 2025

Results information

Result version number	v1 (current)
This version publication date	26 March 2026
First version publication date	26 March 2026

Trial information

Trial identification

Sponsor protocol code	D5180C00024
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05398263
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	151 85, Sodertalje, Sweden,
Public contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.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	24 March 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 March 2025
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 in reducing the prescribed oral corticosteroids (OCS) maintenance dose in participants with asthma requiring chronic treatment with maintenance OCS in addition to high-dose inhaled corticosteroids (ICS) plus long-acting β 2 agonists (LABA)

Protection of trial subjects:

The investigator or his/her representative explained the nature of the study to the participant or his/her legally authorised representative and answered all questions regarding the study. Participants were informed that their participation was voluntary and they were free to refuse to participate and could withdraw their consent at any time and for any reason during the study. Participants or their legally authorised representative were required to sign a statement of informed consent that meets the requirements of 21 CFR 50, local regulations, ICH guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements, where applicable, and the Institutional Review Board/Independent Ethics Committee (IRB/IEC) or study centre. The medical record had to include a statement that written informed consent was obtained before the participant was enrolled in the study and the date the written consent was obtained. The authorised person obtaining the informed consent had also to sign the informed consent form (ICF). Participants had to be re-consented to the most current version of the ICF(s) during their participation in the study. A copy of the ICF(s) had to be provided to the participant or the participant's legally authorised representative. Participants who were re-screened were required to sign a new ICF.

Background therapy:

Participants must have received a physician-prescribed medium- or high-dose ICS (medium dose ICS corresponds to 500 μ g and high dose ICS corresponds to > 500 μ g fluticasone propionate dry powder formulation or equivalents) as per GINA guideline (GINA 2022) for at least 12 months prior to Visit 1. Participants must have received physician-prescribed LABA and high dose ICS (total daily dose > 500 μ g fluticasone propionate dry powder formulation or equivalent) for at least 3 months prior to Visit 1. The ICS and LABA can be parts of a combination product or given by separate inhalers. Participants must have received OCS for the treatment of asthma for at least 6 months prior to Visit 1 and on a stable dose of between ≥ 7.5 to ≤ 30 mg (prednisone or prednisolone) daily or daily equivalent for at least one month prior to Visit 1.

Evidence for comparator: -

Actual start date of recruitment	09 August 2022
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	Thailand: 11
Country: Number of subjects enrolled	United States: 6
Country: Number of subjects enrolled	India: 4
Country: Number of subjects enrolled	Korea, Republic of: 4

Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Chile: 31
Country: Number of subjects enrolled	Mexico: 18
Country: Number of subjects enrolled	Brazil: 8
Country: Number of subjects enrolled	Peru: 11
Country: Number of subjects enrolled	Poland: 11
Country: Number of subjects enrolled	Czechia: 9
Country: Number of subjects enrolled	Türkiye: 8
Worldwide total number of subjects	122
EEA total number of subjects	20

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)	99
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 63 centres (excluding one site that was excluded from the analyses) in 12 countries. A total of 246 subjects were screened between 9AUG2022 and 29NOV2024, of which 122 were randomized and treated. This study was terminated early by the sponsor because of recruitment challenges.

Pre-assignment

Screening details:

Subjects were randomized in 2:1 ratio for tezepelumab or placebo. Randomization was stratified by region and eosinophil count at Visit 1 (< 150 cells/ μ L, 150-< 300 cells/ μ L, $\geq$ 300 cells/ μ L).

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	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Tezepelumab

Arm description:

Tezepelumab 210 mg administered every 4 weeks subcutaneously

Arm type	Experimental
Investigational medicinal product name	Tezepelumab 210 mg administered every 4 weeks subcutaneously
Investigational medicinal product code	
Other name	Tezepelumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

210 mg Q4W

Arm title	Placebo
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Arm description:

Placebo administered every 4 weeks subcutaneously

Arm type	Placebo
Investigational medicinal product name	Placebo administered every 4 weeks subcutaneously
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Q4W

Number of subjects in period 1	Tezepelumab	Placebo
Started	83	39
Completed	59	30
Not completed	24	9
Adverse event, serious fatal	2	1
Consent withdrawn by subject	1	-
Adverse event, non-fatal	1	-
Study terminated by sponsor	18	7
Lost to follow-up	2	-
End of study due to low compliance by participant	-	1

Baseline characteristics

Reporting groups

Reporting group title	Tezepelumab
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Reporting group description:

Tezepelumab 210 mg administered every 4 weeks subcutaneously

Reporting group title	Placebo
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Reporting group description:

Placebo administered every 4 weeks subcutaneously

Reporting group values	Tezepelumab	Placebo	Total
Number of subjects	83	39	122
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	67	32	99
>=65 years	16	7	23
Age Continuous			
-- Select --			
Units: Years			
arithmetic mean	51.6	53.6	
standard deviation	± 12.7	± 13.0	-
Sex: Female, Male			
Units: Participants			
Female	65	27	92
Male	18	12	30
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	3	1	4
Asian	14	5	19
Black or African American	1	1	2
Native Hawaiian or other Pacific Islander	0	0	0
White	42	25	67
Other/Multiple race	21	6	27
Missing	2	1	3
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	42	21	63
Not Hispanic or Latino	41	18	59

End points

End points reporting groups

Reporting group title	Tezepelumab
Reporting group description: Tezepelumab 210 mg administered every 4 weeks subcutaneously	
Reporting group title	Placebo
Reporting group description: Placebo administered every 4 weeks subcutaneously	

Primary: Categorised percent reduction from baseline in the daily maintenance OCS dose at Week 28 whilst maintaining asthma control.

End point title	Categorised percent reduction from baseline in the daily maintenance OCS dose at Week 28 whilst maintaining asthma control.
End point description: Categorised percent reduction from baseline at Week 28. Percent change from baseline is defined as $\{\text{final dose}-\text{baseline dose}\}/\text{baseline dose}\times 100\%$, and the categories of percent change from baseline in daily OCS dose are defined as: $\geq 90\%$ to $\leq 100\%$ reduction, $\geq 75\%$ to $< 90\%$ reduction, $\geq 50\%$ to $< 75\%$ reduction, $> 0\%$ to $< 50\%$ reduction, and, no change or any increase.	
End point type	Primary
End point timeframe: Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Participants				
>=90% to <=100% reduction	30	8		
>=75% to <90% reduction	7	3		
>=50% to <75% reduction	20	6		
>0% to <50% reduction	12	6		
no change or any increase	14	16		

Statistical analyses

Statistical analysis title	Proportional odds model
Statistical analysis description: Response variable: categorised % reduction from baseline in final OCS dose. Covariates in the model: treatment, region, baseline daily OCS dose and logarithm of baseline blood eosinophil counts.	
Comparison groups	Tezepelumab v Placebo

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.003
Method	Proportional odds model
Parameter estimate	Cumulative Odds Ratio
Point estimate	2.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.43
upper limit	6.03

Secondary: Change from baseline in pre-bronchodilator (pre-BD) forced expiratory volume in 1 second (FEV1) at Week 28

End point title	Change from baseline in pre-bronchodilator (pre-BD) forced expiratory volume in 1 second (FEV1) at Week 28
End point description:	Change from baseline in pre-BD FEV1 at Week 28. FEV1 is defined as the volume of air exhaled from the lungs in the first second of a forced expiration.
End point type	Secondary
End point timeframe:	Baseline to Week 28

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	27		
Units: Litre				
arithmetic mean (standard deviation)	0.240 (± 0.498)	-0.019 (± 0.310)		

Statistical analyses

No statistical analyses for this end point

Secondary: Annualised asthma exacerbation rate (AAER) over 28 weeks

End point title	Annualised asthma exacerbation rate (AAER) over 28 weeks
End point description:	The annualized exacerbation rate is based on exacerbations reported by the investigator in the eCRF over 28 weeks.
End point type	Secondary
End point timeframe:	Baseline to Week 28

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Events per year				
number (not applicable)	0.65	1.98		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects with $\geq 50\%$ reduction from baseline in daily OCS dose at Week 28

End point title	Proportion of subjects with $\geq 50\%$ reduction from baseline in daily OCS dose at Week 28
End point description:	Proportion of subjects with $\geq 50\%$ reduction from baseline in daily OCS dose at Week 28. Percent change from baseline is defined as $\{(\text{final dose}-\text{baseline dose})/\text{baseline dose}\} \times 100\%$.
End point type	Secondary
End point timeframe:	
Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Participants	57	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects with daily OCS dose ≤ 5 mg at Week 28

End point title	Proportion of subjects with daily OCS dose ≤ 5 mg at Week 28
End point description:	Proportion of subjects with daily OCS dose ≤ 5 mg at Week 28.
End point type	Secondary
End point timeframe:	
Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Participants	49	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects with 100% reduction from baseline in daily OCS dose at Week 28

End point title	Proportion of subjects with 100% reduction from baseline in daily OCS dose at Week 28
End point description:	Proportion of subjects with 100% reduction from baseline in daily OCS dose at Week 28. Percent change from baseline is defined as $\{((\text{final dose}-\text{baseline dose})/\text{baseline dose})*100\}$.
End point type	Secondary
End point timeframe:	
Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Participants	29	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first asthma exacerbation

End point title	Time to first asthma exacerbation
End point description:	Time to first asthma exacerbation, presented as number of subjects with at least one asthma exacerbation as reported by the investigator in the eCRF
End point type	Secondary
End point timeframe:	
Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Participants	25	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Asthma Control Questionnaire 6 (ACQ-6) score at Week 28

End point title	Change from baseline in Asthma Control Questionnaire 6 (ACQ-6) score at Week 28
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End point description:

Change from baseline in ACQ-6 as compared to placebo at Week 28. The ACQ-6 captures asthma symptoms and short-acting β 2-agonist use via subject-report. Questions are weighted equally and scored from 0 (totally controlled) to 6 (severely uncontrolled). The ACQ-6 score is the mean of the responses.

End point type	Secondary
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End point timeframe:

Baseline to Week 28

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	25		
Units: Score on a scale				
arithmetic mean (standard deviation)	-1.25 ($\pm$ 1.14)	-0.59 ($\pm$ 1.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in weekly mean home peak expiratory flow (PEF) (morning and evening) at Week 28

End point title	Change from baseline in weekly mean home peak expiratory flow (PEF) (morning and evening) at Week 28
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End point description:

Change from baseline in weekly mean morning and evening peak expiratory flow (PEF) as compared to placebo at Week 28. Home PEF testing will be performed by the subject in the morning upon awakening and in the evening at bedtime using an electronic, hand-held spirometer. Each timepoint is calculated as weekly.

End point type	Secondary
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End point timeframe:

Baseline to Week 28

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	27		
Units: L/min				
arithmetic mean (standard deviation)				
Weekly mean morning PEF	27.4 (± 65.0)	-10.6 (± 56.9)		
Weekly mean evening PEF	24.3 (± 70.3)	-12.4 (± 51.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Standardized Asthma Quality of Life Questionnaire for 12 years and older (AQLQ(s)+12) total score at Week 28

End point title	Change from baseline in Standardized Asthma Quality of Life Questionnaire for 12 years and older (AQLQ(s)+12) total score at Week 28
End point description:	
Change from baseline in AQLQ(S)+12 as compared to placebo at Week 28. The AQLQ(S)+12 is a questionnaire that measures the health-related quality of life experienced by asthma subjects. The total score is defined as the average of all 32 questions in the AQLQ(S)+12 questionnaire. AQLQ(S)+12 is a 7-point scale questionnaire, ranging from 7 (no impairment) to 1 (severe impairment).	
End point type	Secondary
End point timeframe:	
Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	26		
Units: Scale of score				
arithmetic mean (standard deviation)	1.42 (± 1.33)	0.44 (± 1.20)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in St George's Respiratory Questionnaire (SGRQ) Score at Week 28

End point title	Change From Baseline in St George's Respiratory Questionnaire (SGRQ) Score at Week 28
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End point description:

Change from baseline in SGRQ as compared to placebo at Week 28. The questionnaire is divided into 2 parts: part 1 consists of 8 items pertaining to the severity of respiratory symptoms in the preceding 4 weeks; part 2 consists of 42 items related to the daily activity and psychosocial impacts of the individual's respiratory condition. The total score indicates the impact of disease on overall health status. This total score is expressed as a percentage of overall impairment, in which 100 represents the worst possible health status and 0 indicates the best possible health status.

End point type	Secondary
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End point timeframe:

Baseline to Week 28

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	26		
Units: Scale of score				
arithmetic mean (standard deviation)	-22.09 (± 24.04)	-6.14 (± 24.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in fractional exhaled nitric oxide (FeNO) at Week 28

End point title	Change from baseline in fractional exhaled nitric oxide (FeNO) at Week 28
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End point description:

Change from baseline in fractional exhaled nitric oxide (FeNO) at Week 28.

End point type	Secondary
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End point timeframe:

Baseline to Week 28

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	30		
Units: ppb				
arithmetic mean (standard deviation)	-14.0 (± 27.0)	2.0 (± 21.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in total serum immunoglobulin E (IgE) at Week 28

End point title	Change from baseline in total serum immunoglobulin E (IgE) at Week 28
End point description: Change from baseline in total serum IgE at Week 28.	
End point type	Secondary
End point timeframe: Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	30		
Units: IU/mL				
arithmetic mean (standard deviation)	-50.006 ($\pm$ 520.663)	-8.107 ($\pm$ 195.584)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in peripheral blood eosinophils at Week 28

End point title	Change from baseline in peripheral blood eosinophils at Week 28
End point description: Change from baseline in blood eosinophil counts at Week 28.	
End point type	Secondary
End point timeframe: Baseline to Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	25		
Units: cells/ μ L				
arithmetic mean (standard deviation)	-112.9 ($\pm$ 314.2)	-79.2 ($\pm$ 279.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Serum trough concentrations at Week 0, 12 and 28

End point title	PK: Serum trough concentrations at Week 0, 12 and 28
End point description: Pharmacokinetics samples are collected at baseline and at Week 12 prior to study intervention administration, and at Week 28 (End of Treatment visit).	
End point type	Secondary
End point timeframe: Baseline, Week 12 and Week 28	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	0 ^[1]		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Week 0	0 (± 0)	()		
Week 12	18.371 (± 50.59)	()		
Week 28	19.849 (± 55.23)	()		

Notes:

[1] - The placebo arm is not applicable since it is not the experimental product.

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity: Incidence of anti-drug antibodies (ADA) at Week 0, 12, 28, and 40

End point title	Immunogenicity: Incidence of anti-drug antibodies (ADA) at Week 0, 12, 28, and 40
End point description: Immunogenicity samples are collected at baseline and at Week 12 prior to study intervention administration, at Week 28 (End of Treatment visit) and at Week 40 (Follow-up visit). Persistently positive is defined as positive at ≥ 2 post baseline assessments (with ≥ 16 weeks between the first and the last positive) or positive at last post baseline assessment. Transiently positive is defined as having at least one post baseline ADA positive assessment and not fulfilling the conditions of persistently positive. Treatment boosted ADA defined as baseline positive ADA that was boosted to a 4 fold or higher level following treatment. Treatment emergent ADA defined as sum of treatment induced ADA and treatment boosted ADA.	
End point type	Secondary
End point timeframe: Baseline to Week 40	

End point values	Tezepelumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	39		
Units: Participants				
ADA positive at baseline and/or post-baseline	6	2		
TE-ADA positive	3	1		
Treatment-induced ADA positive	3	1		
Treatment-boosted ADA positive	0	0		
Non-TE-ADA positive	3	1		
Both baseline and post-baseline positive	0	0		
Only baseline positive	3	1		
ADA persistently positive	2	0		
ADA transiently positive	1	1		
nAb positive at baseline and/or post-baseline	1	0		
Treatment-induced nAb positive	1	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until end of study or withdrawal date.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo administered every 4 weeks subcutaneously

Reporting group title	Tezepelumab
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Reporting group description:

Tezepelumab 210 mg administered every 4 weeks subcutaneously

Serious adverse events	Placebo	Tezepelumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 39 (12.82%)	7 / 83 (8.43%)	
number of deaths (all causes)	1	2	
number of deaths resulting from adverse events	1	2	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Meningioma			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest			

subjects affected / exposed	1 / 39 (2.56%)	0 / 83 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General disorders and administration site conditions			
Sudden cardiac death			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	3 / 39 (7.69%)	2 / 83 (2.41%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Tracheobronchitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 83 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Soft tissue infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 83 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Non-serious adverse events	Placebo	Tezepelumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 39 (53.85%)	33 / 83 (39.76%)	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 39 (2.56%)	3 / 83 (3.61%)	
occurrences (all)	1	3	
Limb injury			
subjects affected / exposed	0 / 39 (0.00%)	3 / 83 (3.61%)	
occurrences (all)	0	3	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 39 (0.00%)	3 / 83 (3.61%)	
occurrences (all)	0	3	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 39 (10.26%)	2 / 83 (2.41%)	
occurrences (all)	5	2	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 39 (0.00%)	3 / 83 (3.61%)	
occurrences (all)	0	3	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 39 (5.13%)	1 / 83 (1.20%)	
occurrences (all)	2	1	
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 39 (10.26%)	2 / 83 (2.41%)	
occurrences (all)	4	2	
Nasopharyngitis			
subjects affected / exposed	7 / 39 (17.95%)	11 / 83 (13.25%)	
occurrences (all)	8	12	
Oral candidiasis			
subjects affected / exposed	2 / 39 (5.13%)	3 / 83 (3.61%)	
occurrences (all)	2	4	
Pharyngitis			

subjects affected / exposed	1 / 39 (2.56%)	3 / 83 (3.61%)	
occurrences (all)	1	3	
Upper respiratory tract infection			
subjects affected / exposed	3 / 39 (7.69%)	7 / 83 (8.43%)	
occurrences (all)	6	8	
Urinary tract infection			
subjects affected / exposed	2 / 39 (5.13%)	5 / 83 (6.02%)	
occurrences (all)	2	5	
Sinusitis			
subjects affected / exposed	2 / 39 (5.13%)	2 / 83 (2.41%)	
occurrences (all)	2	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 August 2022	The main reasons for this amendment include: a) Adding assessment of the pre-specified events by the Independent Adjudication Committee to the study design, b) Removing the requirement of pre-BD FEV1 spirometry for participants who achieve a permanent stop of OCS dose reduction, except for the mandatory spirometry at visits 6, 7, 8, 10, 13 regardless of OCS dose reduction status and revising statistical analyses for secondary endpoints, c) Revising restrictions for COVID-19 vaccination, d) Adding important potential risks and adverse event of special interest (serious cardiac events), e) Revising the estimand for the intercurrent events related to the initiation of other biologic for treatment of asthma. Other reasons include updating wording of the asthma exacerbation definition, as well as, adding clinical chemistry test of blood lipid panel at Visit 1 and 12-lead ECG assessment at Visit 13 and IPD.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported