



Clinical trial results:

A Multicenter, Single-arm, Open-label, Post-Authorization, Phase 4 Effectiveness and Safety Study of Tezepelumab in Adult and Adolescent Participants with Severe Asthma including Several Under-Studied Populations in the United States

Summary

EudraCT number	2026-000081-25
Trial protocol	Outside EU/EEA
Global end of trial date	01 October 2025

Results information

Result version number	v1 (current)
This version publication date	12 April 2026
First version publication date	12 April 2026

Trial information

Trial identification

Sponsor protocol code	D5180C00032
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05329194
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	AstraZeneca AB, Södertälje, Sweden, 151 85
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 January 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2025
Global end of trial reached?	Yes
Global end of trial date	01 October 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe asthma exacerbations in the 12-month periods before (baseline period) and after initiation of tezepelumab (study period).

Protection of trial subjects:

This study was performed in accordance with the relevant International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines - which are based on the ethical principles originating from the Declaration of Helsinki and applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 April 2022
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	United States: 286
Worldwide total number of subjects	286
EEA total number of subjects	0

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)	19
Adults (18-64 years)	190
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted from 29 April 2022 (first subject first visit) to 01 October 2025 (last subject last visit) at 32 study sites in the United States of America (USA).

Pre-assignment

Screening details:

Subjects who met the inclusion criteria and none of the exclusion criteria were enrolled to the study. All study assessments were performed as per the schedule of activities.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Tezepelumab
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Arm description:

Subjects received 210 mg of tezepelumab every 4 weeks (Q4W) from Week 0 until Week 48.

Arm type	Experimental
Investigational medicinal product name	Tezepelumab
Investigational medicinal product code	
Other name	AMG 157 or MEDI9929
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Tezepelumab was administered as a subcutaneous injection every 4 weeks from Week 0 until Week 48.

Number of subjects in period 1	Tezepelumab
Started	286
Completed	255
Not completed	31
Consent withdrawn by subject	16
Death	2
Other	5
Lost to follow-up	6
Development of study-specific withdrawal criteria	2

Baseline characteristics

Reporting groups

Reporting group title	Tezepelumab
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Reporting group description:

Subjects received 210 mg of tezepelumab every 4 weeks (Q4W) from Week 0 until Week 48.

Reporting group values	Tezepelumab	Total	
Number of subjects	286	286	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	19	19	
Adults (18-64 years)	190	190	
From 65-84 years	77	77	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	52.9		
standard deviation	± 16.2	-	
Gender categorical			
Units: Subjects			
Female	186	186	
Male	100	100	
Race (NIH/OMB)			
For single subjects of a particular race, the data has been reported as 'Other' to maintain subject's confidentiality.			
Units: Subjects			
White	204	204	
Black or African American	63	63	
Asian	8	8	
Native Hawaiian or Other Pacific Islander	0	0	
American Indian or Alaska Native	4	4	
Multiple	0	0	
Not reported	2	2	
Other	5	5	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	27	27	
Not Hispanic or Latino	259	259	

End points

End points reporting groups

Reporting group title	Tezepelumab
Reporting group description:	
Subjects received 210 mg of tezepelumab every 4 weeks (Q4W) from Week 0 until Week 48.	

Primary: Annualized asthma exacerbation rate (AAER)

End point title	Annualized asthma exacerbation rate (AAER) ^[1]
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End point description:

Asthma exacerbations were defined by worsening of asthma symptoms that leads to temporary bolus/burst of systemic corticosteroids for at least 3 consecutive days, or an emergency department (ED) or urgent care visit due to asthma that required systemic corticosteroid (SCS), and/or inpatient hospitalization (≥ 24 hours) due to asthma. The AAER was based on exacerbations reported by the investigator over 52 weeks.

The exacerbation rate was compared between the 12-month period before [baseline period (BP)] and the 12-month period after initiation of tezepelumab [up to study Week 52 (Visit 15) - study period (SP)].

Full analysis set (FAS) included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Primary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis was exploratory for this study and hence it has not been presented in the results form.

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Adjusted rate (exacerbations per year)				
number (confidence interval 95%)				
Baseline Period	2.8783 (2.69 to 3.08)			
Study Period	0.8665 (0.71 to 1.05)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects who completed the 52 -week study period with any reduction in total number of asthma exacerbations

End point title	Number of subjects who completed the 52 -week study period with any reduction in total number of asthma exacerbations
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End point description:

The number of subjects who completed the 52 -week study period following tezepelumab initiation with at least 50% reduction, and 100% reduction in total number of asthma exacerbations were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

From Baseline period (Week -52 to Week 0) to Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
At least 50% reduction	209			
100% reduction	148			

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative asthma exacerbation days

End point title	Cumulative asthma exacerbation days
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End point description:

The cumulative asthma exacerbation days over 52 weeks before (baseline period) and after initiation of tezepelumab (study period) was assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Days				
number (not applicable)				
Baseline Period	8855			
Study Period	2326			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with asthma exacerbations

End point title	Number of subjects with asthma exacerbations
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End point description:

The number of subjects with at least one asthma exacerbation in the 12-month period before (baseline period) and after initiation of tezepelumab (study period) (up to study Week 52 - study period) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Baseline Period	285			
Study Period	120			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first asthma exacerbation

End point title	Time to first asthma exacerbation
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End point description:

The time to first exacerbation after initiation of tezepelumab was assessed.

Data for median time to event have been presented for this endpoint. The median is the descriptive statistics median calculated using a subset of subjects with an event.

For this endpoint, 'median' was selected as the measure type, for which a precision/dispersion value is not applicable. However, due to a limitation in the EudraCT tool, a precision/dispersion type must be selected. To resolve the validation error, 'standard deviation' was chosen and an arbitrary value of '9999' was entered to indicate that no precision/dispersion data are available.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

Visit8 = 6 months; Visit15 = 12 months

End point type	Secondary
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End point timeframe:

Baseline (Week 0) to Week 24 (Visit 8 = 6 months) and Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Days				
median (standard deviation)				
Visit8	61 (± 9999)			
Visit15	102 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of asthma exacerbations associated with hospitalizations

End point title	Rate of asthma exacerbations associated with hospitalizations
End point description:	
The rate of asthma exacerbations associated with hospitalization over 52 weeks before (baseline period) and after initiation of tezepelumab (study period) were assessed.	
FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.	
End point type	Secondary
End point timeframe:	
Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Adjusted rate (exacerbations per year)				
number (confidence interval 95%)				
Study Period	0.0364 (0.02 to 0.08)			
Baseline Period	0.1714 (0.12 to 0.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of asthma exacerbations associated with hospitalizations or ED/UC visits

End point title	Rate of asthma exacerbations associated with hospitalizations or ED/UC visits
End point description:	
The rate of asthma exacerbations associated with hospitalizations or ED/UC visits over 52 weeks before (baseline period) and after initiation of tezepelumab (study period) was assessed.	

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
End point timeframe:	
Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Adjusted rate (exacerbations per year)				
number (confidence interval 95%)				
Study Period	0.1647 (0.11 to 0.24)			
Baseline Period	0.6807 (0.55 to 0.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of asthma exacerbations associated with emergency department /urgent care (ED/UC) visits

End point title	Rate of asthma exacerbations associated with emergency department /urgent care (ED/UC) visits
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End point description:

The rate of asthma exacerbations associated with ED/UC visits over 52 weeks before (baseline period) and after initiation of tezepelumab (study period) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
End point timeframe:	
Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Adjusted rate (exacerbations per year)				
number (confidence interval 95%)				
Study Period	0.1568 (0.11 to 0.23)			
Baseline Period	0.6771 (0.55 to 0.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with asthma exacerbations associated with hospitalizations or ED/UC visits

End point title	Number of subjects with asthma exacerbations associated with hospitalizations or ED/UC visits
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End point description:

The number of subjects with asthma exacerbations associated with hospitalizations or ED/UC visits in the 12-month periods before (baseline period) and after initiation of tezepelumab (study period) (up to study Week 52) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Baseline Period	102			
Study Period	34			

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative asthma exacerbation days associated with hospitalizations or ED/UC visits

End point title	Cumulative asthma exacerbation days associated with hospitalizations or ED/UC visits
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End point description:

The cumulative asthma exacerbation days associated with hospitalizations or ED/UC over 52 weeks before (baseline period) and after initiation of tezepelumab (study period) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

Total days of exacerbations resulting in hospitalizations or ED/UC visits have been presented.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Days				
number (not applicable)				
Baseline Period	2518			
Study Period	517			

Statistical analyses

No statistical analyses for this end point

Secondary: Pre-bronchodilator (pre-BD) forced expiratory volume in 1 second (FEV1)

End point title	Pre-bronchodilator (pre-BD) forced expiratory volume in 1 second (FEV1)
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End point description:

Lung function (FEV1) was measured pre-bronchodilator (pre-BD) by spirometry test. FEV1 is defined as the volume of air exhaled from the lungs in the first second of a forced expiration. Here, 'n' in each row represents number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0), Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	285			
Units: Litre (L)				
arithmetic mean (standard deviation)				
Baseline n=285	2.160 (± 0.735)			
Visit 8 n=264	2.257 (± 0.776)			
Visit 15 n=223	2.281 (± 0.743)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in pre-bronchodilator FEV1

End point title	Change from baseline in pre-bronchodilator FEV1
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End point description:

Change from baseline in pre-bronchodilator FEV1 was assessed after initiation of tezepelumab. FEV1 is defined as the volume of air exhaled from the lungs in the first second of a forced expiration. Here, 'n' in each row represents number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) to Week 24 (Visit 8 = 6 months) and Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	263			
Units: Litre (L)				
arithmetic mean (standard deviation)				
Change from baseline: Visit 8 n=263	0.113 (± 0.361)			
Change from baseline: Visit 15 n=222	0.111 (± 0.403)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of pre-BD FEV1 responders

End point title	Number of pre-BD FEV1 responders
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End point description:

Number of pre-BD FEV1 responders was defined as subjects who achieved either at least 5% or 100 mL improvement from baseline.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Visit8 n=286	128			
Visit15 n=286	107			

Statistical analyses

No statistical analyses for this end point

Secondary: Asthma Control Questionnaire (ACQ-6)

End point title	Asthma Control Questionnaire (ACQ-6)
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End point description:

The ACQ-6 is a shortened version of the ACQ that assesses the adequacy of asthma control and change in asthma control which occurs spontaneously or as a result of treatment. ACQ assesses symptoms and rescue bronchodilator use.

Questions are weighted equally and scored from 0 (totally controlled) to 6 (severely uncontrolled). The mean (average) ACQ-6 score is the mean of the responses.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0), Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	280			
Units: Average Score				
arithmetic mean (standard deviation)				
Baseline n=280	2.3863 ($\pm$ 1.1588)			
Visit8 n=262	1.2971 ($\pm$ 1.0078)			
Visit15 n=222	1.1291 ($\pm$ 1.0164)			

Statistical analyses

No statistical analyses for this end point

Secondary: Asthma Impairment and Risk Questionnaire (AIRQ)

End point title	Asthma Impairment and Risk Questionnaire (AIRQ)
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End point description:

The Asthma Impairment and Risk Questionnaire (AIRQ) is a PRO tool intended to identify subjects 12 years and older whose health may be at risk because of uncontrolled asthma. It has 10 questions that ask about respiratory symptoms, activity limitation, sleep, rescue medication use, social activities, exercise, difficulty controlling asthma, and exacerbations. All items have a yes/no response option and the tool is scored by summing the total number of 'yes' responses. This sum score is used to assess level of asthma control where: 0-1 is well controlled, 2-4 is not well controlled, and 5-10 is very poorly controlled. Thus, a higher score indicates worse control status. Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
End point timeframe:	
Baseline (Week 0), Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	280			
Units: Sum Score				
arithmetic mean (standard deviation)				
Baseline n=280	5.1 (± 2.5)			
Visit8 n=262	2.3 (± 2.4)			
Visit15 n=222	2.2 (± 2.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: St. George's Respiratory Questionnaire (SGRQ)

End point title	St. George's Respiratory Questionnaire (SGRQ)
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End point description:

SGRQ is a 50-item PRO instrument used to measure health status of subjects with airway obstruction diseases.

Questionnaire has 2 parts: part 1 consists of 8 items pertaining to severity of respiratory symptoms in preceding 4 weeks; part 2 consists of 42 items related to daily activity and psychosocial impacts of individual's respiratory condition. SGRQ yields a total score and 3 components scores (symptoms, activity, and impacts). Total score indicates impact of disease on overall health status, and it is expressed as percentage of overall impairment, in which 100 represents worst possible health status and 0 indicates best possible health status. Likewise, domain scores range from 0 to 100, with higher scores indicative of greater impairment.

Here, 'n' in each row represents number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in study.

End point type	Secondary
End point timeframe:	
Baseline (Week 0), Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	280			
Units: Total Score				
arithmetic mean (standard deviation)				
Baseline n=280	52.4219 ($\pm$ 19.9071)			
Visit8 n=262	31.7205 ($\pm$ 21.3066)			
Visit15 n=222	29.9202 ($\pm$ 22.6859)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in AIRQ score

End point title	Change from baseline in AIRQ score
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End point description:

Change from baseline in AIRQ score was assessed.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) to Week 24 (Visit 8 = 6 months) and Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	256			
Units: Sum Score				
arithmetic mean (standard deviation)				
Visit8 n=256	-2.9 ($\pm$ 2.7)			
Visit15 n=219	-2.9 ($\pm$ 2.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in ACQ-6 score

End point title	Change from baseline in ACQ-6 score
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End point description:

Change from baseline in ACQ-6 score was assessed.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) to Week 24 (Visit 8 = 6 months) and Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	256			
Units: Average Score				
arithmetic mean (standard deviation)				
Visit8 n=256	-1.0944 ($\pm$ 1.1486)			
Visit15 n=219	-1.2352 ($\pm$ 1.2540)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in SGRQ score

End point title	Change from baseline in SGRQ score
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End point description:

Change from baseline in SGRQ score was assessed.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) to Week 24 (Visit 8 = 6 months) and Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	256			
Units: Total Score				
arithmetic mean (standard deviation)				
Visit8 n=256	-20.9296 ($\pm$ 19.9668)			
Visit15 n=219	-22.2776 ($\pm$ 22.1774)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of ACQ-6 responders

End point title	Number of ACQ-6 responders
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End point description:

Number of ACQ-6 responders were assessed.

Individual changes from baseline of ≥ 0.5 were considered to be clinically meaningful (minimum clinically important difference [MCID]). ACQ-6 responders in this study were defined as subjects who achieved ≥ 1 MCID.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Visit8 n=286	180			
Visit15 n=286	162			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of SGRQ responders

End point title	Number of SGRQ responders
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End point description:

Number of SGRQ responders were assessed.

Individual changes from baseline of ≥ 4 were considered to be clinically meaningful (MCID). SGRQ (total and component score) responders in this study were defined as subjects who achieved ≥ 1 MCID.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Visit8 n=286	207			
Visit15 n=286	175			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of AIRQ responders

End point title	Number of AIRQ responders
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End point description:

Number of AIRQ responders were assessed.

Individual changes from baseline of ≥ 2 were considered to be clinically meaningful (MCID). AIRQ responders in this study were defined as subjects who achieved ≥ 1 MCID.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Week 24 (Visit 8 = 6 months), Week 52 (Visit 15 = 12 months)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Visit8 n=286	168			
Visit15 n=286	139			

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative annualized SCS dose

End point title	Cumulative annualized SCS dose
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End point description:

Cumulative annualized SCS dose in the 12-month periods before (baseline period) and after initiation of tezepelumab (up to study Week 52- study period) were assessed. Cumulative annualized SCS dose for each subject was calculated as followed:

Cumulative annualized SCS dose = [sum of (cumulative SCS dose)/length of the planned treatment period]*365.25

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their

protocol adherence and continued participation in the study.

End point type	Secondary
End point timeframe:	
Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	279			
Units: Milligram (mg)				
arithmetic mean (standard deviation)				
Baseline Period n=279	3671.704 ($\pm$ 24494.741)			
Study Period n=129	1283.780 ($\pm$ 3983.790)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects who require any systemic corticosteroid (SCS) use

End point title	Number of subjects who require any systemic corticosteroid (SCS) use
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End point description:

Number of subjects who require any SCS use in the 12-month periods before (baseline period) and after initiation of tezepelumab (up to study Week 52 -study period) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
End point timeframe:	
Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Baseline Period	279			
Study Period	129			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects who require longer-term (>30 consecutive days) SCS use

End point title	Number of subjects who require longer-term (>30 consecutive days) SCS use
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End point description:

Number of subjects who require longer-term (>30 consecutive days) SCS use in the 12-month periods before (baseline period) and after initiation of tezepelumab (up to study Week 52- study period) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Baseline Period	22			
Study Period	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and type of asthma-related healthcare resource utilization (HRU)

End point title	Number and type of asthma-related healthcare resource utilization (HRU)
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End point description:

Number of subjects with specific type of asthma-related HRU in the 12-month period before (baseline period) and after initiation of tezepelumab (up to study Week 52- study period) were assessed.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

HRE = Health related event, BP = Baseline Period, SP = Study Period, HIC = Hospitalization intensive care, HGC = Hospitalization general care, HCC = Hospitalization coronary care, ED = Emergency department, HC = Health care, APFT = Advanced pulmonary function test, CT = Computed tomography, HA = Hospital admission, MT = Medical testing

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
BP, Any HREs	211			
SP, Any HREs	166			
BP, Asthma HREs	211			
SP, Asthma HREs	166			
BP, Ambulance transport	6			
SP, Ambulance transport	4			
BP, HIC	11			
SP, HIC	2			
BP, HCC	2			
SP, HCC	3			
BP, HGC	24			
SP, HGC	22			
BP, Urgent care visit	63			
SP, Urgent care visit	46			
BP, Emergency room visit	59			
SP, Emergency room visit	54			
BP HA or ED >24 hours	35			
SP, HA or ED >24 hours	28			
BP, Visit to specialist	188			
SP, Visit to specialist	138			
BP, Visit to primary HC physician	98			
SP, Visit to primary HC physician	71			
BP, Other HC visit	22			
SP, Other HC visit	38			
BP, Home visit physician	0			
SP, Home visit physician	0			
BP, Home visit nurse	2			
SP, Home visit nurse	2			
BP, Home visit other HC	0			
SP, Home visit other HC	3			
BP, Telephone call Physician	34			
SP, Telephone call Physician	41			
BP, Telephone call Nurse	26			
SP, Telephone call Nurse	25			
BP, Telephone call Specialist	66			
SP, Telephone call Specialist	64			
BP, Telephone call Other physician/HC	11			
SP, Telephone call Other physician/HC	26			
BP, MT Spirometry	124			
SP, MT Spirometry	75			
BP, MT APFT	35			
SP, MT APFT	12			
BP, MT Plain chest X-ray	80			
SP, MT Plain chest X-ray	57			
BP, MT CT	48			
SP, MT CT	39			
BP, MT Oxygen initiated	20			

SP, MT Oxygen initiated	10			
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Statistical analyses

No statistical analyses for this end point

Secondary: AAER for asthma exacerbations (subgroups of subjects)

End point title	AAER for asthma exacerbations (subgroups of subjects)
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End point description:

AAER based on asthma exacerbations in the 12-month period before [baseline period (BP)] and after initiation of tezepelumab [up to study Week 52- study period (SP)] was assessed in following subgroups of subjects: Blood eosinophil count (BEC) ≥ 300 cells/microliter; BEC < 300 cells/microliter; With clinically-relevant allergy to perennial aeroallergen; Without clinically-relevant allergy to a perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate chronic obstructive pulmonary disease (COPD); Significant smoking history (≥ 10 pack-years of smoking).
Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

FEIA = Fluorescent Enzyme Immunoassay

PFN = Perennial FEIA negative

PFP = Perennial FEIA positive

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: Adjusted rate (exacerbations per year)				
number (confidence interval 95%)				
Baseline BEC: < 300 SP n=163	0.9751 (0.76 to 1.25)			
Baseline BEC: < 300 BP n=163	2.8092 (2.61 to 3.02)			
Baseline BEC: ≥ 300 SP n=121	0.7142 (0.53 to 0.96)			
Baseline BEC: ≥ 300 BP n=121	2.9865 (2.63 to 3.40)			
All PFN SP n=119	1.0585 (0.80 to 1.40)			
All PFN BP n=119	2.8411 (2.57 to 3.14)			
Any PFP SP n=167	0.7352 (0.57 to 0.95)			
Any PFP BP n=167	2.8939 (2.64 to 3.17)			

Baseline BEC <300 & with all PFN SP n=74	1.2936 (0.92 to 1.81)			
Baseline BEC <300 & with all PFN BP n=74	2.8269 (2.51 to 3.18)			
Baseline BEC <300 & with any PFP SP n=89	0.7345 (0.51 to 1.06)			
Baseline BEC <300 & with any PFP BP n=89	2.8020 (2.55 to 3.08)			
Baseline BEC ≥300 & with all PFN SP n=45	0.7032 (0.45 to 1.10)			
Baseline BEC ≥300 & with all PFN BP n=45	2.8677 (2.41 to 3.41)			
Baseline BEC ≥300 & with any PFP SP n=76	0.7175 (0.49 to 1.06)			
Baseline BEC ≥300 & with any PFP BP n=76	3.0649 (2.56 to 3.67)			
Black or African American SP n=63	0.9007 (0.61 to 1.34)			
Black or African American BP n=63	3.2865 (2.81 to 3.85)			
Adolescents SP n=19	0.6684 (0.34 to 1.30)			
Adolescents BP n=19	2.3218 (1.97 to 2.74)			
Mild to moderate COPD SP n=57	0.9377 (0.60 to 1.46)			
Mild to moderate COPD BP n=57	2.7046 (2.42 to 3.03)			
Baseline smoking status SP n=83	1.0363 (0.74 to 1.46)			
Baseline smoking status BP n=83	2.8811 (2.63 to 3.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of asthma-related hospitalizations

End point title	Duration of asthma-related hospitalizations
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End point description:

Duration of asthma-related hospitalization in the 12-month period before (baseline period) and after initiation of tezepelumab (up to study Week 52-study period) was assessed.

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

Hosp. = Hospitalization

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	31			
Units: Crude rate (days per year)				
number (not applicable)				
Study Period, Hosp. n=25	5.7382			
Baseline Period, Hosp. n=31	4.3374			
Study Period, HIC n=2	3.4928			
Baseline Period, HIC n=11	4.9259			
Study Period, HGC n=22	6.0572			
Baseline Period, HGC n=24	3.2612			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with asthma exacerbations (subgroups of subjects)

End point title	Number of subjects with asthma exacerbations (subgroups of subjects)
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End point description:

The number of subjects with at least one asthma exacerbations in the 12-month period before [baseline period (BP)] and after initiation of tezepelumab [up to study Week 52- study period (SP)] were assessed in the following subgroups of subjects: BEC ≥ 300 cells/microliter; BEC < 300 cells/microliter; With a clinically-relevant allergy to a perennial aeroallergen; Without a clinically-relevant allergy to a perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥ 10 pack-years of smoking). Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	89			
Units: Subjects				
Allergic & BEC ≥ 300 BP n=76	75			
Allergic & BEC ≥ 300 SP n=76	30			
Non-allergic & BEC ≥ 300 BP n=45	45			
Non-allergic & BEC ≥ 300 SP n=45	19			
Allergic & BEC < 300 BP n=89	89			
Allergic & BEC < 300 SP n=89	32			
Non-allergic & BEC < 300 BP n=74	74			
Non-allergic & BEC < 300 SP n=74	37			
Black/African American BP n=63	63			
Black/African American SP n=63	27			

Adolescents BP n=19	19			
Adolescents SP n=19	7			
Mild to moderate COPD BP n=57	57			
Mild to moderate COPD SP n=57	26			
Smokers BP n=83	83			
Smokers SP n=83	38			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects who completed the 52-week study with any reduction in total number of asthma exacerbations (subgroups of subjects)

End point title	Number of subjects who completed the 52-week study with any reduction in total number of asthma exacerbations (subgroups of subjects)
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End point description:

The number of subjects who completed the 52-week study period following tezepelumab initiation with at least 50% reduction, and 100% reduction in total number of asthma exacerbations were assessed in the following subgroups of subjects: BEC ≥ 300 cells/microliter; BEC < 300 cells/microliter; With a clinically-relevant allergy to a perennial aeroallergen; Without a clinically-relevant allergy to a perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥ 10 pack-years of smoking).

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.
red = Reduction

End point type	Secondary
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End point timeframe:

From Baseline period (Week -52 to Week 0) to Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Allergic and BEC ≥ 300 $\geq 50\%$ red	60			
Allergic and BEC ≥ 300 100% red	40			
Non-allergic and BEC ≥ 300 $\geq 50\%$ red	36			
Non-allergic and BEC ≥ 300 100% red	26			
Allergic and BEC < 300 $\geq 50\%$ red	68			
Allergic and BEC < 300 100% red	50			
Non-allergic and BEC < 300 $\geq 50\%$ red	44			
Non-allergic and BEC < 300 100% red	32			
Black/African American $\geq 50\%$ red	44			
Black/African American 100% red	31			
Adolescents $\geq 50\%$ red	14			
Adolescents 100% red	10			
Mild to moderate COPD $\geq 50\%$ red	41			
Mild to moderate COPD 100% red	28			

Smokers ≥50% red	56			
Smokers 100% red	39			

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulative asthma exacerbation days (subgroups of subjects)

End point title	Cumulative asthma exacerbation days (subgroups of subjects)
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End point description:

The cumulative asthma exacerbation days over 52 weeks before [baseline period (BP)] and after initiation of tezepelumab [study period (SP)] were assessed in the following subgroups of subjects: BEC ≥300 cells/microliter; BEC <300 cells/microliter; With a clinically-relevant allergy to a perennial aeroallergen; Without a clinically-relevant allergy to a perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥10 pack-years of smoking).

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	89			
Units: Days				
number (not applicable)				
Allergic and BEC ≥300 BP n=76	2539			
Allergic and BEC ≥300 SP n=76	478			
Non-allergic and BEC ≥300 BP n=45	1230			
Non-allergic and BEC ≥300 SP n=45	291			
Allergic and BEC <300 BP n=89	2735			
Allergic and BEC <300 SP n=89	727			
Non-allergic and BEC <300 BP n=74	2322			
Non-allergic and BEC <300 SP n=74	806			
Black/African American BP n=63	1865			
Black/African American SP n=63	441			
Adolescents BP n=19	425			
Adolescents SP n=19	73			
Mild to moderate COPD BP n=57	1679			
Mild to moderate COPD SP n=57	554			
Smokers BP n=83	2384			
Smokers SP n=83	837			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of asthma exacerbations associated with hospitalizations (subgroups of subjects)

End point title	Rate of asthma exacerbations associated with hospitalizations (subgroups of subjects)
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End point description:

Rate of asthma exacerbations associated with hospitalization over 52 weeks before [baseline period (BP)] and after initiation of tezepelumab [study period (SP)] was assessed in the following subgroups of subjects: BEC ≥ 300 cells/ μ L; BEC < 300 cells/ μ L; With a clinically-relevant allergy to perennial aeroallergen; Without a clinically-relevant allergy to perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥ 10 pack-years of smoking).

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: Crude rate (exacerbations per year)				
number (not applicable)				
Baseline BEC: < 300 SP n=163	0.0663			
Baseline BEC: < 300 BP n=163	0.1925			
Baseline BEC: ≥ 300 SP n=121	0.0000			
Baseline BEC: ≥ 300 BP n=121	0.1420			
All PFN SP n=119	0.0626			
All PFN BP n=119	0.1269			
Any PFP SP n=167	0.0188			
Any PFP BP n=167	0.2006			
Baseline BEC < 300 & with all PFN SP n=74	0.1032			
Baseline BEC < 300 & with all PFN BP n=74	0.1361			
Baseline BEC < 300 & with any PFP SP n=89	0.0361			
Baseline BEC < 300 & with any PFP BP n=89	0.2399			
Baseline BEC ≥ 300 & with all PFN SP n=45	0.0000			

Baseline BEC ≥ 300 & with all PFN BP n=45	0.1118			
Baseline BEC ≥ 300 & with any PFP SP n=76	0.0000			
Baseline BEC ≥ 300 & with any PFP BP n=76	0.1600			
Black or African American SP n=63	0.0343			
Black or African American BP n=63	0.4083			
Adolescents SP n=19	0.0000			
Adolescents BP n=19	0.2685			
mild to moderate COPD SP n=57	0.0555			
mild to moderate COPD BP n=57	0.1958			
Baseline smokers SP n=83	0.0387			
Baseline smokers BP n=83	0.2195			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of asthma exacerbations associated with emergency department/urgent care (ED/UC) visits (subgroups of subjects)

End point title	Rate of asthma exacerbations associated with emergency department/urgent care (ED/UC) visits (subgroups of subjects)
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End point description:

Rate of asthma exacerbations associated with ED/UC visits over 52 weeks before [baseline period (BP)] and after initiation of tezepelumab [study period (SP)] was assessed in following subgroups of subjects: BEC ≥ 300 cells/ μ L; BEC < 300 cells/ μ L; With a clinically-relevant allergy to perennial aeroallergen; Without a clinically-relevant allergy to perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥ 10 pack-years of smoking).

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: Crude rate (exacerbations per year)				
number (not applicable)				
Baseline BEC: < 300 SP n=163	0.2205			
Baseline BEC: < 300 BP n=163	0.6567			
Baseline BEC: ≥ 300 SP n=121	0.0679			
Baseline BEC: ≥ 300 BP n=121	0.6340			
All PFN SP n=119	0.1800			
All PFN BP n=119	0.5706			

Any PFP SP n=167	0.1390			
Any PFP BP n=167	0.7007			
Baseline BEC <300 & with all PFP SP n=74	0.2224			
Baseline BEC <300 & with all PFP BP n=74	0.5997			
Baseline BEC <300 & with any PFP SP n=89	0.2189			
Baseline BEC <300 & with any PFP BP n=89	0.7046			
Baseline BEC ≥300 & with all PFP SP n=45	0.1144			
Baseline BEC ≥300 & with all PFP BP n=45	0.5230			
Baseline BEC ≥300 & with any PFP SP n=76	0.0405			
Baseline BEC ≥300 & with any PFP BP n=76	0.7012			
Black or African American SP n=63	0.2595			
Black or African American BP n=63	1.0795			
Adolescents SP n=19	0.0000			
Adolescents BP n=19	0.4866			
Mild to moderate COPD SP n=57	0.2049			
Mild to moderate COPD BP n=57	0.5630			
Baseline smokers SP n=83	0.1688			
Baseline smokers BP n=83	0.6520			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of asthma exacerbations associated with hospitalizations or ED/UC visits (subgroups of subjects)

End point title	Rate of asthma exacerbations associated with hospitalizations or ED/UC visits (subgroups of subjects)
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End point description:

Rate of asthma exacerbations associated with hospitalizations or ED/UC visits over 52 weeks before [baseline period (BP)] and after initiation of tezepelumab [study period (SP)] was assessed in following subgroups of subjects: BEC ≥300 cells/μL; BEC <300 cells/μL; With clinically-relevant allergy to perennial aeroallergen; Without clinically-relevant allergy to perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥10 pack-years of smoking).

Here, 'n' in each row represents the number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: Crude rate (exacerbations per year)				
number (not applicable)				
Baseline BEC: <300 SP n=163	0.2339			
Baseline BEC: <300 BP n=163	0.6632			
Baseline BEC: ≥300 SP n=121	0.0679			
Baseline BEC: ≥300 BP n=121	0.6340			
All PFN SP n=119	0.1981			
All PFN BP n=119	0.5794			
Any PFP SP n=167	0.1390			
Any PFP BP n=167	0.7007			
Baseline BEC <300 & with all PFN SP n=74	0.2524			
Baseline BEC <300 & with all PFN BP n=74	0.6140			
Baseline BEC <300 & with any PFP SP n=89	0.2189			
Baseline BEC <300 & with any PFP BP n=89	0.7046			
Baseline BEC ≥300 & with all PFN SP n=45	0.1144			
Baseline BEC ≥300 & with all PFN BP n=45	0.5230			
Baseline BEC ≥300 & with any PFP SP n=76	0.0405			
Baseline BEC ≥300 & with any PFP BP n=76	0.7012			
Black or African American SP n=63	0.2595			
Black or African American BP n=63	1.0795			
Adolescents SP n=19	0.0000			
Adolescents BP n=19	0.4866			
Mild to moderate COPD SP n=57	0.2236			
Mild to moderate COPD BP n=57	0.5630			
Baseline smokers SP n=83	0.1819			
Baseline smokers BP n=83	0.6520			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and type of asthma-related HRU (subgroups of subjects)

End point title	Number and type of asthma-related HRU (subgroups of subjects)
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End point description:

Number of subjects with specific type of asthma related HRU in the 12-month period before [baseline period (BP)] and after initiation of tezepelumab [up to study Week 52- study period (SP)] were assessed in the following subgroups of subjects: BEC ≥300 cells/microliter; BEC <300 cells/microliter; With a clinically-relevant allergy to a perennial aeroallergen; Without a clinically-relevant allergy to a perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history (≥10 pack-years of smoking).

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

ER = Emergency Room; Phys = Physician; Prim = Primary; TC = Telephone call

End point type	Secondary
End point timeframe:	
Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)	

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
BP, Baseline BEC<300, Any HRE	121			
SP, Baseline BEC<300, Any HRE	99			
BP, Baseline BEC<300, Asthma HRE	121			
SP, Baseline BEC<300, Asthma HRE	99			
BP, Baseline BEC<300, Ambulance transport	2			
SP, Baseline BEC<300, Ambulance transport	4			
BP, Baseline BEC<300, HIC	7			
SP, Baseline BEC<300, HIC	1			
BP, Baseline BEC<300, HCC	1			
SP, Baseline BEC<300, HCC	1			
BP, Baseline BEC<300, HGC	14			
SP, Baseline BEC<300, HGC	19			
BP, Baseline BEC<300, UC visit	30			
SP, Baseline BEC<300, UC visit	29			
BP, Baseline BEC<300, ER visit	33			
SP, Baseline BEC<300, ER visit	39			
BP, Baseline BEC<300, HA or ED>24hours	22			
SP, Baseline BEC<300, HA or ED>24hours	23			
BP, Baseline BEC<300, Visit to specialist	109			
SP, Baseline BEC<300, Visit to specialist	81			
BP, Baseline BEC<300, Visit to prim HC physician	54			
SP, Baseline BEC<300, Visit to prim HC physician	42			
BP, Baseline BEC<300, Other HC visit	13			
SP, Baseline BEC<300, Other HC visit	27			
BP, Baseline BEC<300, Home visit physician	0			
SP, Baseline BEC<300, Home visit physician	0			
BP, Baseline BEC<300, Home visit nurse	0			
SP, Baseline BEC<300, Home visit nurse	1			
BP, Baseline BEC<300, Home visit other HC	0			
SP, Baseline BEC<300, Home visit other HC	2			
BP, Baseline BEC<300, TC physician	20			

SP, Baseline BEC<300, TC physician	26			
BP, Baseline BEC<300, TC nurse	14			
SP, Baseline BEC<300, TC nurse	15			
BP, Baseline BEC<300, TC specialist	35			
SP, Baseline BEC<300, TC specialist	37			
BP, Baseline BEC<300, TC other physician/HC	6			
SP, Baseline BEC<300, TC, other physician/HC	16			
BP, Baseline BEC<300, MT spirometry	66			
SP, Baseline BEC<300, MT spirometry	43			
BP, Baseline BEC<300, MT APFT	17			
SP, Baseline BEC<300, MT APFT	9			
BP, Baseline BEC<300, MT Plain chest X-ray	48			
SP, Baseline BEC<300, MT Plain chest X-ray	42			
BP, Baseline BEC<300, MT CT	29			
SP, Baseline BEC<300, MT CT	32			
BP, Baseline BEC<300, MT Oxygen initiated	14			
SP, Baseline BEC<300, MT Oxygen initiated	7			
BP, Baseline BEC≥300, Any HRE	89			
SP, Baseline BEC≥300, Any HRE	65			
BP, Baseline BEC≥300, Asthma HRE	89			
SP, Baseline BEC≥300, Asthma HRE	65			
BP, Baseline BEC≥300, Ambulance transport	4			
SP, Baseline BEC≥300, Ambulance transport	0			
BP, Baseline BEC≥300, HIC	4			
SP, Baseline BEC≥300, HIC	1			
BP, Baseline BEC≥300, HCC	1			
SP, Baseline BEC≥300, HCC	2			
BP, Baseline BEC≥300, HGC	10			
SP, Baseline BEC≥300, HGC	3			
BP, Baseline BEC≥300, UC visit	32			
SP, Baseline BEC≥300, UC visit	16			
BP, Baseline BEC≥300, ER visit	26			
SP, Baseline BEC≥300, ER visit	15			
BP, Baseline BEC≥300, HA or ED>24hours	13			
SP, Baseline BEC≥300, HA or ED>24hours	5			
BP, Baseline BEC≥300, Visit to specialist	78			
SP, Baseline BEC≥300, Visit to specialist	55			
BP, Baseline BEC≥300, Visit to prim HC physician	44			
SP, Baseline BEC≥300, Visit to prim HC physician	28			
BP, Baseline BEC≥300, Other HC visit	9			
SP, Baseline BEC≥300, Other HC visit	11			
BP, Baseline BEC≥300, Home visit physician	0			

SP, Baseline BEC≥300, Home visit physician	0			
BP, Baseline BEC≥300, Home visit nurse	2			
SP, Baseline BEC≥300, Home visit nurse	1			
BP, Baseline BEC≥300, Home visit other HC	0			
SP, Baseline BEC≥300, Home visit other HC	1			
BP, Baseline BEC≥300, TC physician	14			
SP, Baseline BEC≥300, TC physician	14			
BP, Baseline BEC≥300, TC nurse	12			
SP, Baseline BEC≥300, TC nurse	10			
BP, Baseline BEC≥300, TC specialist	31			
SP, Baseline BEC≥300, TC specialist	25			
BP, Baseline BEC≥300, TC other physician/HC	5			
SP, Baseline BEC≥300, TC other physician/HC	10			
BP, Baseline BEC≥300, MT spirometry	58			
SP, Baseline BEC≥300, MT spirometry	31			
BP, Baseline BEC≥300, MT APFT	18			
SP, Baseline BEC≥300, MT APFT	3			
BP, Baseline BEC≥300, MT Plain chest X-ray	31			
SP, Baseline BEC≥300, MT Plain chest X-ray	14			
BP, Baseline BEC≥300, MT CT	18			
SP, Baseline BEC≥300, MT CT	7			
BP, Baseline BEC≥300, MT Oxygen initiated	6			
SP, Baseline BEC≥300, MT Oxygen initiated	3			
BP, All PFN, Any HRE	88			
SP, All PFN, Any HRE	73			
BP, All PFN, Asthma HRE	88			
SP, All PFN, Asthma HRE	73			
BP, All PFN, Ambulance transport	1			
SP, All PFN, Ambulance transport	1			
BP, All PFN, HIC	2			
SP, All PFN, HIC	0			
BP, All PFN, HCC	0			
SP, All PFN, HCC	0			
BP, All PFN, HGC	8			
SP, All PFN, HGC	11			
BP, All PFN, UC visit	25			
SP, All PFN, UC visit	25			
BP, All PFN, ER visit	20			
SP, All PFN, ER visit	24			
BP, All PFN, HA or ED>24hours	11			
SP, All PFN, HA or ED>24hours	13			
BP, All PFN, Visit to specialist	77			
SP, All PFN, Visit to specialist	57			
BP, All PFN, Visit to prim HC physician	35			
SP, All PFN, Visit to prim HC physician	36			
BP, All PFN, Other HC visit	8			

SP, All PFN, Other HC visit	16			
BP, All PFN, Home visit physician	0			
SP, All PFN, Home visit physician	0			
BP, All PFN, Home visit nurse	0			
SP, All PFN, Home visit nurse	2			
BP, All PFN, Home visit other HC	0			
SP, All PFN, Home visit other HC	2			
BP, All PFN, TC physician	15			
SP, All PFN, TC physician	20			
BP, All PFN, TC nurse	10			
SP, All PFN, TC nurse	14			
BP, All PFN, TC specialist	26			
SP, All PFN, TC specialist	25			
BP, All PFN, TC Other physician/HC	3			
SP, All PFN, Other physician/HC	14			
BP, All PFN, MT spirometry	41			
SP, All PFN, MT spirometry	27			
BP, All PFN, MT APFT	13			
SP, All PFN, MT APFT	7			
BP, All PFN, MT Plain chest X-ray	28			
SP, All PFN, MT Plain chest X-ray	28			
BP, All PFN, MT CT	26			
SP, All PFN, MT CT	24			
BP, All PFN, MT Oxygen initiated	4			
SP, All PFN, MT Oxygen initiated	2			
BP, Any PFP, Any HRE	123			
SP, Any PFP, Any HRE	93			
BP, Any PFP, Asthma HRE	123			
SP, Any PFP, Asthma HRE	93			
BP, Any PFP, Ambulance transport	5			
SP, Any PFP, Ambulance transport	3			
BP, Any PFP, HIC	9			
SP, Any PFP, HIC	2			
BP, Any PFP, HCC	2			
SP, Any PFP, HCC	3			
BP, Any PFP, HGC	16			
SP, Any PFP, HGC	11			
BP, Any PFP, UC visit	38			
SP, Any PFP, UC visit	21			
BP, Any PFP, ER visit	39			
SP, Any PFP, ER visit	30			
BP, Any PFP, HA or ED>24hours	24			
SP, Any PFP, HA or ED>24hours	15			
BP, Any PFP, Visit to specialist	111			
SP, Any PFP, Visit to specialist	81			
BP, Any PFP, Visit to prim HC physician	63			
SP, Any PFP, Visit to prim HC physician	35			
BP, Any PFP, Other HC visit	14			
SP, Any PFP, Other HC visit	22			
BP, Any PFP, Home visit physician	0			
SP, Any PFP, Home visit physician	0			
BP, Any PFP, Home visit nurse	2			

SP, Any PFP, Home visit nurse	0			
BP, Any PFP, Home visit other HC	0			
SP, Any PFP, Home visit other HC	1			
BP, Any PFP, TC physician	19			
SP, Any PFP, TC physician	21			
BP, Any PFP, TC nurse	16			
SP, Any PFP, TC nurse	11			
BP, Any PFP, TC specialist	40			
SP, Any PFP, TC specialist	39			
BP, Any PFP, Other physician/HC	8			
SP, Any PFP, Other physician/HC	12			
BP, Any PFP, MT spirometry	83			
SP, Any PFP, MT spirometry	48			
BP, Any PFP, MT APFT	22			
SP, Any PFP, MT APFT	5			
BP, Any PFP, MT Plain chest X-ray	52			
SP, Any PFP, MT Plain chest X-ray	29			
BP, Any PFP, MT CT	22			
SP, Any PFP, MT CT	15			
BP, Any PFP, MT Oxygen initiated	16			
SP, Any PFP, MT Oxygen initiated	8			
BP, Black/African American, Any HRE	47			
SP, Black/African American, Any HRE	40			
BP, Black/African American, Asthma HRE	47			
SP, Black/African American, Asthma HRE	40			
BP, Black/African American, Ambulance transport	4			
SP, Black/African American, Ambulance transport	3			
BP, Black/African American, HIC	4			
SP, Black/African American, HIC	0			
BP, Black/African American, HCC	1			
SP, Black/African American, HCC	2			
BP, Black/African American, HGC	16			
SP, Black/African American, HGC	8			
BP, Black/African American, UC visit	15			
SP, Black/African American, UC visit	11			
BP, Black/African American, ER visit	28			
SP, Black/African American, ER visit	16			
BP, Black/African American, HA or ED>24hours	18			
SP, Black/African American, HA or ED>24hours	10			
BP, Black/African American, Visit to specialist	42			
SP, Black/African American, Visit to specialist	34			
BP, Black/African American, Visit to primary HC phys	25			
SP, Black/African American, Visit to primary HC phys	17			
BP, Black/African American, Other HC visit	8			

SP, Black/African American, Other HC visit	9			
BP, Black/African American, Home visit physician	0			
SP, Black/African American, Home visit physician	0			
BP, Black/African American, Home visit nurse	2			
SP, Black/African American, Home visit nurse	0			
BP, Black/African American, Home visit other HC	0			
SP, Black/African American, Home visit other HC	1			
BP, Black/African American, TC physician	10			
SP, Black/African American, TC physician	13			
BP, Black/African American, TC nurse	9			
SP, Black/African American, TC nurse	4			
BP, Black/African American, TC specialist	17			
SP, Black/African American, TC specialist	12			
BP, Black/African American, TC other physician/HC	5			
SP, Black/African American, TC other physician/HC	7			
BP, Black/African American, MT spirometry	34			
SP, Black/African American, MT spirometry	24			
BP, Black/African American, MT APFT	12			
SP, Black/African American, MT APFT	2			
BP, Black/African American, MT Plain chest X-ray	28			
SP, Black/African American, MT Plain chest X-ray	16			
BP, Black/African American, MT CT	9			
SP, Black/African American, MT CT	7			
BP, Black/African American, MT Oxygen initiated	9			
SP, Black/African American, MT Oxygen initiated	3			
BP, Adolescents, Any HRE	12			
SP, Adolescents, Any HRE	7			
BP, Adolescents, Asthma HRE	12			
SP, Adolescents, Asthma HRE	7			
BP, Adolescents, Ambulance transport	0			
SP, Adolescents, Ambulance transport	0			
BP, Adolescents, HIC	2			
SP, Adolescents, HIC	1			
BP, Adolescents, HCC	0			
SP, Adolescents, HCC	0			
BP, Adolescents, HGC	1			
SP, Adolescents, HGC	1			
BP, Adolescents, UC visit	3			
SP, Adolescents, UC visit	1			

BP, Adolescents, ER visit	4			
SP, Adolescents, ER visit	1			
BP, Adolescents, HA or ED>24hours	3			
SP, Adolescents, HA or ED>24hours	1			
BP, Adolescents, Visit to specialist	9			
SP, Adolescents, Visit to specialist	6			
BP, Adolescents, Visit to prim HC physician	7			
SP, Adolescents, Visit to prim HC physician	1			
BP, Adolescents, Other HC visit	0			
SP, Adolescents, Other HC visit	0			
BP, Adolescents, Home visit physician	0			
SP, Adolescents, Home visit physician	0			
BP, Adolescents, Home visit nurse	0			
SP, Adolescents, Home visit nurse	0			
BP, Adolescents, Home visit other HC	0			
SP, Adolescents, Home visit other HC	0			
BP, Adolescents, TC pnphysician	0			
SP, Adolescents, TC physician	2			
BP, Adolescents, TC nurse	1			
SP, Adolescents, TC nurse	0			
BP, Adolescents, TC specialist	1			
SP, Adolescents, TC specialist	4			
BP, Adolescents, TC other physician/HC	0			
SP, Adolescents, TC other physician/HC	0			
BP, Adolescents, MT spirometry	10			
SP, Adolescents, MT spirometry	2			
BP, Adolescents, MT APFT	3			
SP, Adolescents, MT APFT	1			
BP, Adolescents, MT Plain chest X-ray	2			
SP, Adolescents, MT Plain chest X-ray	1			
BP, Adolescents, MT CT	0			
SP, Adolescents, MT CT	0			
BP, Adolescents, MT Oxygen initiated	2			
SP, Adolescents, MT Oxygen initiated	1			
BP, mild to moderate COPD, Any HRE	42			
SP, mild to moderate COPD, Any HRE	35			
BP, mild to moderate COPD, Asthma HRE	42			
SP, mild to moderate COPD, Asthma HRE	35			
BP, mild to moderate COPD, Ambulance transport	1			
SP, mild to moderate COPD, Ambulance transport	2			
BP, mild to moderate COPD, HIC	2			
SP, mild to moderate COPD, HIC	0			
BP, mild to moderate COPD, HCC	2			
SP, mild to moderate COPD, HCC	2			
BP, mild to moderate COPD, HGC	6			
SP, mild to moderate COPD, HGC	8			
BP, mild to moderate COPD, UC visit	15			
SP, mild to moderate COPD, UC visit	11			

BP, mild to moderate COPD, ER visit	12			
SP, mild to moderate COPD, ER visit	15			
BP, mild to moderate COPD, HA or ED>24hours	6			
SP, mild to moderate COPD, HA or ED>24hours	10			
BP, mild to moderate COPD, Visit to specialist	36			
SP, mild to moderate COPD, Visit to specialist	31			
BP, mild to moderate COPD, Visit to prim HC phys	17			
SP, mild to moderate COPD, Visit to prim HC phys	18			
BP, mild to moderate COPD, Other HC visit	9			
SP, mild to moderate COPD, Other HC visit	12			
BP, mild to moderate COPD, Home visit physician	0			
SP, mild to moderate COPD, Home visit physician	0			
BP, mild to moderate COPD, Home visit nurse	0			
SP, mild to moderate COPD, Home visit nurse	1			
BP, mild to moderate COPD, Home visit other HC	0			
SP, mild to moderate COPD, Home visit other HC	2			
BP, mild to moderate COPD, TC physician	8			
SP, mild to moderate COPD, TC physician	10			
BP, mild to moderate COPD, TC nurse	2			
SP, mild to moderate COPD, TC nurse	6			
BP, mild to moderate COPD, TC specialist	8			
SP, mild to moderate COPD, TC specialist	12			
BP, mild to moderate COPD, TC other physician/HC	2			
SP, mild to moderate COPD, TC other physician/HC	9			
BP, mild to moderate COPD, MT spirometry	21			
SP, mild to moderate COPD, MT spirometry	17			
BP, mild to moderate COPD, MT APFT	7			
SP, mild to moderate COPD, MT APFT	2			
BP, mild to moderate COPD, MT Plain chest X-ray	17			
SP, mild to moderate COPD, MT Plain chest X-ray	22			
BP, mild to moderate COPD, MT CT	13			
SP, mild to moderate COPD, MT CT	13			
BP, mild to moderate COPD, MT Oxygen initiated	7			
SP, mild to moderate COPD, MT Oxygen initiated	5			

BP, Baseline Smokers, Any HRE	58			
SP, Baseline Smokers, Any HRE	51			
BP, Baseline Smokers, Asthma HRE	58			
SP, Baseline Smokers, Asthma HRE	51			
BP, Baseline Smokers, Ambulance transport	0			
SP, Baseline Smokers, Ambulance transport	2			
BP, Baseline Smokers, HIC	5			
SP, Baseline Smokers, HIC	0			
BP, Baseline Smokers, HCC	2			
SP, Baseline Smokers, HCC	2			
BP, Baseline Smokers, HGC	7			
SP, Baseline Smokers, HGC	7			
BP, Baseline Smokers, UC visit	24			
SP, Baseline Smokers, UC visit	17			
BP, Baseline Smokers, ER visit	16			
SP, Baseline Smokers, ER visit	21			
BP, Baseline Smokers, HA or ED>24hours	9			
SP, Baseline Smokers, HA or ED>24 hours	10			
BP, Baseline Smokers, Visit to specialist	49			
SP, Baseline Smokers, Visit to specialist	44			
BP, Baseline Smokers, Visit to prim HC physician	24			
SP, Baseline Smokers, Visit to prim HC physician	24			
BP, Baseline Smokers, Other HC visit	7			
SP, Baseline Smokers, Other HC visit	14			
BP, Baseline Smokers, Home visit physician	0			
SP, Baseline Smokers, Home visit physician	0			
BP, Baseline Smokers, Home visit nurse	0			
SP, Baseline Smokers, Home visit nurse	1			
BP, Baseline Smokers, Home visit other HC	0			
SP, Baseline Smokers, Home visit other HC	2			
BP, Baseline Smokers, TC physician	13			
SP, Baseline Smokers, TC physician	17			
BP, Baseline Smokers, TC nurse	9			
SP, Baseline Smokers, TC nurse	9			
BP, Baseline Smokers, TC specialist	19			
SP, Baseline Smokers, TC specialist	21			
BP, Baseline Smokers, TC Other physician/HC	2			
SP, Baseline Smokers, TC Other physician/HC	9			
BP, Baseline Smokers, MT spirometry	26			
SP, Baseline Smokers, MT spirometry	24			
BP, Baseline Smokers, MT APFT	6			
SP, Baseline Smokers, MT APFT	2			
BP, Baseline Smokers, MT Plain chest X-ray	25			

SP, Baseline Smokers, MT Plain chest X-ray	27			
BP, Baseline Smokers, MT CT	18			
SP, Baseline Smokers, MT CT	19			
BP, Baseline Smokers, MT Oxygen initiated	6			
SP, Baseline Smokers, MT Oxygen initiated	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of asthma-related hospitalizations (subgroups of subjects)

End point title	Duration of asthma-related hospitalizations (subgroups of subjects)
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End point description:

Duration of asthma-related hospitalization in 12-month period before [baseline period (BP)] and after initiation of tezepelumab [up to study Week 52- study period (SP)] was assessed in following subgroups of subjects: BEC $\geq$ 300 cells/ μ L; BEC<300 cells/ μ L; With clinically-relevant allergy to perennial aeroallergen; Without clinically-relevant allergy to perennial aeroallergen; Subjects who identify as Black/African American; Adolescents (12-17 years); Comorbid diagnosis of mild to moderate COPD; Significant smoking history ($\geq$ 10 pack-years of smoking).

Here, 'n' in each row represents number of subjects analyzed for each timepoint.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

Here, 0.9999 indicates that data could not be calculated due to less than 10 subjects in that subgroup or when the subgroup had less than 3 subjects who experienced exacerbation in each population.

End point type	Secondary
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End point timeframe:

Baseline period (Week -52 to Week 0), Study period (Week 0 to Week 52)

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: Crude Rate (days per year)				
number (not applicable)				
SP, Baseline BEC: <300, Hosp. n=20	6.5463			
BP, Baseline BEC: <300, Hosp. n=18	4.9057			
SP, Baseline BEC: <300, HIC	0.9999			
BP, Baseline BEC: <300, HIC	0.9999			
SP, Baseline BEC: <300, HGC n=19	6.6300			
BP, Baseline BEC: <300, HGC n=14	3.2970			
SP, Baseline BEC $\geq$ 300, Hosp. n=5	2.7070			
BP, Baseline BEC $\geq$ 300, Hosp. n=13	3.5506			
SP, Baseline BEC $\geq$ 300, HIC	0.9999			
BP, Baseline BEC $\geq$ 300, HIC	0.9999			
SP, Baseline BEC $\geq$ 300, HGC n=3	2.6136			
BP, Baseline BEC $\geq$ 300, HGC n=10	3.2110			

SP, All PFN, Hosp. n=11	5.6316			
BP, All PFN, Hosp. n=8	2.7594			
SP, All PFN, HIC	0.9999			
BP, All PFN, HIC	0.9999			
SP, All PFN, HGC n=11	5.6316			
BP, All PFN, HGC n=8	2.1323			
SP, Any PFP, Hosp. n=14	5.8273			
BP, Any PFP, Hosp. n=23	4.8863			
SP, Any PFP, HIC n=2	3.4928			
BP, Any PFP, HIC n=9	5.4631			
SP, Any PFP, HGC n=11	6.5206			
BP, Any PFP, HGC n=16	3.8256			
SP, Baseline BEC <300 & with all PFN, Hosp. n=10	5.9877			
BP, Baseline BEC <300 & with all PFN, Hosp. n=5	3.2110			
SP, Baseline BEC <300 & with all PFN, HIC	0.9999			
BP, Baseline BEC <300 & with all PFN, HIC	0.9999			
SP, Baseline BEC <300 & with all PFN, HGC n=10	5.9877			
BP, Baseline BEC <300 & with all PFN, HGC n=5	2.4082			
SP, Baseline BEC ≥300 & with all PFN, Hosp.	0.9999			
BP, Baseline BEC ≥300 & with all PFN, Hosp.	0.9999			
SP, Baseline BEC ≥300 & with all PFN, HIC	0.9999			
BP, Baseline BEC ≥300 & with all PFN, HIC	0.9999			
SP, Baseline BEC ≥300 & with all PFN, HGC	0.9999			
BP, Baseline BEC ≥300 & with all PFN, HGC	0.9999			
SP, Baseline BEC ≥300 & with any PFP, Hosp. n=4	2.8760			
BP, Baseline BEC ≥300 & with any PFP, Hosp. n=10	4.0137			
SP, Baseline BEC ≥300 & with any PFP, HIC	0.9999			
BP, Baseline BEC ≥300 & with any PFP, HIC	0.9999			
SP, Baseline BEC ≥300 & with any PFP, HGC	0.9999			
BP, Baseline BEC ≥300 & with any PFP, HGC	0.9999			
SP, Black/African American, Hosp. n=9	5.5664			
BP, Black/African American, Hosp. n=17	3.6006			
SP, Black/African American, HIC	0.9999			
BP, Black/African American, HIC	0.9999			
SP, Black/African American, HGC n=8	5.9368			
BP, Black/African American, HGC n=16	2.8849			
SP, Adolescents, Hosp.	0.9999			
BP, Adolescents, Hosp.	0.9999			
SP, Adolescents, HIC	0.9999			
BP, Adolescents, HIC	0.9999			

SP, Adolescents, HGC	0.9999			
BP, Adolescents, HGC	0.9999			
SP, mild to moderate COPD, Hosp. n=9	6.6060			
BP, mild to moderate COPD, Hosp. n=7	6.7373			
SP, mild to moderate COPD, HIC	0.9999			
BP, mild to moderate COPD, HIC	0.9999			
SP, mild to moderate COPD, HGC n=8	7.3133			
BP, mild to moderate COPD, HGC n=6	4.1810			
SP, Baseline smokers, Hosp. n=8	9.2988			
BP, Baseline smokers, Hosp. n=10	3.4117			
SP, Baseline smokers, HIC	0.9999			
BP, Baseline smokers, HIC	0.9999			
SP, Baseline smokers, HGC n=7	10.5870			
BP, Baseline smokers, HGC n=7	1.5768			
SP, Baseline BEC <300 & with any PFP, Hosp. n=10	7.1639			
BP, Baseline BEC <300 & with any PFP, Hosp. n=13	5.5575			
SP, Baseline BEC <300 & with any PFP, HIC	0.9999			
BP, Baseline BEC <300 & with any PFP, HIC	0.9999			
SP, Baseline BEC <300 & with any PFP, HGC n=9	7.4268			
BP, Baseline BEC <300 & with any PFP, HGC n=9	3.7908			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of subjects with serious adverse events (SAEs), adverse events that lead to tezepelumab treatment discontinuation (DAEs), and adverse events of special interest (AESIs)

End point title	Number of subjects with serious adverse events (SAEs), adverse events that lead to tezepelumab treatment discontinuation (DAEs), and adverse events of special interest (AESIs)
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End point description:

The safety and tolerability of tezepelumab were assessed. Data for adverse events on-treatment period have been presented.

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

Study intervention = SI

End point type	Other pre-specified
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End point timeframe:

Up to Week 52

End point values	Tezepelumab			
Subject group type	Reporting group			
Number of subjects analysed	286			
Units: Subjects				
Any SAE	28			
Any SAE with outcome of death	1			
Any AE leading to SI discontinuation	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 52

Adverse event reporting additional description:

FAS included all enrolled subjects who received at least 1 dose of tezepelumab, irrespective of their protocol adherence and continued participation in the study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.1
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Reporting groups

Reporting group title	Tezepelumab
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Reporting group description:

Subjects received 210 mg of tezepelumab every 4 weeks (Q4W) from Week 0 until Week 48.

Serious adverse events	Tezepelumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 286 (10.84%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Arterial occlusive disease			

subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Non-cardiac chest pain			
subjects affected / exposed	2 / 286 (0.70%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	6 / 286 (2.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Hallucination, auditory			

subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			

subjects affected / exposed	3 / 286 (1.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth infection			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	4 / 286 (1.40%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Lactic acidosis			

subjects affected / exposed	1 / 286 (0.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Tezepelumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 286 (1.40%)		
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Nervous system disorders			
Neuralgia			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Rash erythematous			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			

Spinal stenosis			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Intervertebral disc degeneration			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Muscle twitching			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Osteoarthritis			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		
Scoliosis			
subjects affected / exposed	1 / 286 (0.35%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 January 2022	Amendment 1, Version 2.0 - PGI-C was removed from Visit 2. - Text was added regarding approval of tezepelumab in the US. - Citation for TEZSPIRE USPI was added. - "Uncontrolled asthma" was changed to "severe asthma", where needed. - Text was added regarding adequate enrollment of patients with comorbid nasal polyps. - "Male or female" subject was added.
12 January 2023	Amendment 2, Version 3.0 - The endpoints (annualized rate of ED/UC visits and hospitalizations) related to the secondary objective on asthma-related HRU were removed. - New secondary objective 'To describe the time to first exacerbation after initiation of tezepelumab' was added. - Clinical remission assessment was removed from the Schedule of Activities. - Weight and height were added to the Schedule of Activities. - Inclusion criterion related to the requirement to complete the full course of COVID-19 vaccination at least 28 days prior to the administration of tezepelumab were removed. - ICF signing requirements for re-screened subjects were updated. - The reporting of device malfunctions in paper form (AstraZeneca Product Complaint Intake form) instead of eCRF was modified. - Text on medical device deficiencies including reporting requirements was added. - A new section was added to explain that 'X-ray, CT scan, and/or FeNO' assessments performed as per routine clinical practice would be collected retrospectively. - 'Serious cardiac events' as one of the AESIs for tezepelumab was added. AESI definition and reporting requirements were updated. - Analysis of SAEs, DAEs and AESIs to include summarization of these events during the on-treatment and on study periods and by causality/relatedness and maximum intensity was updated. - Interim analysis text was updated to remove specific timings, to explain the rationale for interim analysis, to explain that the results of the interim analysis would not result in study design changes. - Table was updated to add additional maintenance therapy options and update total daily doses.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported