Real-World Clinical Outcomes in Patients with Severe Asthma Treated with Tezepelumab: A Retrospective Observational Study of CHRONICLE and ISAR (SYNERGY)

First published: 27/03/2026

Last updated: 27/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000951

Study ID

1000000951

DARWIN EU® study

No

Study countries

Belgium

Brazil

Canada
Germany
Greece
Hungary
Italy
Japan
Mexico
Netherlands
Norway
Poland
Saudi Arabia
Singapore
Spain
Switzerland
United Arab Emirates
United Kingdom
United States

Study description

Aim: Assess the real-world effectiveness of tezepelumab in severe asthma across global routine practice, leveraging the CHRONICLE (US) and ISAR registries to characterize use and clinical outcomes in heterogeneous patient populations.

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

Study Design: This is a multi-country, multi-centre, single-arm, retrospective, observational cohort study in patients with severe asthma who initiated tezepelumab while enrolled in CHRONICLE and ISAR. The index date is the date

of first tezepelumab dose. The baseline period is the 12 months prior to the index date, and the study period is the 12 months after the index date. Patients will be followed from their index date until the earliest of the following: end of study (12 months), switching to a different biologic therapy for asthma, death, or lost to follow-up.

Study status

Ongoing

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Study contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/07/2025

Actual: 11/07/2025

Study start date

Planned: 15/12/2025

Actual: 15/12/2025

Data analysis start date

Planned: 30/04/2026

Date of final study report

Planned: 31/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a multi-country, multi-centre, single-arm, retrospective, observational cohort study in patients with severe asthma who initiated tezepelumab while

enrolled in CHRONICLE and ISAR.

Main study objective:

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

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TEZSPIRE

Study drug International non-proprietary name (INN) or common name

TEZEPELUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX11) tezepelumab

tezepelumab

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Study Population: Patients with severe asthma enrolled in CHRONICLE and ISAR who initiated tezepelumab and meet all the inclusion criteria will be included in this study.

Inclusion Criteria: Enrolled in CHRONICLE or ISAR; Aged ≥18 years at the index date; Received at least one tezepelumab injection; Have medical records available for the ≥6 months preceding the index date; Documented history of ≥1 asthma exacerbation during the 12 months prior to index date

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Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

1000

Study design details

Setting

This is a multi-country, multi-centre, single-arm, retrospective, observational cohort study in patients with severe asthma who initiated tezepelumab while

enrolled in CHRONICLE and ISAR.

CHRONICLE (NCT03373045) is a non-interventional, US-based severe asthma registry that collected data from February 2018 through February 2025. It included adult patients (18 years or older) either receiving biologic therapy or maintenance systemic corticosteroids or who remain uncontrolled despite high-dose inhaled corticosteroids plus additional controllers. Between February 2018 and 2025, CHRONICLE enrolled 4366 evaluable patients with severe asthma from 142 sites, with more than 400 patients having initiated tezepelumab.

The International Severe Asthma Registry (ISAR) is a global collaborative project established to collect ongoing data from patients with severe asthma. To be included in the registry, patients must be at least 18 years of age, visit a participating centre, and have a diagnosis of severe asthma. In addition, patients must provide informed consent for their data to be used in ISAR research. Severe asthma is defined by either persistent uncontrolled symptoms despite optimal therapy or the need for intensive treatment, as described in steps 4 and 5 of the GINA guidelines. Data collection began in January 2018 and is ongoing. ISAR has enrolled 34,649 patients with severe asthma from 29 countries to date, with an estimated 500 non-US patients having initiated tezepelumab.

Comparators

None

Outcomes

Exacerbations – number of asthma exacerbations in the baseline and study periods. The definition of exacerbation is the worsening of asthma that leads to one of the following:

• Use of systemic corticosteroids for 3 days or more or a temporary increase in a stable, background dosage of oral corticosteroids,
• An emergency department or urgent care visit (<24 hours) due to asthma that required SCS, or
• An inpatient admission to hospital (≥24 hours) due to asthma.

Data analysis plan

Annualized asthma exacerbation rate (AAER) for each of these exacerbation classifications will be defined as the total number of exacerbations × 365.25 / total duration of baseline/study (days). Total number of exacerbations and rates will be reported crude. In addition, AAER and 95% confidence intervals (CIs) will be estimated using negative binomial regression (or other appropriate regression). The logarithm of time at risk (follow up time) for an exacerbation during the study will be added as an offset variable. The absolute change in AAER will be reported between the baseline period and study period. The relative change in AAER from index will also be reported for these timepoints. The relative change will be calculated as a ratio, (e.g., 52-week/baseline) and proportion change with 95% CIs based on a negative binomial model.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

International Severe Asthma Registry

Data source(s), other

CHRONICLE

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction