Effectiveness and Safety of Avacopan as Add-on to Standard of Care (SOC) Versus SOC Alone in ANCA-associated Vasculitis (LIBRA) (20240051)

First published: 08/05/2026

Last updated: 08/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000985

Study ID

1000000985

DARWIN EU® study

No

Study countries

United States

Study description

LIBRA is a retrospective, observational comparative effectiveness study designed to assess the real-world effectiveness and safety of avacopan as an add-on to standard of care (SOC) versus SOC alone among adults with newly diagnosed or relapsing granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA). The study uses longitudinal secondary data from US-based closed claims sources, including Optum Market Clarity and Komodo Healthcare Map, and applies a sequential nested trial framework to emulate treatment comparisons in routine clinical practice. The primary objectives are to compare time to first relapse, major adverse kidney events (MAKE) within 12 months, and the proportion of patients achieving a 30-day average prednisone-equivalent daily dose (PEDD) less than or equal to 7.5 mg at prespecified follow-up timepoints. Secondary objectives include glucocorticoid-related complications, relapse incidence by 12 months, individual MAKE components, hepatotoxicity/drug-induced liver injury, and serious hypersensitivity reactions. For hepatotoxicity/drug-induced liver injury and serious hypersensitivity reactions (endpoints with an anticipated low number of events), analyses will be descriptive only; cumulative risk will be estimated by treatment arm, and no between-arm comparative analysis will be conducted. Primary and secondary analyses were prespecified before conduct of the comparative analyses. To support transparency and reduce the potential for bias, the study used a staged analytic process with predefined checkpoints so that any design refinements or protocol modifications were made before the comparative analyses were conducted and were not informed by the comparative analysis results. Analyses are conducted separately in each database using a common prespecified framework and then combined using meta-analytic methods.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/02/2026

Actual: 10/02/2026

Study start date
Planned: 10/02/2026

Actual: 10/02/2026

Data analysis start date
Planned: 17/03/2026

Actual: 13/04/2026

Date of final study report
Planned: 30/12/2027

Sources of funding

- No external funding

Study protocol

Protocol-Published Amendment avacopan 20240051 1 .pdf (667.67 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Study design:

This is a retrospective observational comparative effectiveness cohort study of avacopan + SOC vs SOC with sequential nested trials.

Main study objective:

The main objective of this study is to estimate the real-world effectiveness of avacopan + SOC versus SOC among adults with antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TAVNEOS

Medicinal product name, other

Avacopan

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

AVACOPAN

Anatomical Therapeutic Chemical (ATC) code

(L04) IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Medical condition to be studied

Granulomatosis with polyangiitis

Microscopic polyangiitis

Population studied

Short description of the study population

Adults with newly diagnosed or relapsing GPA/MPA.

Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects

6000

Study design details

Setting

This study will be conducted in multiple real-world data sources, including the Optum Market Clarity database and the Komodo Healthcare Map. Only closed claims will be used for this study. The study period will be from October 1, 2015, to the latest available date. The indexing period will be October 1, 2021, to 3 months prior to the latest available date.

Comparators

Patients starting treatment for new/relapsing GPA/MPA with rituximab (RTX) or cyclophosphamide (CYC).

Outcomes

The primary outcomes of this study are:

1. Time to first relapse.
2. Number of Major Adverse Kidney Events (MAKE) within 12 months (composite endpoint of mortality, dialysis, kidney transplant, end-stage kidney disease).
3. 30-day average prednisone-equivalent daily dose (PEDD) ≤ 7.5mg at 90, 120, 180, 270, and 365 days post- index.

The secondary outcomes of this study are:

1. Incidence of GC-related events within 12 months (composite of serious infection requiring hospitalization, initiation of new class of anti-hyperglycemic medication, major osteoporotic fractures [vertebra, pelvis, humerus, radius/ulna, hip, other femur]).
2. Incidence of relapse within 12 months.
3. Incidence of MAKE components within 12 months:

a. Mortality

b. Dialysis

c. Kidney transplant

d. End-stage kidney disease

4. Incidence within 12 months of hepatotoxicity and drug-induced liver injury, and serious hypersensitivity reactions, including angioedema and anaphylaxis.

Data analysis plan

Analyses will be conducted separately within Optum Market Clarity and Komodo Healthcare Map using the same prespecified analytic framework. Within each database, analyses will proceed in stages with prespecified checkpoints to (a) confirm comparability of treatment groups after weighting, and (b) review of results from negative control outcome analyses. Descriptive analyses will summarize baseline characteristics overall and by treatment group, including disease severity proxies and treatment patterns. After completion of database-specific analyses, estimates from the two databases will be combined using meta-analytic methods.

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.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No