Avacostar - A Post Authorization Safety Study (PASS) to Evaluate the Incidence of Safety Events of Interest in Patients Treated With Avacopan for ANCAassociated Vasculitis (AAV)

First published: 15/06/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS105408

Study ID

106869

DARWIN EU® study

No

Study countries

Germany

United Kingdom

Study description

The Avacostar PASS is a non-interventional, multi-national, prospective cohort study that will collect data from 2 cohorts of patients: those treated with avacopan for active severe AAV, and a second cohort treated with a cyclophosphamide or rituximab-based induction regimen without avacopan for active severe AAV. The overall study duration is anticipated to be up to 7 years, including a recruitment period of approximately 3 years. Enrolled patients will be followed until the last patient last visit (LPLV) milestone, which will be 4 years after the last participant is enrolled.

Study status

Ongoing

Research institutions and networks

Institutions

Vifor Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

charlotte.pollet@viforpharma.com

Primary lead investigator

Charlotte Pollet

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/06/2022

Study start date
Planned: 01/12/2023

Actual: 11/09/2023

Date of final study report
Planned: 31/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Vifor Fresenius Medical Care Renal Pharma Ltd

Study protocol

2023-01-13_PASS_Protocol_CS-AVA-2022_0016_V3.0_Pub.pdf (1.08 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To evaluate the incidence of defined MESIs in patients with AAV commencing avacopan.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TAVNEOS

Medical condition to be studied

Anti-neutrophil cytoplasmic antibody positive vasculitis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

500

Study design details

Outcomes

- To evaluate the incidence of defined MESIs. MESIs include liver injury,cardiac safety, serious infection, and malignancy. Incidence rates of AEs, AEs leading to discontinuation of therapy, SAEs, ADRs SADRs, change in recorded laboratory assessments over time, time to first flare, and change in VDI score over time for the avacopan group. Incidence rates of AEs, MESIs, SAEs, change in lab results over time, time to first flare, and change in VDI score over time for the non-avacopan group. Refer to protocol for more.

Data analysis plan

Statistical analyses will be exploratory in nature. All variables will be analysed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by descriptive statistics (i.e. number of patients, mean, standard deviation, minimum, median, quartiles, and maximum). Continuous variables will be summarised by absolute value and changes from baseline per analysis time point, if applicable. 95% confidence intervals will be provided where appropriate. Comparisons between treatment groups will be performed using appropriate methods to adjust for potential bias. Outcomes of statistical comparisons will be interpreted with caution. All statistical issues including calculated variables, handling of missing data, and the format and content of tables will be detailed in the Statistical Analysis Plan (SAP). The SAP will be finalised before study database lock.

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 sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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