Cold Agglutinin Disease Real World Evidence Registry (Cadence)

First published: 14/07/2022

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS47940

Study ID

47941

DARWIN EU® study

No

Study countries

- Austria
- France
- Germany
- Italy
- Japan
- Spain

United Kingdom

United States

Study description

The aim of the Cadence registry is to develop a large, international database of patients with cold agglutinin disease (CAD) or cold agglutinin syndrome (CAS, previously known as secondary CAD) to prospectively collect longitudinal data and better understand patient and clinical characteristics, complications, long-term clinical and patient-reported outcomes associated with the different CAD and CAS treatments and health-resource utilization. This registry will also improve the understanding of the natural history of CAD and CAS and will help raise awareness of CAD and CAS and their management. In addition, the registry will include a cohort study to assess the safety and the effectiveness of sutimlimab in patients with CAD in a real-world setting.

Study status

Planned

Research institutions and networks

Institutions

Prof Alexander Röth

Contact details

Study institution contact

Ronnie Yoo Ronnie.Yoo@sanofi.com

Study contact

Ronnie.Yoo@sanofi.com

Primary lead investigator

Alexander Röth

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2019

Study start date
Planned: 30/06/2022

Data analysis start date
Planned: 01/09/2023

Date of interim report, if expected
Planned: 29/12/2023

Date of final study report
Planned: 31/12/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi US Services Inc.

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

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To develop an international database of patients with CAD or CAS (previously known as secondary CAD) to prospectively collect longitudinal data and better understand patient and clinical characteristics, disease progression, complications, treatment impact, and patient-reported outcomes. To assess the safety and the effectiveness of sutimlimab in patients with CAD in a real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ENJAYMO

Medical condition to be studied

Cold type haemolytic anaemia

Additional medical condition(s)

Cold agglutinin syndrome

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

400

Study design details

Data analysis plan

Continuous variables will be characterized with non-missing observations, mean and standard deviation, median, 1st and 3rd quartiles, minimum and maximum, and number of missing data. Categorical variables will be characterized by the frequency and percent distribution in each category and the number of missing data. 95% confidence intervals of means and percentages will be provided, if relevant. Time-to-event outcomes will be assessed using Kaplan-Meier analysis. Repeated measures analyses may be used for outcomes collected at more than one time point, such as HRQoL or laboratory values.

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