Cold Agglutinin Disease
Real World EvidENCE (CADENCE) Registry

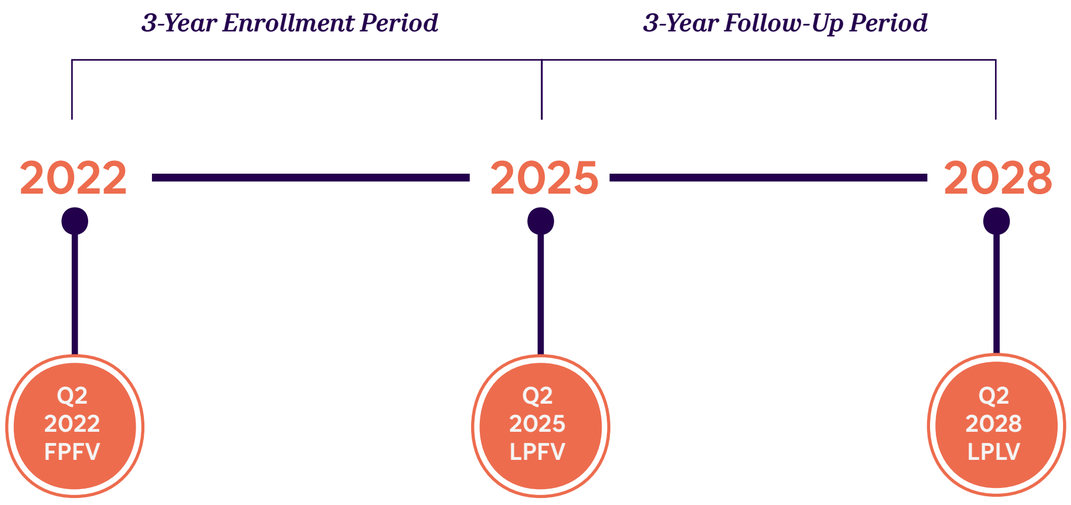
Cadence
REGISTRY
COLD AGGLUTININ DISEASE
Real World evidENCE Registry

sanofi

Objectives

Develop a large, international, prospective registry of patients with CAD or CAS to better understand:

- Patient and clinical characteristics; patterns of use of CAD and CAS treatments; long-term clinical outcomes; patients' health-related quality of life; and healthcare resource utilisation
- Natural history of CAD and CAS including complications and comorbidities
- In addition, the study will include a drug registry component* to assess the safety and effectiveness of sutimlimab in patients with CAD in a real-world setting



Design

Multinational, multicentre, observational, prospective, longitudinal registry

Patients will be followed up throughout the study duration and data will be collected according to standard of care, with sites (eCRF) and patients (PRO) providing status updates at ~6-month intervals

Study Length

Each patient will be followed for up to 3 years after enrollment in the registry. Thus, patients will be followed for up to 6 years (3-year enrollment period + at least 3 years of follow-up).

To find out more information about this registry: please contact USRBDmedical@sanofi.com

CAD, cold agglutinin disease; CAS, cold agglutinin syndrome; eCRF, electronic case report form; FPFV, first patient first visit; LPFV, last patient first visit; LPLV, last patient last visit; PRO, patient-reported outcome. *The decision to treat CAD patients with sutimlimab will be made at the discretion of the Investigator and must be independent from the decision to enroll patients in the registry

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Main Inclusion Criteria

1. Adults ≥18 years of age
2. Diagnosed with CAD or CAS

- *CAD diagnostic criteria:* Monospecific direct antiglobulin test strongly positive for C3d and negative or weakly positive for IgG and a cold agglutinin titre of ≥64
- *CAS diagnostic criteria:* Meet CAD diagnostic criteria. Additionally patients must have one of the following identified as the cause of their CAS: infection, autoimmune disorder, overt malignancy (including overt evidence of a B-cell lymphoproliferative disease)

Main Exclusion Criteria

1. Diagnosed with warm AIHA, or mixed warm and cold AIHA
2. Actively participating in a CAD or CAS interventional clinical trial. After trial participation is completed, the patient may be eligible to enroll in the registry

AIHA, autoimmune hemolytic anaemia; CAD, cold agglutinin disease; CAS, cold agglutinin syndrome; IgG, immunoglobulin G; PRO, patient-reported outcome.

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Enrollment

~400 patients with CAD and CAS across ~90 sites

Among them, ~30 patients with CAD treated with sutimlimab are expected to take part in the drug registry part of the study

Key Data to be Collected

- Disease characteristics
- Disease complications (eg, thromboembolic events, myocardial infarction, stroke)
- Comorbidities
- Clinical outcomes
- Treatment regimens
- Transfusion history
- Healthcare resource utilisation
- PROs
- For patients taking part in drug registry: sutimlimab treatment information, safety data

To find out more information about this registry: please contact USRBDmedical@sanofi.com

This registry is funded/sponsored by Sanofi.
Please see US prescribing information:
https://products.sanofi.us/enjaymo/enjaymo.pdf

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