Prospective observational study to assess the long term safety profile of venetoclax in a Swedish cohort of Chronic Lymphocytic Leukaemia (CLL) patients

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## Administrative details

**Study description** 

EU PAS number	
EUPAS19010	
Study ID	
49279	
DARWIN FUS strake	
DARWIN EU® study	
No	
Study countries	
Sweden	

A large national cohort of CLL patients will be identified based on data from the national health registers (National Patient Register, Swedish Cancer Registry, Swedish Prescribed Drug Register and Cause of Death Register), which will allow for capturing adverse events, co-morbidities, prescribed medication, surgical and other procedures (including whole body skin scans, when performed), outcomes/progression (including adverse events and new malignancies) and mortality data.

Research question and objectives:

- To characterize long term safety of venetoclax, including determining the incidence of selected adverse events in CLL patients exposed to venetoclax (Primary objective)
- To further characterize long term safety of venetoclax, by describing the treated patient population and factors associated with events of interest (Secondary objective a)
- To compare safety profile of venetoclax against alternative treatment modalities (Secondary objective b)
- To describe clinical characteristics of CLL patients at diagnosis such as age, gender, staging, comorbidities and prognostic factors (e.g. cytogenetic factors, renal and hepatic function) (Secondary objective c)
- To describe treatment regimens and sequence of therapy based on patient characteristics and risk factors (Exploratory objective)
- To assess any clinical outcome as a result of contraindicated medications use in patients who have received venetoclax in a real world setting.

### Study status

Ongoing

Research institutions and networks

Institutions



## Contact details

## **Study institution contact**

Vanessa Marzola PAS\_registrations@iqvia.com

Study contact

PAS\_registrations@iqvia.com

## **Primary lead investigator**

Hansson Lotta

**Primary lead investigator** 

## Study timelines

## Date when funding contract was signed

Planned: 07/07/2017

Actual: 18/01/2018

## Study start date

Planned: 30/11/2018

Actual: 02/01/2019

### Data analysis start date

Planned: 01/01/2019 Actual: 26/09/2019

### Date of interim report, if expected

Planned: 31/12/2019 Actual: 10/12/2020

### Date of final study report

Planned: 31/03/2026

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

AbbVie

# Study protocol

p16-562-protocol-pmos-v3\_redacted.pdf (3.1 MB)

p16562-protocol-pmos-v6\_Redacted.pdf (1.95 MB)

# Regulatory

Was the study required by a regulatory body?

### 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

Other

## If 'other', further details on the scope of the study

Adverse events assessment

### Main study objective:

Main objective: To determine the incidence of selected adverse events (including Richter's transformation) in CLL patients using venetoclax following long term use in the Real World.

# Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

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

#### Medical condition to be studied

Chronic lymphocytic leukaemia

# 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**

3600

# Study design details

#### **Outcomes**

The primary outcome is the incidence of selected adverse events in CLL patients treated with venetoclax. Adverse events will be stratified by selected patient characteristics and risk factors. Information on adverse events will be captured via different sources (e.g. National Patient Register and Swedish Cancer Registry and EMRs).

### Data analysis plan

Statistical analysis will be conducted separately for each objective. Time-to-event and case mix methodologies will be applied, as necessary (e.g. primary objective and secondary objective b). Incidence rates of adverse events will be calculated per unit of observational time. Adverse events will be stratified by relevant patient characteristics and risk factors. Descriptive analysis of patient and clinical characteristics will also be performed.

## 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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

### Data source(s), other

Electronic Medical Records Sweden, National Health registries Sweden

### **Data sources (types)**

Disease registry

Drug dispensing/prescription data

## 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**