Venetoclax (ABT-199) in Patients with Chronic Lymphocytic Leukemia: Experience through the Pre-Approval Access Program in European Countries: A Medical ChartReview (ExPloReR)

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Study Finalised

Administrative details

EU PAS number

EUPAS32308

Study ID

37622

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

This study aims to collect real-world evidence of the effectiveness, safety and tolerability of Venetoclax treatment for Chronic Lymphocytic Leukemia (CLL) from medical charts of participants who received Venetoclax as part of Pre-Approval Access (PAA) cohort programs in Europe.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 26 centres are involved in the study

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/12/2017

Study start date
Actual: 01/04/2018

Date of final study report
Actual: 30/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

H17-215 (EXPLORER) Final Protocol_Redacted.pdf (1.22 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

H17-215

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study was to collect real-world evidence on the effectiveness, safety and tolerability of venetoclax treatment for CLL among patients who received venetoclax as part of PAA cohort programs in Europe

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Chart Review

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

Short description of the study population

The target population will be adults who participated in the Pre-Approval Access (PAA) cohort program for Venetoclax for the treatment of Chronic Lymphocytic Leukemia (CLL) in France, Germany, Netherland, Sweden and United Kingdom and received atleast one dose of the treatment.

Age groups

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

Special population of interest

Other

Special population of interest, other

Chronic lymphocytic leukemia patients

Estimated number of subjects

47

Study design details

Outcomes

The effectiveness of venetoclax, measured as overall response rate (ORR) according to physician assessment at week 36, ORR and complete response rate (CRR) according to physician assessment at week 52CRR according to physician assessment at week 36Overall survival at week 52Time to progression at week 52Progression-free survival at week 52Proportion of patients starting treatment in the PAA cohorts and remaining on treatment at week 36Adverse events experienced during ramp-up and throughout treatment

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Data analysis plan

Data were summarized using descriptive statistics, and presented as means, standard deviations (SDs), medians, and ranges for continuous variables, and numbers and percentages for categorical variables. Overall survival was

summarized using Kaplan-Meier curves. Survival was measured from the time of venetoclax initiation. All summarized data are presented in aggregate, no stratifications were undertaken due to the small sample size.

Documents

Study results

H17-215 Results Abstract.pdf (132.52 KB)

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)

Other

Data sources (types), other

Retrospective medical chart review

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