Drug Utilization Study of eliglustat in the US population using MarketScan® Database (ELIGLC06912)

First published: 21/09/2017

Last updated: 25/06/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS21025

Study ID

29327

DARWIN EU® study

No

Study countries

United States

Study description

Retrospective cohort study to estimate the proportion of patients taking concomitant medications of interest including strong CYP3A inducers, strong and moderate CYP2D6 inhibitors and CYP3A inhibitors, and P-gp or CYP2D6 substrate medications prior to starting eliglustat and those who continue or start these medications concurrently while on eliglustat treatment in the US.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Trial transparency team Contact-Us@sanofi.com

Study contact

Contact-Us@sanofi.com

Primary lead investigator

Trial transparency team

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/06/2016

Actual: 30/06/2016

Study start date
Planned: 30/06/2016

Actual: 30/06/2016

Data analysis start date
Planned: 30/06/2016

Actual: 30/06/2016

Date of interim report, if expected
Planned: 30/09/2016

Actual: 25/09/2016

Date of final study report
Planned: 30/09/2018

Actual: 05/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Genzyme

Study protocol

CLB-DOC-72938 on 01Aug2018.pdf (554.75 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Objectives:
1) To estimate the proportion of patients in the U.S. who have been genotyped for CYP2D6 prior to the initiation of eliglustat therapy,
2) To estimate the dose and duration of eliglustat therapy, as well as the prevalence, duration and type of past and concomitant medication use of strong and moderate inhibitors of CYP2D6 and CYP3A, strong CYP3A inducers, P-gp and CYP2D6 substrates, in patients treated with eliglustat in the U.S.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

CERDELGA

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

ELIGLUSTAT

Anatomical Therapeutic Chemical (ATC) code

(A16AX10) eliglustat

eliglustat

Population studied

Short description of the study population

Patients with at least one prescription of eliglustat in the MarketScan™ database from September 18, 2014 (date of market availability) until September 30, 2017.

Also, to assess the proportion of patients who were genotyped for CYP2D6, US patients from the ICGG Gaucher Registry database will be used as an alternative data source for estimating the proportion of eliglustat treated patients who were genotyped for CYP2D6.

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

50

Study design details

Data analysis plan

The following data analyses were performed:

• Descriptive analysis of patients who have a genotyping procedure for CYP2D6 prior to treatment initiation of eliglustat (i.e. N, proportion) in the claims

records.

• Descriptive analysis of patient’s dose and duration on eliglustat therapy within the study period from index date until the end of continuous treatment (i.e. N, mean, standard deviation, median, min, max).

• Descriptive analyses of the prior medication use of concomitant medication of interest (proportion, type, and duration) in the year prior to treatment initiation of eliglustat therapy.

• Descriptive analyses of the concomitant medication use of concomitant medication of interest (proportion, type, and duration) in patients while receiving eliglustat therapy.

Documents

Study results

study-report-eligl06912.pdf (911.36 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)

Administrative healthcare records (e.g., claims)

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

Unknown