A prospective, multicenter, observational, post-authorization safety study (PASS) to evaluate the long term safety profile of LEMTRADA® (alemtuzumab) treatment in patients with relapsing forms of multiple sclerosis (RMS) (GZ402673-OBS13434)

First published: 24/09/2014

Last updated: 21/02/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS7346

Study ID

28499

DARWIN EU® study

No

Study countries

Australia
Austria
Belgium
Bulgaria
Canada
Croatia
Denmark
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Mexico
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom

Study description

A prospective, multicenter, observational PASS to evaluate the long term safety profile of LEMTRADA® (alemtuzumab) treatment in patients with relapsing forms of multiple sclerosis (RMS). The specific Adverse Events of Special

Interests (AESIs) to be monitored include but are not limited to serious infection serious infection, malignancy, and auto-immune mediated conditions including ITP, cytopenias, thyroid disorders, and nephropathies including anti-GBM disease for a period of 10 years. The overall goal of the study is to further evaluate the necessary duration and appropriate conditions of monitoring LEMTRADA treatment in RMS patients by determining the incidence of AESIs to further characterize the long-term safety profile.

Study status

Ongoing

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team contact-US@sanofi.com

Study contact

contact-US@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2014

Actual: 31/07/2014

Study start date

Planned: 01/11/2014

Actual: 10/12/2014

Date of final study report

Planned: 29/07/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The overall goal of the study is to better characterize the long-term safety profile of LEMTRADA treatment in relapsing multiple sclerosis (RMS) patients and to determine the incidence of AESI.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

LEMTRADA

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

ALEMTUZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG06) alemtuzumab

alemtuzumab

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

3000

Study design details

Outcomes

To further evaluate the necessary duration of monitoring following treatment with LEMTRADA for MS and to further inform appropriate monitoring conditions. Incidence of AESIs, associations between risk factors and incidence of AESI, Descriptive statistics on the incidence of AEs, SAEs, deaths.

Data analysis plan

The incidence proportion of each AESI (number of patients with at least one event divided by total number of patients) will be reported together with an exact binomial 95% two-sided CI. Supportive analyses will include, but will not be limited to, the rates over time (number of events and the number of patients with at least one event divided by the total number of person-years at risk of follow-up for the period) of each AESI with an exact Poisson 95% two-sided CI. For temporally associated AESIs, only incidence proportions, but not rates, will be considered.

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)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, Danish MS registry (DMSR), Belgian MS registry (BELTRIMS), social security databases of Belgium (AIM-IMA), reginal healthcare databases of Lombardy (Italy) (HUCD) are participating to the external comparison cohort study.

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