An Observational Study Utilising Data From Big MS Data Registries to Evaluate the Long-Term Safety of Vumerity and Tecfidera

First published: 27/08/2024

Last updated: 25/09/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000285

Study ID

1000000285

DARWIN EU® study

No

Study countries

Denmark

France

Sweden

Study description

This study’s overall research question and objective is to assess and compare the long-term safety of Vumerity and Tecfidera in participants with newly exposed to treatment, especially with regard to the important potential risks of malignancies and serious and opportunistic infections.

Study status

Ongoing

Research institutions and networks

Institutions

Biogen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Director ctrr@biogen.com

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/03/2024

Study start date
Actual: 08/06/2024

Date of interim report, if expected
Planned: 01/05/2024

Date of final study report
Planned: 01/06/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen-100%

Study protocol

272MS403 PASS Protocol V3.0 Final_11 Sep 2024_Redacted.pdf (375.81 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)

Other study registration identification numbers and links

272MS403,

NCT05767736

https://clinicaltrials.gov/study/NCT05767736?term=272ms403&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to estimate the incidence rate of serious adverse events (SAEs), including but not limited to malignancies and serious and opportunistic infections, among participants with MS treated with Vumerity, Tecfidera, other selected disease modifying therapies (DMTs [teriflunomide, beta interferons, or glatiramer acetate]), or Vumerity after switching from Tecfidera. The secondary objective of the study is to compare the incidence rate of SAEs, including but not limited to malignancies and serious and opportunistic infections, among MS participants treated with Vumerity, Tecfidera, and Vumerity after switching from Tecfidera with the incidence rate of MS participants treated with other selected DMTs (teriflunomide, beta-interferons, or glatiramer acetate), if the sample size allows.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TECFIDERA

TERIFLUNOMIDE

VUMERITY

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

DIMETHYL FUMARATE

DIROXIMEL FUMARATE

GLATIRAMER ACETATE

INTERFERON BETA-1A

INTERFERON BETA-1B

TERIFLUNOMIDE

Anatomical Therapeutic Chemical (ATC) code

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b

(L03AB13) peginterferon beta-1a

peginterferon beta-1a

(L03AX13) glatiramer acetate

glatiramer acetate

(L04AA31) teriflunomide

teriflunomide

(L04AX07) dimethyl fumarate

dimethyl fumarate

(L04AX09) diroximel fumarate

diroximel fumarate

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Participants with MS who are treated with Vumerity, Tecfidera, or other selected DMTs (teriflunomide, beta-interferons, or glatiramer acetate) at the initiation of the treatment and participating in Big Multiple Sclerosis Data (BMSD) network registry are eligible to participate in the study.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

10500

Study design details

Outcomes

Number of Participants With Confirmed Serious Adverse Events (SAEs) in the Vumerity, Tecfidera, Other Selected DMTs (Teriflunomide, Beta-interferons, or Glatiramer Acetate), or Vumerity/Tecfidera Switch Cohorts

Hazard Ratio of Confirmed SAEs in Vumerity, Tecfidera, or Vumerity/Tecfidera Switch Cohorts Versus Other Selected DMTs (Teriflunomide, Beta-interferons, or Glatiramer acetate) Cohort

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Data analysis plan

The incidence and incidence rates per 100,000 person-years with 95% CIs will be provided for each treatment cohort. Incidence of all reported SAEs will be summarized and presented by system organ class (SOC) and/or preferred term PT, as appropriate. Comparisons of SAEs will be performed between the Vumerity cohort and the other selected DMTs cohort, between the Tecfidera cohort and the other selected DMTs cohort, and between the Vumerity/Tecfidera switch cohort and the other selected DMTs cohort, if the sample size allows. Cox proportional-hazards regression model will be performed adjusting for potential predictors for each comparison. At the end of the study, the propensity score calculated using logistic regression model will be applied to compare the risks between cohorts to control confounders within each registry.

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), other

Big Multiple Sclerosis Data (BMSD) network MS registries

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No