Survey among healthcare professionals (neurologists treating patients with MS along with MS specialist nurses) and patients in selected European countries plus Canada to evaluate the knowledge required for the safe use of Mayzent (siponimod)

First published: 22/12/2021

Last updated: 04/07/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS44782

Study ID

44783

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] Croatia
- [ ] Denmark
- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden

Study description

The objective of this survey is to evaluate whether HCPs and patients/caregivers receive the educational materials and to capture their knowledge of specific Mayzent (siponimod) safety measures.
The web-based survey will be conducted in some EU countries and Canada where Mayzent (siponimod) is available on the market and reimbursed for at least 6 months, to capture the knowledge and understanding of specific Mayzent safety measures by HCPs and patients/caregivers with access to Mayzent (siponimod).
A total sample of N=220 completed surveys from HCPs (160 neurologists treating patients with MS and 60 MS specialist nurses) and N=115 completed surveys from patients/caregivers will take part.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/05/2020

Actual: 27/05/2020

Study start date

Planned: 31/10/2021

Actual: 02/12/2021

Data analysis start date
Planned: 30/05/2025

Actual: 16/05/2025

Date of final study report
Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceutical SA

Study protocol

CBAF312A2006-Amended protocol v1.4_Clean version_29Mar2021_Redacted.pdf(569.96 KB)

CBAF312A2006_ProtocolAmendment_V3_25Jan2024_Clean Version_Redacted.pdf(400.87 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CBAF312A2006

Link to Clinicaltrials.gov

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The objective of this survey is to evaluate whether HCPs and patients/caregivers receive the educational materials and to capture their knowledge of specific Mayzent (siponimod) safety measures.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multinational, questionnaire-based, cross-sectional survey to be conducted among 1) healthcare professionals and 2) patients/caregivers

Study drug and medical condition

Name of medicine

MAYZENT

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

SIPONIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04) IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

335

Study design details

Data analysis plan

The analysis will be descriptive in nature. For continuous variables, counts, means (with standard deviations), medians and ranges will be provided. For categorical variables, frequencies and percentages (with 95% confidence intervals) will be provided. Missing data will be noted for each variable.

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

For Healthcare professionals: eligibility materials administered through recruitment screener document, self-administered online survey questionnaire;

For Patients: eligibility materials administered through recruitment screener document, self-administered online survey questionnaire

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