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: 29/05/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/44783

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 institution and networks

Institutions

Novartis Pharmaceuticals
First published: 01/02/2024
Last updated 01/02/2024
Institution

Contact details

Study institution contact
Novartis Clinical Disclosure Officer
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:
30/09/2024

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

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

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