Plegridy™ (peginterferon β 1a) Real World Effectiveness and Safety Observational Program (POP)

First published: 29/01/2019

Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48914

EU PAS number

EUPAS27459

Study ID

48914

DARWIN EU® study

No

Study countries

☐ Australia

- [ ] Austria
- [ ] Canada
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

The primary objectives of the study are to determine the incidence of serious adverse events (SAEs) in participants with relapsing forms of multiple sclerosis (MS) in routine clinical practice and to assess the overall long-term clinical effectiveness of Plegridy in participants with relapsing forms of MS in routine clinical practice. The secondary objectives of this study in this study population are to describe Plegridy prescription and utilization adherence patterns in routine clinical practice, to assess the specific long-term clinical effectiveness of Plegridy in participants with relapsing forms of MS in routine clinical practice, to monitor the safety and tolerability of Plegridy in routine clinical practice by assessing the incidence of adverse events (AEs) of flu-like symptoms (FLS), injection site reactions (ISRs), and AEs (including laboratory abnormalities) leading to treatment discontinuation, to assess the effect of FLS on participant-reported effectiveness of, and satisfaction with, prophylactic management using a FLS-Visual Analog Scale (FLS-VAS), to evaluate the change in health-related quality of life (HRQoL), FLS, FLS-VAS, healthcare resource consumption,

and treatment adherence over time.

Study status

Finalised

Research institutions and networks

Institutions

Biogen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 172 centres are involved in the study

Contact details

Study institution contact

Study Director Biogen

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 28/08/2013

Study start date
Actual: 12/11/2014

Date of final study report
Planned: 14/06/2022

Actual: 01/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

105MS401 Protocol V5 Final 16Apr2019_Redacted.pdf(1.87 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

105MS401,,NCT02230969: https://clinicaltrials.gov/ct2/show/NCT02230969

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary purpose of this study is to determine the incidence of serious adverse events (SAEs) in participants with relapsing forms of multiple sclerosis (MS) in routine clinical practice and to assess the overall long-term clinical effectiveness of Plegridy in participants with relapsing forms of MS in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, global, observational study

Study drug and medical condition

Name of medicine

PLEGRIDY

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Patients with multiple sclerosis (MS) aged 18 years or older, who were newly and currently prescribed Plegridy according to the local label under routine clinical care. The study also included patients participated in the Study 105MS302 (ATTAIN) or Study 105MS303 (ALLOW). The patients were identified from 160 sites in multiple regions, including the US, the United Kingdom (UK), the EU, Australia, Canada.

Inclusion criteria:

• Patient and or legal representative is willing and able to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information (PHI) in accordance with national and local patient privacy regulations.

• Patient with MS who is newly, or is currently, prescribed Plegridy according to local label including patients who participated in Study 105MS302 or Study105MS303.

• Patient age 18 years or older.

• Patient willing and able to complete PROs with minimal assistance.

Exclusion criteria:

• Concurrent enrollment in any clinical trial of an investigational product. Participation in non interventional study can be allowed as long as this participation does not interfere with this protocol or is likely to affect the patient’s ability to comply with the protocol.

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)

Special population of interest

Other

Special population of interest, other

Patients with multiple sclerosis

Estimated number of subjects

1208

Study design details

Outcomes

Safety of Plegridy will be evaluated by assessment of the incidence proportion and incidence rate of SAEs, Effectiveness of Plegridy on clinical no evidence of disease activity (cNEDA) will be evaluated by assessment of the proportion of patients with no relapses and no disability progression. Plegridy prescription and utilization adherence patterns, specific long-term clinical effectiveness of Plegridy, safety and tolerability of Plegridy, effect of FLS on patient-reported effectiveness of and satisfaction with prophylactic management using a FLS-Visual Analog Scale (VAS), change in HRQoL, FLS, FLS-VAS, healthcare resource consumption, and treatment adherence over time.

Data analysis plan

Descriptive analyses will be performed to gain a better understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied. Categorical variables will be summarized as number and proportion of the total study population and by subgroups where appropriate. Continuous variables will be reported as mean (and standard deviation) or

median and range, where appropriate. Categorical outcomes on healthcare resource consumption, treatment adherence, patient determined disease steps (PDDS), and Plegridy prescription and utilization patterns will be summarized using frequencies and percentages. If necessary, a 95% CI based on binomial distribution might be provided for some of the categorical variables like patient adherence.

Documents

Study results

105MS401 CSR Full V1 Synopsis 01Aug22_Redacted.pdf(275.2 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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