Prospective Observational Study Aimed at Evaluating Treatment Satisfaction and Effectiveness in Patients with Relapsing Multiple Sclerosis Starting CLADRibinE TAbLets (CLADREAL)

First published: 17/10/2022

Last updated: 02/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS49334

Study ID

49335

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This is an observational, multicenter, prospective study which aims to assess the effectiveness of cladribine tablets, in terms of treatment satisfaction and other patient reported and clinical outcomes in patients with relapsing multiple sclerosis (RMS) initiating treatment with cladribine tablets in a real world setting.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

Communication Center Merck KGaA
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Study contact

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Primary lead investigator

Communication Center Merck KGaA

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/04/2022

Study start date

Planned: 05/12/2022

Actual: 22/12/2022

Data analysis start date

Planned: 04/03/2027

Date of interim report, if expected

Planned: 31/05/2024

Date of final study report

Planned: 31/08/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck KGaA

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To assess the change in patient’s global treatment satisfaction at 24 months after cladribine tablet treatment initiation among patients with RMS switching from 1st-line DMT and patients with RMS switching from 2nd-line DMT.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

MAVENCLAD

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

CLADRIBINE

Anatomical Therapeutic Chemical (ATC) code

(L04AA40) cladribine

cladribine

Medical condition to be studied

Multiple sclerosis

Relapsing multiple sclerosis

Population studied

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)

Estimated number of subjects

Study design details

Outcomes

- Change in the global satisfaction domain of TSQM V1.4 at Visit 5 (Month 24) from Baseline (Visit 0) in patients with RMS switching from 1st-line DMT and patients with RMS switching from 2nd-line DMT.
- Change in TSQM domains score.
- Time from 1st dose of cladribine tablets to 1st relapse ARR over 1st and 2nd year after cladribine initiation.
- Proportion of patients with sustained disability progression improvement, or stability confirmed over 6 months as assessed by EDSS Proportion of patients free from lesions Number of CUA lesions.
- Change in EuroQoL-5D-5L, PSQI, PROMIS SF-15 and SF-8 scores.

Data analysis plan

All patients enrolled in study who received at least 1 dose of cladribine tablets will be included in analysis. Primary outcome will be analyzed using descriptive statistics for continuous variables. CIs will be provided.Secondary outcomes of TSQM V1.4 will be analyzed with descriptive statistics, including Group A, B,C.In addition, time from cladribine tablet initiation to 1st relapse will be described using Kaplan-Meier method and ARR in 1st year and 2nd year after cladribine tablet initiation will be reported,accompanied by respective 95% CI. Furthermore, proportion of patients with disability progression, stability or improvement as assessed by EDSS, proportion of patients free from T1 Gd+ lesions, and proportion of patients free from new/enlarging T2 will be summarized at Visit 3 and Visit 5 using descriptive statistics. For other PRO scores (EQ-5D-5L scores, PSQI,Brief IPQ scores,PROMIS SF-15 and PROMIS SF-8) at Visit 1, 3, and 5, descriptive statistics will be provided

Data management

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

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