



# Evaluating the Long-Term Outcomes and Durability of Effect Following Treatment with Cladribine Tablets for Multiple Sclerosis

05/04/2025 15:43:58

## Main Information

**Primary registry identifying number**

LBCTR2020030215

**Protocol number**

MS700568\_0026

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Prospective

**Type of registration: Justify**

N/A

**Date of registration in national regulatory agency**

25/07/2019

**Primary sponsor**

Merck KGaA

**Primary sponsor: Country of origin**

Germany

**Date of registration in primary registry**

18/03/2020

**Date of registration in national regulatory agency**

25/07/2019

**Public title**

Evaluating the Long-Term Outcomes and Durability of Effect Following Treatment with Cladribine Tablets for Multiple Sclerosis

**Acronym**

**Scientific title**

An Exploratory Phase IV Ambispective Study of Patients Who Previously Participated in the CLARITY/CLARITY-EXT and ORACLE MS Clinical Trials

**Acronym**

**Brief summary of the study: English**

The purpose of this study is to explore the long-term outcomes, durability of effect, and real-world treatment patterns in patients previously participating in the Phase III ORACLE MS and CLARITY/CLARITY-EXT clinical trials (i.e. parent studies). The results from this study may be of benefit to patients with multiple sclerosis (MS) and clinicians by helping to inform future treatment approaches and treatment decision-making.

**Brief summary of the study: Arabic**

تقييم النتائج طويلة الأمد و مدة تأثير العلاج بأقراص Cladribine عند مرضى مصابين بتصلب المتعدد

**Health conditions/problem studied: Specify**

Multiple Sclerosis

**Interventions: Specify**

No Intervention, except:

\*Optional blood sample: Patients willing to consent to provide an optional blood sample and who are seen at a site with available capabilities to store and ship samples, will have a blood draw taken at Study Visit 1 for pharmacogenetics testing.

**Key inclusion and exclusion criteria: Inclusion criteria**

1. Patients with MS randomised in CLARITY/CLARITY-EXT clinical trial(s) who have received  $\geq 1$  course of IMP (Cladribine Tablets or





placebo).

or

Patients with their FCDE randomised in ORACLE MS clinical trial who have received  $\geq 1$  course of IMP (Cladribine Tablets or placebo).

2. Informed Consent

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

65

**Key inclusion and exclusion criteria: Exclusion criteria**

1. Medical Conditions:

Any condition, including any uncontrolled disease state other than MS, that in the Investigator's opinion, constitutes an inappropriate risk or a contraindication for participation in the study or that could interfere with the study objectives, conduct, or evaluation.

For the MRI sub-study:

1. Female Participants Who are pregnant

2. Patient taking Cladribine Tablets as part of another study at the time of the start of this study

**Type of study**

Observational

**Type of intervention**

N/A

**Type of intervention: Specify type**

N/A

**Trial scope**

N/A

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

N/A

**Study design: Masking**

N/A

**Study design: Control**

N/A

**Study phase**

N/A

**Study design: Purpose**

N/A

**Study design: Specify purpose**

N/A

**Study design: Assignment**

N/A

**Study design: Specify assignment**

N/A

**IMP has market authorization**

**IMP has market authorization: Specify**

**Name of IMP**

**Year of authorization**

**Month of authorization**

**Type of IMP**

**Pharmaceutical class**

**Therapeutic indication**

**Therapeutic benefit**

**Study model**

Cohort

**Study model: Explain model**

NA

**Study model: Specify model**

N/A

**Time perspective**

Other

**Time perspective: Explain time perspective**

Ambispective: Retrospective and Prospective

**Time perspective: Specify perspective**

Ambispective

**Target follow-up duration**

6

**Target follow-up duration: Unit**

Weeks

**Number of groups/cohorts**

4

**Biospecimen retention**

Samples with DNA\*\*

**Biospecimen description**

8ml blood sample will be collected for DNA analysis from consenting participants

**Target sample size**

8

**Actual enrollment target size****Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

15/08/2019

**Date of study closure: Type**

Actual

**Date of study closure: Date**

28/02/2021

**Recruitment status**

Recruiting

**Recruitment status: Specify****Date of completion****IPD sharing statement plan**

No

**IPD sharing statement description**

NO Individual Patient Data Sharing

**Additional data URL****Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

| Full name of issuing authority    | Secondary identifying number   |
|-----------------------------------|--------------------------------|
| European Clinical Trials Database | EudraCT number: 2019-000069-19 |

## Sources of Monetary or Material Support

| Name               |
|--------------------|
| Merck KGaA Germany |

## Secondary Sponsors

| Name |
|------|
| N/A  |

## Contact for Public/Scientific Queries

| Contact type | Contact full name | Address  | Country                  | Telephone          | Email                         | Affiliation                                  |
|--------------|-------------------|--|--------------------------|--------------------|-------------------------------|--|
| Public       | Dr. Bassem Yamout | Hamra, Cairo Street                                      | Lebanon                  | +9613221<br>222    | -                             | American University of Beirut Medical Center |
| Scientific   | Kristin Gabriel   | EMD Serono, Inc. One Technology Place, Rockland MA 02370 | United States of America | +1 781<br>427 1502 | Kristin.Gabriel@emdserono.com | EMD Serono, Inc.                             |

## Centers/Hospitals Involved in the Study

| Center/Hospital name                         | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Bellevue Medical Center                      | Dr. Souheil Gbeily              | Neurology                          | Approved         |
| American University of Beirut Medical Center | Dr. Bassem Yamout               | Neurology                          | Not approved     |



## Ethics Review

| Ethics approval obtained | Approval date | Contact name         | Contact email             | Contact phone |
|--------------------------|---------------|----------------------|---------------------------|---------------|
| Bellevue Medical Center  | 10/09/2019    | Prof. Souheil Jbeily | souheil.gebeily@gmail.com | 9611682666    |

## Countries of Recruitment

| Name              |
|-------------------|
| Australia         |
| Austria           |
| Belgium           |
| Bulgaria          |
| Canada            |
| Croatia           |
| Czech Republic    |
| Estonia           |
| Finland           |
| France            |
| Georgia           |
| Germany           |
| Greece            |
| Italy             |
| Republic of Korea |
| Latvia            |
| Lithuania         |
| Morocco           |
| Norway            |
| Poland            |
| Portugal          |



|                          |
|--------------------------|
| Romania                  |
| Russian Federation       |
| Republic of Serbia       |
| Spain                    |
| Sweden                   |
| Switzerland              |
| Tunisia                  |
| Ukraine                  |
| United Kingdom           |
| United States of America |
| Lebanon                  |

## Health Conditions or Problems Studied

| Condition          | Code                     | Keyword                |
|--------------------|--------------------------|------------------------|
| Multiple Sclerosis | Multiple sclerosis (G35) | MS, Multiple Sclerosis |

## Interventions

| Intervention            | Description                        | Keyword        |
|-------------------------|------------------------------------|----------------|
| Optional Blood Sampling | Purpose: Pharmaco-genetics Testing | blood sampling |



## Primary Outcomes

| Name  | Time Points  | Measure   |
|---|--|---|
| To evaluate long-term mobility after treatment with an investigational medicinal product (IMP; Cladribine Tablets or placebo) as part of the Phase III ORACLE MS and CLARITY/CLARITY-EXT clinical trials. | Proportion of study participants using a wheelchair (defined as unable to walk beyond approximately 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day) the majority of the time in the 3 months prior to Study Visit 1 for the CLARITY/CLARITY-EXT and ORACLE MS populations, | <ul style="list-style-type: none"><li>• Expanded Disability Status Scale (EDSS) score of 7.0 or higher (if available), or</li><li>• Alternative clinical description data in medical records.</li></ul> |



## Key Secondary Outcomes

| Name  | Time Points   | Measure   |
|---|---|---|
| To assess the long-term disability status after treatment with IMP as part of the Phase III ORACLE MS and CLARITY/CLARITY-EXT clinical trials for the CLARITY/CLARITY-EXT and ORACLE MS populations.  | Proportion of study participants with 3-month sustained (i.e. ambulatory disability consistent with EDSS on at least 2 clinic visits no less than 3 months apart)   | EDSS of 6.0 or higher in the last year prior to enrollment or corresponding clinical description in medical records |
| To evaluate differences in clinical characteristics between long-term responders and study participants requiring alternate therapies following treatment with IMP for the CLARITY/CLARITY-EXT and ORACLE MS populations.                         | Clinical characteristics at Study Visit 1 of long-term responders (defined as study participants who did not demonstrate any evidence of disease reactivation based on Investigator assessment of clinical and imaging outcomes until Year 4 or later following their last dose of IMP and who did not receive disease modifying treatment until Year 4 or later following their last dose of IMP) compared to those of other study participants who started on alternate therapy less than 4 years following their last dose of IMP for the CLARITY/CLARITY-EXT and ORACLE MS populations. | -   |
| To evaluate differences in magnetic resonance imaging (MRI) characteristics between long-term responders and study participants requiring alternate therapies following treatment with IMP for the CLARITY/CLARITY-EXT and ORACLE MS populations. | MRI characteristics at Study Visit 2 of long-term responders (defined as study participants who did not demonstrate any evidence of disease reactivation based on Investigator assessment of clinical and imaging outcomes until Year 4 or later following their last dose of IMP and who did not receive disease modifying treatment until Year 4 or later following their last dose of IMP) compared to those of other study participants who started on alternate therapy less than 4 years following their last dose of IMP for the CLARITY/CLARITY-EXT and ORACLE MS populations.      | -   |





## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**