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

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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
11/06/2021

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 مدّة تأثير العلاج بأقراص Cladribine عند مرضى مصابين بتصلّب 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 ≥ 1 course of IMP (Cladribine Tablets or

placebo).
or
Patients with their FCDE randomised in ORACLE MS clinical trial who have received≥ 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
27/02/2021

Recruitment status
Complete

Recruitment status: Specify

Date of completion
27/02/2021

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 222	-	American University of Beirut Medical Center
Scientific	Kristin Gabriel	EMD Serono, Inc. One Technology Place, Rockland MA 02370	United States of America	+1 781 427 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,	• Expanded Disability Status Scale (EDSS) score of 7.0 or higher (if available), or • Alternative clinical description data in medical records.

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 doseb of IMP and who did not receive disease modifying treatment until Year 4 or later following their last doseb of IMP) compared to those of other study participants who started on alternate therapy less than 4 years following their last doseb 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 doseb of IMP and who did not receive disease modifying treatment until Year 4 or later following their last doseb of IMP) compared to those of other study participants who started on alternate therapy less than 4 years following their last doseb 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