An Open-label Study Evaluating Ofatumumab Treatment Effectiveness and PROs in Subjects With RMS Transitioning From Dimethyl Fumarate or Fingolimod to Ofatumumab

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Main Information

Primary registry identifying number
LBCTR2021034775

Protocol number
COMB157G23101

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

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
09/12/2022

Date of registration in national regulatory agency

Public title
An Open-label Study Evaluating Ofatumumab Treatment Effectiveness and PROs in Subjects With RMS Transitioning From Dimethyl Fumarate or Fingolimod to Ofatumumab

Acronym

Scientific title
A Single-arm, Prospective, Multicentre, Open-label Study to Evaluate Ofatumumab Treatment Effectiveness and Patient Reported Outcomes in Patients With Relapsing Multiple Sclerosis Transitioning From Dimethyl Fumarate or Fingolimod Therapy

Acronym

Brief summary of the study: English
The open label study to evaluate effectiveness of treatment with ofatumumab in patients transitioning from commonly used oral MS therapies - fingolimod or dimethyl fumarate, due to breakthrough disease.

Brief summary of the study: Arabic
دراسة تقدّميّة متعددة المراكز مفتوحة اللصاقة ذات مجموعة واحدة لتقييم فعاليّة العلاج بأوفاتومومااب والنتائج التي يفيد عنها المرضى المصابين بالتصلّب اللويحي الانتكاسي الذين ينتقلون من العلاج بثنائي ميثيل الفومارات أو بفينغوليمود

Health conditions/problem studied: Specify
Relapsing Multiple Sclerosis

Interventions: Specify
Biological: Ofatumumab
Patients in the ofatumumab will receive injections of ofatumumab provided in an autoinjector (AI) for subcutaneous administration containing 20 mg ofatumumab (50 mg/ml, 0.4 ml content)
Other Name: OMB157

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:

Diagnosis of multiple sclerosis (MS)
Relapsing MS (RRMS or SPMS) course
Subject transitioning from either fingolimod or dimethyl fumarate, following min 6 months treatment with either drug
Breakthrough disease as evidence by clinical relapses or MRI
EDSS score of 0 to 4

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

60

Key inclusion and exclusion criteria: Exclusion criteria

Primary progressive MS or SPMS without disease activity
Disease duration of more than 10 years since diagnosis
Patients with an active chronic disease of the immune system other than MS
Patients at risk of developing or having reactivation of hepatitis
Patients with active systemic infections or with neurological findings consistent with PML Other protocol-defined inclusion/exclusion criteria may apply

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Single Arm Study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

USA, UK, UAE, KSA, Albania, Argentina, Australia, Canada, Singapore , Switzerland, Belgium, Netherlands, France, Lebanon

Name of IMP

Ofatumumab

Year of authorization

2021

Month of authorization

11

Type of IMP

Immunological

Pharmaceutical class

Monoclonal antibodies

Therapeutic indication

Patients with:
relapsing multiple sclerosis

Therapeutic benefit

potential efficacy of ofatumumab in patients with relapsing MS.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples without DNA

Biospecimen description

Covance Central lab : Ambient and Frozen conditions

Target sample size

10

Actual enrollment target size

15

Date of first enrollment: Type

Actual

Date of first enrollment: Date

10/08/2021

Date of study closure: Type

Actual

Date of study closure: Date

25/06/2025

Recruitment status

Complete

Recruitment status: Specify

Date of completion

04/10/2022

IPD sharing statement plan

Yes

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT04353492?term=ofatumumab+treatment+effectiveness&cond=relapsing+multiple+sclerosis+transitioning&draw=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NCT04353492	Clinical trials.gov

Sources of Monetary or Material Support

Name
Novartis Pharma services Inc.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Taghrid El Hajj	Beirut	Lebanon	9613494008	taghridelhajj@gmail.com	Rafik Hariri University Hospital
Scientific	Hind Khairallah	Sinelfil	Lebanon	01512002#271	Hind.khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l
Public	Halim Abboud	Beirut	Lebanon	9613535711	halimabboud@hotmail.com	Hotel Dieu De France
Public	Salam Koussa	Beirut	Lebanon	9613726771	drkoussa@hotmail.com	Lebanese Geitaoui Hospital
Public	Samia Khoury	Beirut	Lebanon	9611350000#7422	sk88@aub.edu.lb	American University of Beirut Medical Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Rafik Hariri University Hospital	Taghrid El Hajj	Neurology	Approved
Hotel Dieu De France	Halim Abboud	Neurology	Approved
Lebanese Hospital Geitaoui	Salam Koussa	Neurology	Approved
American University of Beirut Medical Center	Samia Khoury	Neurology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Rafic Hariri University Hospital	02/12/2020	Rawan Yammout	rawan.yamout@crurhuh.com	018300000 ext 2037
Hotel Dieu de France	03/11/2020	Sami Richa	cue@usj.edu.lb	961421229
Hopital Libanais Getaoui Centre Hospitalier Universitaire	23/03/2021	Raja Chaftari	irb@hopital-libanais.com	961 1 590 000 # 8872 8859
American University of Beirut Medical Center	25/05/2021	Fuad Ziyadeh	fz05@aub.edu.lb	9611350000#5445

Countries of Recruitment

Name
Lebanon
Australia
Austria
Belgium
Bulgaria
Czech Republic
Germany
Greece
Hungary
Norway
Poland
Portugal
Russian Federation
Slovakia
Spain
Switzerland
Turkey
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Relapsing Multiple sclerosis	Multiple sclerosis (G35)	MS

Interventions

Intervention	Description	Keyword
Informed Consent form , IMP administration , Visit assessment and schedule	Informed Consent form , IMP administration , Visit assessment and schedule	ICF, IMP

Primary Outcomes

Name	Time Points	Measure
Annual Relapse Rate	96 weeks	number of confirmed relapses in a year calculated based on cumulative number of relapses by patient adjusted for time-in-study by patient

Key Secondary Outcomes

Name	Time Points	Measure
Safety evaluation	96 weeks	Proportion of patients with adverse events, including injection related reactions, abnormal laboratory results or vital signs as well as proportion of patients discontinuing treatment due to insufficient effectiveness or safety

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