



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

07/02/2022

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 تقدّمية متعددة المراكز مفتوحة اللصافة ذات مجموعة واحدة لتقييم فعالية العلاج بأوفاتوموماب والنتائج التي يفيد عنها المرضى المصابين بالتصلب 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

US, UAE, Albania, Argentina, Canada, Singapore, Switzerland, 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

3

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

Recruiting

Recruitment status: Specify**Date of completion**

31/08/2022

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.yammout@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