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

**10/09/2025 18:17:54**

## 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**
10/09/2021

**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 بأوفاتوموماب 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, Worldwide

**IMP has market authorization: Specify**

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

**Name of IMP**

Ofatumumab

**Year of authorization**

**Month of authorization**

**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**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

29/04/2021

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

25/06/2025

**Recruitment status**

Pending

**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.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**