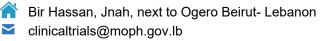
# REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

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

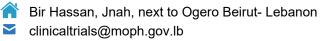
10/09/2025 16:27:40

Main Information	
Primary registry identifying number	Protocol number
LBCTR2021034775	COMB157G23101
MOH registration number	
Study registered at the country of origin Yes	Study registered at the country of origin: Specify
Type of registration	Type of registration: Justify
Prospective	N/A
Date of registration in national regulatory agency	
Primary sponsor	Primary sponsor: Country of origin
Novartis Pharma Services Inc.	Novartis Pharmaceuticals
Date of registration in primary registry	Date of registration in national regulatory agency
12/10/2021	
Public title	Acronym
An Open-label Study Evaluating Ofatumumab Treatment Effectiveness and PROs in Subjects With RMS Transitioning From Dimethyl Fumarate or Fingolimod to Ofatumumab	
Scientific title	Acronym
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	
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	
اللصاقة ذات مجموعة واحدة لتقييم فعاليّة العلاج بأوفاتوموماب والنتائج التي يفيد عنها المرضى المصابين بالتصلّب اللويحي الانتكاسي الذين ينتقلون من العلاج بثنائي ميثيّل الفومارات أو بفينغوليمود	دراسة تقدّميّة متعددة المراكز مفتوحة ا
Health conditions/problem studied: Specify	
Relapsing Multiple Sclerosis	
Interventions: Specify	
Biological: Ofatumumab Patients in the ofatumumab will receive injections of ofatumumab provided mg ofatumumab (50 mg/ml, 0.4 ml content) Other Name: OMB157	t in an autoinjector (AI) for subcutaneous administration containing 20



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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 Breakthrough disease as evidence by clinical relapses or MRI EDSS score of 0 to 4	min 6 months treatment with either drug
Key inclusion and exclusion criteria: Gender	Key inclusion and exclusion criteria: Specify gender
Both	
Key inclusion and exclusion criteria: Age minimum	Key inclusion and exclusion criteria: Age maximum
18	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 M Patients at risk of developing or having reactivation of hepatitis Patients with active systemic infections or with neurological findings consist apply	
Type of study	
Interventional	
Type of intervention	Type of intervention: Specify type
Pharmaceutical	N/A
Trial scope	Trial scope: Specify scope
Therapy	N/A
Study design: Allocation	Study design: Masking
Single Arm Study	Open (masking not used)
Study design: Control	Study phase
N/A	3
Study design: Purpose	Study design: Specify purpose
Treatment	N/A
Study design: Assignment	Study design: Specify assignment
Single	N/A
IMP has market authorization	IMP has market authorization: Specify
Yes, Worldwide	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	



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Therapeutic benefit	
potential efficacy of ofatumumab in patients with relapsing MS.	
Study model	Study model: Explain model
N/A	N/A
Chudu madalı Onacifu madal	
Study model: Specify model N/A	
Time perspective	Time perspective: Explain time perspective
N/A	N/A
Time perspective: Specify perspective	
N/A	
To see 6 for House and a second second	<b>T</b>
Target follow-up duration	Target follow-up duration: Unit
Number of groups/cohorts	
Biospecimen retention	Biospecimen description
Samples without DNA	Covance Central lab : Ambient and Frozen conditions
Target sample size	Actual enrollment target size
10	
Date of first enrollment: Type	Date of first enrollment: Date
Anticipated	29/04/2021
	Data of study classing Data
Date of study closure: Type Anticipated	Date of study closure: Date 25/06/2025
Recruitment status	Recruitment status: Specify
Pending	
Date of completion	
31/08/2022	
IPD sharing statement plan	IPD sharing statement description
Yes	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

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

privacy of patients who have participated in the trial in line with applicable laws and regulations.

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### Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT04353492?

 $term = of a tumumab + treatment + effectiveness\& cond = relapsing + multiple + sclerosis + transitioning\& draw = 2\& rank = 1 \\ for all the sclerosis + transitioning\& draw = 1 \\ for all the sclerosis + transitioning\& draw = 2\& rank = 1 \\ for all the sclerosis + transitioning\& draw = 2\& rank = 1 \\ for all the sclerosis + transitioning\& draw = 2\& rank = 1 \\ for all the sclerosis + transitioning\& draw = 2\& rank = 1 \\ for all the sclerosis + transitioning\& draw = 1 \\ for all the sclerosis + transitioning\& draw = 1 \\ for all the sclerosis + tra$ 

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	961349400 8	taghridelhajj@gm ail.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	961353571 1	halimabboud@h otmail.com	Hotel Dieu De France
Public	Salam Koussa	Beirut	Lebanon	961372677 1	drkoussa@hotm ail.com	Lebanese Geitaoui Hospital
Public	Samia Khoury	Beirut	Lebanon	961135000 0#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         Ethic		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