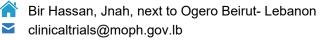
REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

A randomized patient-and-physician blinded, placebo- controlled, 24-week study to assess the safety, tolerability and efficacy of LMB763 in patients with diabetic nephropathy

12/08/2025 01:04:34

Main Information	
Primary registry identifying number	Protocol number
LBCTR2019020193	CLMB763X2202
MOH registration number	
7936/2019	
Study registered at the country of origin	Study registered at the country of origin: Specify
Yes	
The standard sector	The second se
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
Novalus Filamia Services Inc.	Novalus Filamaceulicais
Date of registration in primary registry	Date of registration in national regulatory agency
26/03/2020	
Public title	Acronym
	Actonym
A randomized patient-and-physician blinded, placebo- controlled, 24 -week study to assess the safety, tolerability and efficacy of	
LMB763 in patients with diabetic nephropathy	
Scientific title	Acronym
A randomized patient-and-physician blinded, placebo- controlled, 24	
-week study to assess the safety, tolerability and efficacy of LMB763 in patients with diabetic nephropathy	
Brief summary of the study: English	
LMB763 addresses fibrosis, oxidative stress, inflammation and cell death, and therefore has the potential to improve the management	
of diabetic kidney disease when added to the standard of care	
(angiotensin converting enzyme inhibitor or angiotensin receptor blocker). This non-confirmatory Phase 2 study is designed to	
determine the safety, tolerability, efficacy, pharmacokinetics and	
pharmacodynamics of LMB763 in combination with maximally tolerated doses of angiotensin converting enzyme inhibitor (ACEI)	
or angiotensin receptor blocker (ARB) in patients with type 2	
diabetes and nephropathy.	
Brief summary of the study: Arabic	
دوجة التعمية من جهة المريض والطبيب ومرتكزة على المقارنة بدواء وهميّ لتقييم سلامة24دراسة من لدى المرضى المصابين باعتلال الكلية السكري LMB763 وقدرة تحمّل وفعاليّة دواء	أسبوعًا عشوانيَّة التوزيع ومز
Health conditions/problem studied: Specify	
Patients with Diabetic Nephropathy	
Interventions: Specify	



REPUBLIC OF LEBANON Lebanon Clinical Trials Registry MINISTRY OF PUBLIC HEALTH Drug: LMB763 LMB763 capsule •Other: Placebo Placebo capsule Key inclusion and exclusion criteria: Inclusion criteria Inclusion Criteria: •Male/female patients, 18-75 years Written informed consent •Diagnosis of Type 2 diabetes mellitus, with diagnosis made at least 6 months prior to screening •Diabetic nephropathy as evidenced by Urine albumin-Cr ratio (UACR) ≥300 mg/g Cr while receiving a maximally tolerated (optimal) dose of angiotensin converting enzyme inhibitor or angiotensin receptor blocker 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 75 Key inclusion and exclusion criteria: Exclusion criteria Exclusion Criteria: •History of type 1 diabetes mellitus •Severe renal impairment manifesting as serum creatinine eGFR < 30 mL/min/1.73 m^2 at screening •Pregnant or nursing (lactating) women •Women of child-bearing potential, unless they are using highly effective methods of contraception during dosing and for 5 days after stopping study medication Uncontrolled diabetes mellitus ·History or current diagnosis of ECG abnormalities ·History of kidney disease other than diabetic nephropathy Type of study Interventional Type of intervention Type of intervention: Specify type Pharmaceutical N/A **Trial scope** Trial scope: Specify scope Other Study design: Allocation Study design: Masking Randomized controlled trial Blinded (masking used) Study design: Control Study phase Placebo 2 Study design: Purpose Study design: Specify purpose Treatment N/A Study design: Assignment Study design: Specify assignment Parallel N/A IMP has market authorization IMP has market authorization: Specify No Name of IMP Year of authorization Month of authorization LMB763 (Nidufexor) Type of IMP Others

Pharmaceutical class

REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH Lebanon Clinical Trials Registry

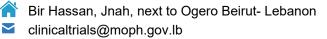
Nidufexor (LMB763) is a potent partial agonist of the Farnesoid X Receptor (FXR).

Therapeutic indication

Patients with intrahepatic cholestasis and for non-alcoholic steatohepatitis (NASH), and diabetic nephropathy.

Therapeutic benefit •effect of LMB763 to placebo on albuminuria in patients with diabetic nephropathy already receiving treatment with an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker Study model Study model: Explain model

N/A	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	Biospecimen description
Samples with DNA**	All blood samples will be sent to Covance-central laboratories, as per study protocol to assess patient disease response following treatment administration. Primary plasma samples for PK are stored at the bioanalytical lab (Veeda – address below) and are destroyed 6 months after study finalization.
Target sample size	Actual enrollment target size
20	3
Date of first enrollment: Type	Date of first enrollment: Date
Actual	15/05/2019
Date of study closure: Type	Date of study closure: Date
Actual	09/02/2021
Recruitment status Suspended	Recruitment status: Specify
Date of completion 04/02/2020	
IPD sharing statement plan No	IPD sharing statement description





Not provided on clinical trials.gov

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT03804879?term=CLMB763X2202&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers		
Full name of issuing authority	Secondary identifying number	
Clinical Trials. gov	NCT03804879	

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	Hilal Abu Zeinab	Saida	Lebanon	961381161 1	hilal@abouzeina b.com	Hammoud Hospital
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@ fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Sola Aoun	Beirut	Lebanon	961 1 786456 ext. 2336	sola.bahous@lau .edu.lb	UMC Rizk Hospital
Public	Hiba Azar	Beirut	Lebanon	70 528 328	hibaazar@hotma il.com	Hotel Dieu





Centers/Hospitals Involved in the Study			
Center/Hospital name	bital nameName of principles investigatorPrinciples investigator specialityEthical appro		Ethical approval
Hammoud Hospital University Medical Center	Dr Hilal Abuzeinab	Nephrology	Approved
University Medical Center Rizk Hospital	Dr Sola Aoun	Nephrology	Approved
Hotel Dieu De France	Dr Hiba Azar	Nephrology	Approved

Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	29/01/2019	Ahmad Zaatari	zaatari@hammoudhospital.com	+961 (0) 7 723111 ext 1160
Lebanese American University- University Medical Center Rizk Hospital	11/04/2019	Christine Chalhoub	christine.chalhoub@lau.edu.lb	961 9 547254 ext. 2340
Hotel Dieu de France	05/02/2019	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335

Countries of Recruitment
Name
Argentina
Czech Republic
Germany
Jordan
Lebanon
United States of America
Turkey

Health Conditions or Problems Studied		
Condition	Code	Keyword
Diabetic nephropathy	Nephropathy induced by unspecified drug, medicament or biological substance (N14.2)	Nephropathy





Interventions		
Intervention	Description	Keyword
Reference table 8-1 of the study protocol: Mainly ICF, IMP administration , Lab tests , ECG	ICF, IMP, Lab tests and ECG , diary completion	ICF, IMP, Lab tests and ECG , diary completion

Primary Outcomes			
Name	Time Points	Measure	
To compare the effect of LMB763 to	at serial timepoints as discrived in protoocl	serial timepoints as per protocol	
•Adverse event profile and safety endpoints of LMB763	197 days	197 days	

Key Secondary Outcomes		
Name	Time Points	Measure
To determine the effect of LMB763 on	Estimated glomerular filtration rate (eGFR), as	eGFR



Trial Results Summary results Study results globally Date of posting of results summaries 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