

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

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Primary registry identifying number

LBCTR2019020193

MOH registration number

7936/2019

Study registered at the country of origin

Type of registration

Prospective

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharma Services Inc.

Date of registration in primary registry

17/12/2019

Public title

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

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

أسبوعًا عشوائيّة التوزيع ومزدوجة التعمية من جهة المريض والطبيب ومرتكزة على المقارنة بدواء وهميّ لتقييم سلامة24دراسة من لدى المرضى المصابين باعتلال الكلية السكري LMB763 وقدرة تحمّل وفعاليّة دواء

Health conditions/problem studied: Specify

Patients with Diabetic Nephropathy

Interventions: Specify

Protocol number

CLMB763X2202

Study registered at the country of origin: Specify

Type of registration: Justify

N/A

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in national regulatory agency

Acronym

Acronym



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

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

Study design: Purpose Study design: Specify purpose

Treatment

Study design: Assignment Study design: Specify assignment

Parallel

IMP has market authorization IMP has market authorization: Specify

No

Name of IMP Year of authorization Month of authorization

2

N/A

LMB763 (Nidufexor)

Type of IMP

Others

Pharmaceutical class



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

Study model: Specify model

N/A

Time perspective 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 with DNA**

Target sample size

Date of first enrollment: Type

Actual enrollment target size

Date of first enrollment: Date

destroyed 6 months after study finalization.

Biospecimen description

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

Actual 15/05/2019

Date of study closure: Type Date of study closure: Date

09/02/2021 Actual

Recruitment status **Recruitment status: Specify**

Recruiting

Date of completion

04/02/2020

IPD sharing statement plan 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
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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



Lebanon Clinical Trials Registry

Centers/Hospitals Involved in the Study			
Center/Hospital name	Name of principles investigator	Principles investigator speciality	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		Keyword	
Diabetic nephropathy	Nephropathy induced by unspecified drug, medicament or biological substance (N14.2) Nephropathy		



Lebanon Clinical Trials Registry

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



Lebanon Clinical Trials Registry

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	