



# 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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## Main Information

**Primary registry identifying number**

LBCTR2019020193

**Protocol number**

CLMB763X2202

**MOH registration number**

7936/2019

**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**

24/11/2020

**Date of registration in national regulatory agency**

**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

**Acronym**

**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

**Acronym**

**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 عشوائية التوزيع ومزدوجة التعمية من جهة المريض والطبيب ومرتكزة على المقارنة بدواء وهمي لتقييم سلامة 24 دراسة من لدى المرضى المصابين باعتلال الكلية السكري LMB763 وقدرة تحمل وفعالية دواء

**Health conditions/problem studied: Specify**

Patients with Diabetic Nephropathy

**Interventions: Specify**





•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)  $\geq 300$  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**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

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<sup>2</sup> 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**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Other

**Trial scope: Specify scope**

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Placebo

**Study phase**

2

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

No

**IMP has market authorization: Specify**

**Name of IMP**

LMB763 (Nidufexor)

**Year of authorization**

**Month of authorization**

**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**

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 with DNA\*\*

**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 destroyed 6 months after study finalization.

**Target sample size**

20

**Actual enrollment target size**

3

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

15/05/2019

**Date of study closure: Type**

Actual

**Date of study closure: Date**

09/02/2021

**Recruitment status**

Recruiting

**Recruitment status: Specify****Date of completion**

04/02/2020

**IPD sharing statement plan**

No

**IPD sharing statement description**



Not provided on clinicaltrials.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	9613811611	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@hotmail. il.com	Hotel Dieu



## 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
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 first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**