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
26/03/2020

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

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) ≥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^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

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

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	9613811611	hilal@abouzeinab.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@hotmail.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