



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

02/11/2019

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

أسبوعاً عشوائية التوزيع ومزدوجة التعمية من جهة المريض والطبيب ومركزية 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) ≥ 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 m² 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

2

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 |
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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