



COMPLEEMENT-1: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease

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Main Information

Primary registry identifying number

LBCTR2019010184

Protocol number

CLEE011A2404

MOH registration number

20521/2017

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

LCTR was already initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency

01/06/2017

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

06/07/2020

Date of registration in national regulatory agency

01/06/2017

Public title

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Acronym

COMPLEEMENT 1

Scientific title

COMPLEEMENT-1: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease

Acronym

Brief summary of the study: English

The purpose of this Phase IIIb study is to collect additional safety and efficacy data for the combination of ribociclib + letrozole in men and pre/postmenopausal women with HR+HER2- advanced breast cancer.

Brief summary of the study: Arabic



بالاشتراك مع ليتروزول لعلاج (LEE011) دراسة مفتوحة اللصاق، متعددة المراكز في المرحلة الثالثة ب تقييم سلامة وفعالية ريبوسيكليب
الذين (HER2-) 2وسلبي الهير (HR+) الرجال والنساء قبل/بعد انقطاع الطمث المصابين بسرطان الثدي المتقدم الإيجابي مستقبلات الهرمون
لم يتلقوا أي علاج هرموني سابق للمرض المتقدم

Health conditions/problem studied: Specify

Advanced Breast Cancer

Interventions: Specify

- Drug: Ribociclib
- Drug: Letrozole
- Drug: Goserelin

Key inclusion and exclusion criteria: Inclusion criteria

- Male or female advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy.
- In the case of women, both pre/perimenopausal and postmenopausal patients are eligible
- Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer
- Patient has HER2-negative breast cancer defined as a negative in situ hybridization test or an IHC status of 0, 1+ or 2+. If IHC is 2+, a negative in situ hybridization (FISH, CISH, or SISH) test is required
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
- Patient has adequate bone marrow and organ function as defined by ALL of the following laboratory values (as assessed by local laboratory):
 - Absolute neutrophil count $\geq 1.5 \times 10^9/L$
 - Platelets $\geq 100 \times 10^9/L$
 - Hemoglobin ≥ 9.0 g/dL
 - Potassium, sodium, calcium corrected for serum albumin and magnesium within normal limits or corrected to within normal limits with supplements before first dose of the study medication
 - INR ≤ 1.5
 - Serum creatinine < 1.5 mg/dl or creatinine clearance ≥ 50 mL/min
 - In absence of liver metastases, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) should be below $2.5 \times$ ULN. If the patient has liver metastases, ALT and AST should be $< 5 \times$ ULN.
 - Total serum bilirubin $<$ ULN; or total bilirubin $\leq 3.0 \times$ ULN with direct bilirubin within normal range in patients with well-documented Gilbert's Syndrome
- Patient must have a 12-lead ECG with ALL of the following parameters at screening:
 - QTcF interval at screening < 450 msec (using Fridericia's correction)
 - Resting heart rate ≥ 50 bpm

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

99

Key inclusion and exclusion criteria: Exclusion criteria

- Patient who received any CDK4/6 inhibitor
- Patient who received any prior systemic hormonal therapy for advanced breast cancer; no more than one prior regimen of chemotherapy for the treatment of metastatic disease is permitted

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

Study phase

N/A	3
Study design: Purpose Treatment	Study design: Specify purpose N/A
Study design: Assignment Single	Study design: Specify assignment N/A
IMP has market authorization Yes, Lebanon and Worldwide	IMP has market authorization: Specify USA, EU & other countries
Name of IMP Ribociclib (Kisqali)	Year of authorization 2017
	Month of authorization 8
Type of IMP Others	
Pharmaceutical class Orally bioavailable, highly selective small molecule inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6).	
Therapeutic indication Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2 -) Advanced Breast Cancer	
Therapeutic benefit increase Overall survival and progression free survival	
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 None retained	Biospecimen description Local lab is being used, no samples will be shipped outside Lebanon, Lab samples are mainly CBC, Chemistry to follow up on patient safety



Target sample size 20	Actual enrollment target size 17
Date of first enrollment: Type Actual	Date of first enrollment: Date 10/08/2018
Date of study closure: Type Actual	Date of study closure: Date 31/12/2020
Recruitment status Complete	Recruitment status: Specify
Date of completion 12/01/2018	
IPD sharing statement plan Yes	IPD sharing statement description Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.
Additional data URL https://clinicaltrials.gov/ct2/show/record/NCT02941926?recrs=d&rslt=Without&type=Intr&cond=Advanced+Breast+Cancer&titles=complement&spons=novartis&phase=2&rank=1	
Admin comments	
Trial status Approved	

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical Trials.Gov	NCT02941926

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	Fadi Farhat	Saida	Lebanon	+961 3 753 155	drfadi.trials@gmail.com	Hammoud Hospital
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Public	Fadi El Karak	Mansourieh	Lebanon	+961 3 061 621	felkarak@yahoo.com	Bellevue Medical Center
Public	Georges Chahine	Beirut	Lebanon	+9613 647778	Chahine_georges@hotmail.com	Hotel Dieu De France

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Dr Fadi Farhat	Hematology Oncology	Approved
Hotel Dieu De France	Dr Georges Chahine	Hematology Oncology	Approved
Bellevue Medical Center	Dr Fadi El Karak	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	02/05/2017	Georges Chahine	Chahine_georges@hotmail.com	009613 647778
Bellevue Medical Center	21/08/2017	Fadi El Karak	felkarak@yahoo.com	00961 3 061 621
Hammoud Hospital University Medical Center	02/05/2017	Fadi Farhat	drfadi.trials@gmail.com	00961 3 753 155



Countries of Recruitment

Name
Lebanon
Argentina
Austria
Belgium
Bulgaria
Canada
Jordan
Oman
Saudi Arabia
Spain
United Kingdom
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Advanced Breast Cancer	Breast, unspecified (C50.9)	Breast Cancer

Interventions

Intervention	Description	Keyword
> Hematology tests: WBC, ANC, lymphocyte, hemoglobin, platelets (as clinically indicated), Chemistry tests: Alkaline phosphatase, ALT (SGPT), AST (SGOT), calcium corrected for serum albumin, creatinine or creatinine clearance, potassium, sodium, magnesium, direct bilirubin, total bilirubin (as clinically indicated), ECG	Lab tests , ECG , Radiology assessment	Lab tests , Radiology , ECG

Primary Outcomes

Name	Time Points	Measure
The number of participants with adverse events as a measure of safety and tolerability	PFS	Progression free survival



Key Secondary Outcomes

Name	Time Points	Measure
Time-to-Progression (TTP), Overall response rate (ORR), , Clinical Benefit Rate (CBR)	PFS	Progression free survival

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