Real-World Evidence Study on AbeMaciclib Treatment Patterns and Effectiveness in Patients with HR+/HER2- Locally Advanced or Metastatic BReAst CancEr in Kuwait and Lebanon.

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Main Information

Primary registry identifying number
LBCTR2022035014

Protocol number
TRACE 2020-9591

MOH registration number

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
Eli Lilly

Primary sponsor: Country of origin
United Arab Emirates

Date of registration in primary registry
09/12/2022

Date of registration in national regulatory agency

Public title
Real-World Evidence Study on AbeMaciclib Treatment Patterns and Effectiveness in Patients with HR+/HER2- Locally Advanced or Metastatic BReAst CancEr in Kuwait and Lebanon.

Acronym

Scientific title
Real-World Evidence Study on AbeMaciclib Treatment Patterns and Effectiveness in Patients with HR+/HER2- Locally Advanced or Metastatic BReAst CancEr in Kuwait and Lebanon.

Acronym

Brief summary of the study: English
The current observational study aims to obtain real-world data about the treatment patterns of patients with HR+/HER2- receiving Abemaciclib in locally advanced or metastatic breast cancer in Kuwait and Lebanon.
The study also aims to obtain real-world data on the clinical characteristics, the response rate, and the progression-free survival of the locally advanced or metastatic breast cancer patients receiving Abemaciclib.

Brief summary of the study: Arabic
تهدف الدراسة القائمة على الملاحظة الحالية إلى الحصول على بيانات من العالم الحقيقي حول أنماط العلاج للمرضى في سرطان الثدي المتقدم محليًا أو النقيلي في الكويت ولبنان تلقي Abemaciclib HR + / HER2-.
تهدف الدراسة أيضًا إلى الحصول على بيانات واقعية حول الخصائص السريرية ومعدل الاستجابة و البقاء على قيد الحياة دون تقدم لمرضى سرطان الثدي المتقدمين محليًا أو النقيلي الذين يتلقون العلاج

Health conditions/problem studied: Specify
locally advanced or metastatic breast cancer

Interventions: Specify

Abemaciclib (VERZENIO™)

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion criteria
Patients eligible for inclusion in this study have to fulfill all of the following criteria:
1. Adult breast cancer female patients ≥18 years old at the start of receiving Abemaciclib, whether as a single-agent treatment or combination treatment
2. Premenopausal or postmenopausal patients with histologically proven HR-positive, HER2-negative with locally advanced or metastatic breast cancer (De-novo or recurrence/progression of early breast cancer)
3. Patients who are being treated or have been treated with Abemaciclib (VERZENIO™), whether as a single-agent treatment or combination treatment, for at least three months before data collection
4. Patients treated with Abemaciclib (VERZENIO™), whether as a single-agent treatment or combination treatment, according to the SmPC.

Key inclusion and exclusion criteria: Gender

Female

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

90

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion criteria
1. Patients previously included in Abemaciclib clinical trial
2. Patients with evidence of other prior second primary concurrent malignancy apart from locally advanced or metastatic breast cancer.

Type of study

Observational

Type of intervention

N/A

Type of intervention: Specify type

N/A

Trial scope

N/A

Trial scope: Specify scope

N/A

Study design: Allocation

N/A

Study design: Masking

N/A

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

N/A

Study design: Specify purpose

N/A

Study design: Assignment

N/A

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Therapeutic indication

Therapeutic benefit

Study model

Case-Control

Study model: Specify model

N/A

Study model: Explain model

This is an observational, retrospective, multicenter, single-arm cohort study based on the review
of medical records of HR-positive/HER2-negative locally advanced or metastatic breast cancer
patients receiving Abemaciclib

Time perspective

Retrospective

Time perspective: Specify perspective

N/A

Time perspective: Explain time perspective

All study data will be collected retrospectively from the electronic or paper medical records and
will cover the period from the date of HR-positive/HER2-negative locally advanced or metastatic
breast cancer patients' diagnosis until patients' inclusion dates.

Target follow-up duration

3

Target follow-up duration: Unit

months

Number of groups/cohorts

1

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

100

Actual enrollment target size

100

Date of first enrollment: Type

Actual

Date of first enrollment: Date

19/10/2021

Date of study closure: Type

Actual

Date of study closure: Date

25/04/2022

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

N/A

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

Name
Eli Lilly, UAE

Secondary Sponsors

Name
CTI

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Sarah Kharsa	Beirut	Lebanon	+96181209199	s.kharsa@ctifacts.com	CRO
Scientific	Sarah Kharsa	Beirut	Lebanon	+96181209199	s.kharsa@ctifacts.com	CRO

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu de France Hospital	Dr Joseph Kattan	Oncology	Approved
American University of Beirut Medical Center	Dr Nagi El Saghir	Oncology	Approved
Rizk Hospital (LAUMCRH)	Dr Hady Ghanem	Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	15/09/2021	May Ammar	ma117@aub.edu.lb	+961 1 350000 ext: 2979
Hotel Dieu de France	26/07/2021	Nancy El Alam	nancy.alam@usj.edu.lb	+961 421 400
Lebanese American University- University Medical Center Rizk Hospital	02/12/2021	Karmen Baroudy	karmen.baroudy@lau.edu.lb	+961 9 547254 ext. 2546

Countries of Recruitment

Name
Lebanon
Kuwait

Health Conditions or Problems Studied

Condition	Code	Keyword
Breast Cancer	2-Propanol (T51.2)	Breast Cancer

Interventions

No Interventions

Primary Outcomes

Name	Time Points	Measure
Treatment patterns	3	N/A

Key Secondary Outcomes

Name	Time Points	Measure
Progression free survival	3	N/A

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