# 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.

**21/11/2024 23:28:17**

## 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**