A phase III randomized double-blind, placebo controlled study of alpelisib in combination with fulvestrant for men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment

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Main Information

Primary registry identifying number
LBCTR2019020190

Protocol number
CBYL719C2301

MOH registration number
7829/ص

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 recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency
27/08/2015

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
13/02/2019

Date of registration in national regulatory agency
27/08/2015

Public title
A phase III randomized double-blind, placebo controlled study of alpelisib in combination with fulvestrant for men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment

Acronym
SOLAR-1

Scientific title
SOLAR-1: A phase III randomized double-blind, placebo controlled study of alpelisib in combination with fulvestrant for men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment

Acronym

Brief summary of the study: English
To determine whether treatment with alpelisib plus fulvestrant prolongs progression-free survival compared to fulvestrant and placebo in men and postmenopausal women with hormone receptor positive (HR+), HER2-negative advanced breast cancer, who received prior treatment with an Aromatase Inhibitor either as (neo) adjuvant or for advanced disease

Brief summary of the study: Arabic
دراسة عشوائيّة التوزيع، مزدوجة التعمية، مضبطة الدواء الوهمي في المرحلة الثالثة حول ألبيليسيب بالاشتراك مع فولفسترانت1سولار – سلبي الذي تطوّر عند أو بعد – HER2- للرجال والنساء ما بعد انقطاع الطمث المصابين بسرطان الثدي المتقدّم مع مستقبل هورمون إيجابي علاج بمثبّط للأروماتاز :

Health conditions/problem studied: Specify

men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment

Interventions: Specify

IMP : BYL719 Alpelisib

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:
•If female, patient is postmenopausal
•Patient has identified PIK3CA status

•Patients may be:
◦relapsed with documented evidence of progression while on (neo) adjuvant endocrine therapy or within 12 months from completion of (neo) adjuvant endocrine therapy with no treatment for metastatic disease;
◦relapsed with documented evidence of progression more than 12 months from completion of (neo)adjuvant endocrine therapy and then subsequently; progressed with documented evidence of progression while on or after only one line of endocrine therapy for metastatic disease;
◦newly diagnosed advanced breast cancer, then relapsed with documented evidence of progression while on or after only one line of endocrine therapy

•Patient has recurrence or progression of disease during or after AI therapy (i.e.

letrozole, anastrozole, exemestane).
•Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive breast cancer by local laboratory and has HER2 negative breast cancer
•Patient has either measurable disease per RECIST 1.1 criteria OR at least one predominantly lytic bone lesion must be present
•Patient has adequate bone marrow function

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

Exclusion Criteria:
•Patient with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine therapy per the investigator's best judgment
•Patient has received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant, any PI3K, mTOR or AKT inhibitor (pre-treatment with CDK4/6 inhibitors is allowed)
•Patient with inflammatory breast cancer at screening
•Patients with Child pugh score B or C
•Patients with an established diagnosis of diabetes mellitus type I or not controlled type II
•Patient has Eastern Cooperative Oncology Group (ECOG) performance status 2 or more
•Patient with CNS involvement unless he/she is at least 4 weeks from prior therapy completion to starting the study treatment and has stable CNS tumor at time of screening and not receiving steroids and/or enzyme inducing ant-epileptic medications for brain metastases
•Patient has participated in a prior investigational study within 30 days prior to enrollment or within 5 half-lives of the investigational product, whichever is longer
•Patient has a history of acute pancreatitis within 1 year of screening or a past medical history of chronic pancreatitis
•Patient who relapsed with documented evidence of progression more than 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for metastatic disease

Other protocol-defined inclusion/esclusion criteria may apply

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

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

3

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

BYL719 (ALpelisib)

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

α-specific class I phosphatidylinositol-3-kinase (PI3K) inhibitor belonging to the 2-aminothiazole class of compounds.

Therapeutic indication

hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment

Therapeutic benefit

Progression-free survival (PFS) [Time Frame: Up to approximatly 36 months]
Overall survival (OS) for patients with PI3KCA mutant status [Time Frame: Up to approximatly 59 months]
Overall response rate (ORR) [Time Frame: Up to approximatly 36 months]
Time to definitive deterioration of Eastern Cooperative Oncology Group (ECOG) performance status [Time Frame: Baseline, Up to approximatly 36 months]

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 without DNA

Biospecimen description

Blood, urine and Tissue samples shipped to Quintiles central Lab or Genoptix BioPharma Lab in the UK ; Laboratory (Hematology, chemistry, biomarkers, pharmacokinetics), Urinalysis shipped to Quintiles (Q2) central Lab in the UK and Tissue Slides sent to Genoptix Central Lab in the UK

Target sample size

8

Actual enrollment target size

8

Date of first enrollment: Type

Actual

Date of first enrollment: Date

16/02/2016

Date of study closure: Type

Actual

Date of study closure: Date

28/04/2022

Recruitment status

Complete

Recruitment status: Specify

Date of completion

09/06/2017

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.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

https://clinicaltrials.gov/ct2/show/NCT02437318?term=CBYL719C2301&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
National Institute of Health (clinicaltrials.gov)	NCT02437318

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

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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
Bellevue Medical Center	Dr Fadi El Karak	Hematology Oncology	Approved
Hotel Dieu De France	Dr Joseph Kattan	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	01/06/2015	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Bellevue Medical Center	04/09/2015	Ghassan Maalouf	gmaalouf@bmc.com.lb	+961 (0) 1 682666 ext 7600
Hammoud Hospital University Medical Center	05/08/2015	Ahmad Zaatari	zaatari@hammoudhospital.com	+961 (0) 7 723111 ext 1160

Countries of Recruitment

Name
Argentina
Australia
Austria
Belgium
Brazil
Bulgaria
Canada
Chile
Lebanon
China
Germany
Italy
France
India

Health Conditions or Problems Studied

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

Interventions

Intervention	Description	Keyword
Laboratory (Hematology, chemistry, biomarkers, pharmacokinetics), Urinalysis, ECG, Echocardio, Physical Exma, Vital Signs	Lab, ICF, ECG, IMP administration	ICF, Lab, ECG, IMP

Primary Outcomes

Name	Time Points	Measure
Progression-free survival (PFS) for patients with PIK3CA mutant status	Up to approximatly 36 months	36 Months

Key Secondary Outcomes

Name	Time Points	Measure
Overall survival (OS) for patients with PI3KCA mutant status	59 months	59 months
Overall response rate (ORR)	36 months	36 months

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