Study to Compare the Combination of Ribociclib Plus Goserelin Acetate With Hormonal Therapy Versus Combination Chemotherapy in Premenopausal or Perimenopausal Patients With Advanced or Metastatic Breast Cancer (Right Choice)

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Main Information

Primary registry identifying number
LBCTR2019060241

Protocol number
CLEE011A3201C

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
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
19/09/2019

Date of registration in national regulatory agency

Public title
Study to Compare the Combination of Ribociclib Plus Goserelin Acetate With Hormonal Therapy Versus Combination Chemotherapy in Premenopausal or Perimenopausal Patients With Advanced or Metastatic Breast Cancer (Right Choice)

Acronym
RIGHT CHOICE

Scientific title
A Phase II Randomized Study of the Combination of Ribociclib Plus Goserelin Acetate With Hormonal Therapy Versus Physician Choice Chemotherapy in Premenopausal or Perimenopausal Patients With Hormone Receptor-positive/ HER2-negative Inoperable Locally Advanced or Metastatic Breast Cancer

Acronym

Brief summary of the study: English
To compare the combination of Ribociclib plus goserelin acetate with hormonal therapy versus combination chemotherapy in premenopausal or perimenopausal patients with advanced or metastatic breast cancer
A phase II randomized study of the combination of Ribociclib plus goserelin acetate with Hormonal Therapy versus physician choice hemotherapy in premenopausal or perimenopausal patients with hormone receptorpositive/ HER2-negative inoperable locally advanced or metastatic breast cancer - RIGHT Choice Study

Brief summary of the study: Arabic
دراسة مرحلة ثانية عشوائيّة التوزيع حول العلاج المشترك المؤلف من ريبوسيكليب وخلات الغوسيريلين مع العلاج الهورموني مقابل العلاج الكيميائي المختار من الطبيب لدى المريضات ما قبل انقطاع الطمث أو في فترة ما حول انقطاع الطمث المصابات بسرطان الثدي المتقدّم محليًّا أو النقيلي غير القابل للجراحة الإيجابيّ مستقبلة الهورمون/السلبيّ HER2 – (الخيار الصحيح) "رايت تشويس" دراسة

Health conditions/problem studied: Specify

Advanced Breast Cancer

Interventions: Specify

•Combination Product: Docetaxel / Capecitabine

Docetaxel (IV Infusion) / Capecitabine (Tablets for oral use):

Docetaxel once, on day 1 of the 3-weeks cycle Capecitabine twice daily, on Days 1 to 14, followed by a 1-week rest period, in 3 weeks cycle.

Docetaxel (60 - 75 mg/m²)/capecitabine (1600 - 2500 mg/m²)

Other Names:◦Combination chemotherapy group.
◦The chemotherapy regimen will be decided by the treating physician.

•Combination Product: Capecitabine / Vinorelbine

Capecitabine (Tablets for oral use) / Vinorelbine (Capsule for Oral use/IV infusion)

Capecitabine twice daily on days 1 to 14, followed by a 1-week rest period, in 3 weeks cycle Vinorelbine, once, on Day 1 and Day 8 in 3 weeks cycles

Capecitabine (1600 - 2500 mg/m2/day)/vinorelbine (60 to 80 mg/m2 [oral] or (25 to 30 mg/m2 [IV infusion]

Other Names:◦Combination chemotherapy group.
◦The chemotherapy regimen will be decided by the treating physician.

•Combination Product: Paclitaxel / Gemcitabine

Paclitaxel (IV Infusion) / Gemcitabine (IV Infusion):

Paclitaxel via 3-hour intravenous (IV) infusion on Day 1 in 3-weeks cycles, OR Paclitaxel via 1 hour intravenous (IV) infusion on Day 1 and day 8- in 3-weeks cycles.

Gemcitabine at via 30 minute IV infusion on Day 1 and Day 8 in 3 weeks cycles.

Paclitaxel (175 mg/m2) (on Day 1 in 3-weeks cycles)/ gemcitabine (1000 - 1250 mg/m2/day)

OR

Paclitaxel (80 - 90 mg/m2) (on Day 1 and Day 8 in 3-weeks cycles) / gemcitabine (800 1000 mg/m2)

Other Names:◦Combination chemotherapy group.
◦The chemotherapy regimen will be decided by the treating physician.

•Drug: Ribociclib
dose: 600 mg Days 1 to 21 of each 28 day cycle Tablets for oral use

Other Names:◦Endocrine treatment arm:
◦NSAI + goserelin+ ribociclib

•Drug: Letrozole OR Anastrozole

Letrozole:

Dose: 2.5 mg All days of every cycle without interruption). Tablets for oral use

Anastrozole:

dose: 1 mg All days of every cycle without interruption. Tablets for oral use

The NSAI (letrozole or anastrozole) will be decided by the treating physician.

Other Names:◦Endocrine treatment arm:
◦NSAI + goserelin+ ribociclib

•Drug: Goserelin
dose: 3.6 mg Day 1 of each 28 day cycle Subcutaneous implant

Other Names:◦Endocrine treatment arm:
◦NSAI + goserelin+ ribociclib

•Combination Product: Capecitabine / Vinorelbine

Capecitabine (Tablets for oral use) / Vinorelbine (Capsule for Oral use/IV infusion)

Capecitabine twice daily on days 1 14, followed by a 1-week rest period, in 3 weeks cycle Vinorelbine, once, on Day 1 and Day 8 in 3 weeks cycles

Capecitabine (1600 - 2500 mg/m2/day)/vinorelbine (60 to 80 mg/m2 [oral] or (25 to 30 mg/m2 [IV infusion]

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OR

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Other Names:◦Combination chemotherapy group.
◦The chemotherapy regimen will be decided by the treating physician.

Key inclusion and exclusion criteria: Inclusion criteria

1.Patient is an adult female ≥ 18 years old and < 60 years old at the time of informed consent.
2.Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer based on the most recently analyzed tissue sample and all tested by local laboratory. ER should be more than 10% ER positive or Allred ≥5 by local laboratory testing.
3.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

4.Women with advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy. Patients must fulfill at least one of the following criteria to be considered that combination chemotherapy is needed according to PI's judgment:
◦Symptomatic visceral metastases
◦Rapid progression of disease or impending visceral compromise.
◦Markedly symptomatic non visceral disease if the treating physician opt to give chemotherapy for rapid palliation of patients symptoms.

5.Patient is premenopausal or perimenopausal at the time of study entry.

a.Premenopausal status is defined as either:
□Patient had last menstrual period within the last 12 months. OR
□If on tamoxifen within the past 14 days, plasma estradiol must be ≥ 10 pg/mL and/or FSH ≤ 40 IU/l or in the premenopausal range, according to local laboratory definition.
□In case of therapy induced amenorrhea, with a plasma estradiol ≥10 pg/mL and/or FSH ≤40 IU/l or in the premenopausal range according to local laboratory definition.
□Patients who have undergone bilateral oophorectomy are not eligible.

b.Perimenopausal status is defined as neither premenopausal nor postmenopausal

6.Patients must have not received any prior hormonal therapy and chemotherapy for advanced breast cancer, except LHRH agonist. Patients who received ≤ 14 days of tamoxifen or a NSAI (letrozole or anastrozole) with or without LHRH agonist for advanced breast cancer prior to randomization are eligible. Patient must have measurable disease.

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

59

Key inclusion and exclusion criteria: Exclusion criteria

1.Patient has received prior systemic anti-cancer therapy (including hormonal therapy and chemotherapy, or any CDK4/6 inhibitor for advanced

breast cancer.
◦Patients who received (neo) adjuvant therapy for breast cancer are eligible. If the prior neo (adjuvant) therapy included aromatase inhibitors, the disease free interval must be greater than 12 months from the completion of aromatase inhibitor treatment until randomization.
◦Patients who are receiving ≤ 14 days of tamoxifen or NSAI or LHRH agonists ≤ 28 days for advanced breast cancer prior to randomization are eligible.

2.Patient has received extended-field radiotherapy or limited field radiotherapy ≤ 2 weeks prior to randomization, and has not recovered to grade 1 or better from related side effects of such therapy (with the exception of alopecia or other toxicities not considered a safety risk for the patient at investigator's discretion). Patient from whom ≥ 25% of the bone marrow has been previously irradiated are also excluded.
3.Patient has a concurrent malignancy or malignancy within 3 years of randomization, with the exception of adequately treated, basal or squamous cell skin carcinoma, non-melanomatous skin cancer or curatively resected cervical cancer.
4.Patients who have lung metastases with oxygen demand in resting status.
5.Patients who have liver metastases with bilirubin > 1.5 mg/dL

6.Patients with CNS involvement unless they meet ALL of the following criteria:
◦At least 4 weeks from prior therapy completion (including radiation and/or surgery) to starting the study treatment.
◦Clinically stable CNS tumor at the time of screening and not receiving steroids and/or enzyme inducing anti-epileptic medications for brain metastases
◦Leptomeningeal metastases is not allowed, even with stable clinical condition

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

Open (masking not used)

Study design: Control

Active

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

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

US,EU, other countries. For Lebanon: Postmenopausal women

Name of IMP

Ribociclib

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

Premenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer

Therapeutic benefit

Increase PFS (Progression Free Survival)

Study model

Study model: Explain model

N/A

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

NA

Target sample size

10

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

15/08/2019

Date of study closure: Type

Anticipated

Date of study closure: Date

15/12/2022

Recruitment status

Pending

Recruitment status: Specify

Date of completion

09/02/2021

IPD sharing statement plan

No

IPD sharing statement description

Undecided

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT03839823?id=right+choice&rank=1&view=record

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT03839823

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	03753155	drfadi.trials@gmail.com	Hammoud Hospital
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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
Makassed General Hospital	Dr Anas Mugharbel	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Makassed General Hospital	30/04/2019	Mariam Rajab	research.makassed@hotmail.com	01636941
Hammoud Hospital University Medical Center	05/04/2019	Ahmad Zaatari	zaatari@hammoudhospital.com	+961 (0) 7 723111 ext 1160

Countries of Recruitment

Name
Lebanon
Malaysia
Singapore
Taiwan

Health Conditions or Problems Studied

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

Interventions

Intervention	Description	Keyword
ICF, Physical Exam, Radiology , ECG, local Labs	ICF, Physical Exam, Radiology , ECG, local Labs	ICF, Physical Exam, Radiology , ECG, local Labs

Primary Outcomes

Name	Time Points	Measure
Progression Free Survival	12 months	12 months

Key Secondary Outcomes

Name	Time Points	Measure
•Overall response rate (ORR)	12 months	12 months
Clinical Benefit Rate	12 months	12 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