



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

09/12/2022

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 chemotherapy 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 عشوائية التوزيع حول العلاج المشترك المؤلف من ريبوسيكليب و خلاص الغوسريلين مع العلاج الهرموني مقابل العلاج الكيميائي المختار من الطبيب لدى المريضات ما قبل انقطاع الطمث أو في فترة ما حول انقطاع الطمث المصابات بسرطان الثدي المتقدم محلياً أو دراسة "رايت تشويس" (الخيار الصحيح) - HER2 النقيلي غير القابل للجراحة الإيجابي مستقبله الهرمون/السلبى





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

Paclitaxel (80 - 90 mg/m²)/ gemcitabine (800 1000 mg/m²)

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 NSAID 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 $\geq 25\%$ 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

Pre-menopausal 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

5

Actual enrollment target size

5

Date of first enrollment: Type

Actual

Date of first enrollment: Date

06/04/2020

Date of study closure: Type

Actual

Date of study closure: Date

15/12/2022

Recruitment status

Complete

Recruitment status: Specify

Date of completion

05/11/2021

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

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| Public | Mona Ayoubi | Tripoli | Lebanon | 03-280069 | AYOUBI_MONA@HOTMAIL.COM | Nini Hospital |



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 |
| Hotel Dieu De France | Dr Marwan Ghosn | Hematology Oncology | Approved |
| American University of Beirut Medical Center | Dr Nagi El Saghir | Hematology Oncology | Approved |
| Nini Hospital | Dr Mona Ayoubi | 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 |
| Hotel Dieu de France | 06/06/2019 | Sami Richa | cue@usj.edu.lb | 961421229 |
| American University of Beirut Medical Center | 14/10/2019 | Fuad Ziyadeh | fz05@aub.edu.lb | 961 (0) 1 350 000 ext:5445 |
| Nini Hospital | 25/11/2019 | Nabil Kabbara | Nabil.kabbara@hopitalnini.com | 961 (0) 6 431 400 ext 1062 |



Countries of Recruitment

| Name |
|-----------|
| Lebanon |
| Malaysia |
| Singapore |
| Taiwan |
| Egypt |
| India |
| Jordan |
| Turkey |
| 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