



# 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)

23/11/2024 18:22:44

## 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 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 خلات الغوسيريلين 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/m<sup>2</sup>)/capecitabine (1600 - 2500 mg/m<sup>2</sup>)

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/m<sup>2</sup>/day)/vinorelbine (60 to 80 mg/m<sup>2</sup> [oral] or (25 to 30 mg/m<sup>2</sup> [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/m<sup>2</sup>) (on Day 1 in 3-weeks cycles)/ gemcitabine (1000 - 1250 mg/m<sup>2</sup>/day)

OR

Paclitaxel (80 - 90 mg/m<sup>2</sup>) (on Day 1 and Day 8 in 3-weeks cycles) / gemcitabine (800 1000 mg/m<sup>2</sup>)

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/m<sup>2</sup>/day)/vinorelbine (60 to 80 mg/m<sup>2</sup> [oral] or (25 to 30 mg/m<sup>2</sup> [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  $\geq 18$  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  $\geq 5$  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  $\geq 10$  pg/mL and/or FSH  $\leq 40$  IU/l or in the premenopausal range, according to local laboratory definition.

In case of therapy induced amenorrhea, with a plasma estradiol  $\geq 10$  pg/mL and/or FSH  $\leq 40$  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  $\leq 14$  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  $\leq 14$  days of tamoxifen or NSAID or LHRH agonists  $\leq 28$  days for advanced breast cancer prior to randomization are eligible.

2. Patient has received extended-field radiotherapy or limited field radiotherapy  $\leq 2$  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**

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
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Anas Mugharbel	Beirut	Lebanon	03776142	anasml@hotmail.com	Makassed General 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



## 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**