A Phase I/II, Dose Finding and Optimization Study of [177Lu]Lu-NeoB in Combination With Capecitabine in Patients With GRPR+, ER+, HER2- Metastatic Breast Cancer After Progression on Previous Endocrine Therapy in Combination With a CDK4/6 Inhibitor.

Last Update: May 21, 2025

A Phase I/II, Open-label, Multi-center Trial of [177Lu]Lu-NeoB in Combination With Capecitabine in Adult Patients With Gastrin Releasing Peptide Receptor Positive, Estrogen Receptor-positive, Human Epidermal Growth Factor Receptor-2 Negative Metastatic Breast Cancer After Progression on Previous Endocrine Therapy in Combination With a CDK4/6 Inhibitor.

ClinicalTrials.gov Identifier:
NCT06247995

Novartis Reference Number:CAAA603D12101

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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

In the phase I part, to determine the recommended doses (RD) and dosing regimens of \[177Lu\]Lu-NeoB in combination with capecitabine in adult patients with gastrin releasing peptide receptor positive, estrogen receptor-positive, human epidermal growth factor receptor-2 negative metastatic breast cancer after progression on previous endocrine therapy in combination with a CDK4/6 inhibitor. In the phase II part, to evaluate the preliminary anti-tumor activity of two different doses/regimens of \[177Lu\]Lu-NeoB in combination with capecitabine (dose optimization). Despite remarkable clinical results with the use of CDK4/6i, breast cancer patients will experience progression of disease requiring alternative treatment options. The optimal sequence of therapy after progression on CDK4/6i has not been established and it depends on multiple factors, including previous regimens, mutational profile, comorbidities, patient preference or disease burden (NCCN v4, 2023). Thus, new targeted treatment modalities are needed for treatment of patients with endocrine-resistant mBC.

The purpose of this Phase I/II study conducted in participants with ER+/HER2-, gastrin releasing peptide receptor positive (GRPR+) mBC after progression on CDK4/6i-based therapy is:

In the Phase I (dose escalation part) to determine the recommended doses and regimens of \[177Lu\]Lu-NeoB in combination with capecitabine in post-menopausal women and men not requiring gonadotropin releasing hormone agonist.

In the Phase II (dose optimization part) to evaluate preliminary efficacy across 2 different dose levels and regimens of \[177Lu\]Lu-NeoB in combination with capecitabine in adults including pre/peri-menopausal and post-menopausal women, and men, regardless of their need of a gonadotropin releasing hormone agonist (GnRha).

During screening, study participants will receive the radioligand imaging agent \[68Ga\]Ga-NeoB for a positron emission tomography (PET)/computed tomography (CT) or PET/magnetic resonance imaging (MRI). An additional \[68Ga\]Ga-NeoB for PET/CT or PET/MRI will be performed after their last administration of \[177Lu\]Lu-NeoB for phase II participants only.

During the treatment period participants will be required to attend a site visit approximately every 3 weeks for the first 9 months and every 6 weeks thereafter, on the first day of every cycle (defined as a period of 3 weeks) or every other cycle, respectively, to undergo study treatment administration or dispensing, dosimetry and safety assessments. Tumor assessments are performed every 9 weeks until month 18, every 12 weeks until month 46 and as clinically indicated thereafter, until disease progression. After study treatment discontinuation, participants will be followed up for safety for 8 weeks after their last study treatment administration. Beyond the initial 8 weeks of safety follow-up, all participants will be followed up as per the Schedule of Assessments, for a total of 5 years from their last \[177Lu\]Lu-NeoB administration, or until death, lost to follow-up, participant/guardian's or investigator's decision or withdrawal of consent (WoC).

The end of study is defined as the date of the last visit, scheduled procedure or follow up (or date of death, participant/guardian's or investigator's decision, WoC or lost to follow up, whichever occurs first) of the last participant in the study globally, or at 5 years from the last \[177Lu\]Lu-NeoB administration to the last study participant, whichever occurs last.

This study includes \[177Lu\]Lu-NeoB and capecitabine as study treatment and \[68Ga\]Ga-NeoB as an imaging agent. Participants will receive \[177Lu\]Lu-NeoB in combination with capecitabine (and a GnRHa, where applicable, as per local clinical practice, for pre-/peri-menopausal women and men in the Phase II part only).

\[68Ga\]Ga-NeoB is a PET imaging agent being investigated in studies with \[177Lu\]Lu-NeoB treatment in patients with tumors overexpressing GRPR, including mBC patients. \[68Ga\]Ga-NeoB has shown favorable technical and diagnostic performance to identify GRPR-expressing malignancies, both in preclinical and in clinical studies, with good image quality that allows interpretation.

\[177Lu\]Lu-NeoB has shown high affinity to the GRPR and its ability to target the GRPR expressing tumor has been confirmed in in vivo imaging and biodistribution studies in tumor models. \[177Lu\]Lu-NeoB is rapidly cleared from the blood, quickly eliminated through the renal system, with no retention in kidneys. \[177Lu\]Lu-NeoB is currently being evaluated as a single agent in an ongoing Phase I/IIa, open-label, multi-center study (NeoRay) which evaluates the safety, tolerability, whole-body distribution, radiation dosimetry and anti-tumor activity of \[177Lu\]Lu-NeoB administered in patients with advanced solid tumors known to overexpress GRPR who have no available therapeutic options. Data show that \[177Lu\]Lu-NeoB has shown a good tolerability and safety profile and a favorable biodistribution with low uptake in organs considered to be at risk due to GRPR-expression, such as the pancreas, or due to radioligand therapy (RLT), such as the red marrow, and the route of excretion, such as the kidneys.

Capecitabine is an oral fluoropyrimidine carbamate that is converted to 5-fluorouracil (5-FU) preferentially in tumor tissue through exploitation of high intratumoral concentrations of thymidine phosphorylase. It is one of the most frequent chemotherapy treatment choices for HR+/HER2- mBC patients post-CDK4/6i failure from 2nd line and beyond as reflected in real word data. It is also considered to be a potent radiosensitizer. The

synergistic combination of chemotherapy and radionuclides has the potential to enhance efficacy.

This study will enroll a total of between 36 and 58 participants, depending on the applicable scenario. In the Phase I part, about 18 participants will be either enrolled or assigned to treatment/randomized (as applicable). In the Phase II part, between 28 and 40 participants will be randomized, depending on the applicable scenario.

* The screening period of 42 days is followed by the treatment period until disease progression, discontinuation of study treatment due to any other reason such as unacceptable toxicity, symptomatic deterioration, WoC, lost to follow up, investigator decision or death, whichever occurs first. The post treatment follow up period comprises the safety follow up for 8 weeks after treatment discontinuation and the long term safety and survival follow up for up to 5 years from the date of the participant's last dose of \[177Lu\]Lu-NeoB
* During screening, each participant will receive \[68Ga\]Ga-NeoB for PET/CT or PET/MRI imaging to confirm eligibility. Additionally, within 4-8 weeks from the last administration of \[177Lu\]Lu-NeoB, another administration of \[68Ga\]Ga-NeoB for PET/CT or PET/MRI will be performed, in the phase II part only.
* In the phase I part, participants will receive \[177Lu\]Lu-NeoB at a starting dose of 150mCi +/- 10% (iv infusion) Q6W in combination with capecitabine (tablet, 1000 mg/m2 twice daily for 14 consecutive days followed by 7 days off treatment). If dose escalation is supported, then two higher dose levels of \[177Lu\]Lu-NeoB in combination with capecitabine are planned to be explored, in a randomized way: 200mCi Q6W and 100mCi Q3W. These correspond to the same total dose given in a 6 weeks timeframe but exploring a different dose fractionation.
* If dose escalation from the starting dose is not supported, then lower dose levels will be explored (100mCi Q6W and if shown safe, 100mCi Q3W). If none of these are shown safe then the study will be terminated
* In the phase II part, there are four potential scenarios that may apply, depending on the outcome of the phase I part:
* Scenario 1 (if both higher dose levels in phase I were shown safe) participants will be randomized to either \[177Lu\]Lu-NeoB 200mCi Q6W or 100mCi Q3W, in combination with capecitabine
* Scenario 2 (if only one of the two higher dose levels in phase I were shown safe) participants will be randomized to either \[177Lu\]Lu-NeoB 200mCi Q6W / 100mCi Q3W (whichever was shown safe in phase I) or 150 mCi Q6W, in combination with capecitabine
* Scenario 3 (if none of the higher doses in phase I are shown safe): participants will be randomized to either \[177Lu\]Lu-NeoB 150mCi Q6W or 100mCi Q6W, in combination with capecitabine
* Scenario 4 (if dose escalation from the starting dose was no supported in phase I and lower investigational dose levels and regimens are shown safe in phase I part): participants will be randomized to either \[177Lu\]Lu-NeoB 100 mCi Q6W or 100 mCi Q3W, in combination with capecitabine.
* Treatment duration with \[177Lu\]Lu-NeoB is 6 administrations for Q6W regimens and 12 administrations for Q3W regimens. Additional \[177Lu\]Lu-NeoB administrations may be considered based on an individual benefit-risk assessment performed by the Investigator, participant and Sponsor

Condition
Breast Cancer
Phase
Phase1, Phase2
Overall Status
Recruiting
Number of Participants
58
Start Date
Aug 14, 2024
Completion Date

Sep 09, 2031
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Capecitabine

Capecitabine is a chemotherapy drug.
Drug

[177Lu]Lu-NeoB

\[177Lu\]Lu-NeoB is a radioligand therapy drug.
Drug

[68Ga]Ga-NeoB

68Ga\]Ga-NeoB serves as a radioactive imaging compound to be used for PET imaging for localization of GRPR positive lesions.

Eligibility Criteria

Inclusion Criteria:

1. Signed informed consent must be obtained prior to participation in the study.
2. Participant is female or male adult ≥ 18 years old at the time of informed consent(s).
3. Participant has a histologically and/or cytologically documented diagnosis of ER+ breast cancer (ER expression \>10% of tumor cell nuclei stain (regardless of PgR expression) (based on the most recently analyzed tissue sample tested by a local laboratory).
4. Participant has HER2-negative (as per ASCO-CAP guidelines Wolff et al 2018) breast cancer defined as a negative in situ hybridization test (ISH) or an IHC status of 0, 1+ or 2+. If IHC is 2+, a negative ISH (e.g., FISH, CISH, or SISH) (based on the most recently analyzed tissue sample tested by a local laboratory) is required.

5a. Participant received no more than three prior endocrine therapies (single agent or in combination with targeted therapy) regimen/s in the metastatic setting of which at least one included endocrine therapy in combination with a CDK4/6i. In addition:

* in case of confirmed presence of deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation, the participant may also have received a PARP inhibitor-based therapy.
* In case of HER2-low breast cancer (IHC 1+ or IHC 2+ with ISH negative as per ASCO-CAP guidelines Wolff et al 2023), the participant may also have received trastuzumab deruxtecan \[Enhertu®\]).

6. Participant has metastatic breast cancer with radiologically confirmed progression of disease after the most recent therapy 7. Participant must have measurable disease, i.e., at least one measurable lesion as per RECIST 1.1. (a lesion at a previously irradiated site may only be counted as a target lesion if there is a clear

sign of progression since the irradiation) as per local assessment.

Note: If only lytic bone lesions are present, they must have at least one lesion with a soft tissue component that can be evaluated by CT or MRI and meets the definition of measurability as per RECIST 1.1 criteria (participants with only one predominantly lytic bone lesion that has been previously irradiated are eligible if there is documented evidence of disease progression of the bone lesion after irradiation).

8a. Participant has at least one target lesion \[as per RECIST 1.1 and based on the baseline stand-alone contrast-enhanced CT (or MRI)\] with \[68Ga\]Ga-NeoB uptake greater than the physiological uptake of the liver at PET/CT or PET/MRI, as per local reading. In addition:

• Participants with liver or lung disease involvement must show \[68Ga\]Ga-NeoB uptake greater than the physiological uptake of the liver as follows:

* If there is liver disease involvement (in the absence of lung involvement), in ≥ 50% of all CT measurable liver lesions (RECIST 1.1)
* If there is lung disease involvement (in the absence of liver involvement), in ≥ 50% of all CT measurable lung lesions (RECIST 1.1)
* Participants with both liver and lung disease involvement must show \[68Ga\]Ga-NeoB uptake above the liver in ≥ 50% of all CT measurable lesions either in liver or lung (RECIST 1.1) and in at least one measurable lesion in the remaining organ (lung or liver) 9a. Participants with central nervous system (CNS) involvement are eligible provided that they meet ALL the following criteria:
* At least 2 weeks from prior therapy completion (including radiation and/or surgery) to initiation of the study treatment
* Clinically stable CNS tumor at the time of screening
* Participant is not receiving steroids and/or anti-epileptic medications for brain metastases at the time of initiation of the radioligand study treatment 10. Participant has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

11. Participant has adequate bone marrow and organ function as defined by the following laboratory values (as assessed by local laboratory):
* Absolute neutrophil count ≥ 1.5 × 109/L
* Platelets ≥ 100 × 109/L
* Hemoglobin ≥ 9.0 g/dL
* International Normalized Ratio (INR) ≤1.5
* Creatinine Clearance ≥60 mL/min using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation
* Total bilirubin (TBIL) \< 1.5 × ULN (any elevated bilirubin should be asymptomatic at enrollment) except for participants with Gilbert's syndrome who may only be included if the total bilirubin is ≤ 3.0 × ULN or direct bilirubin ≤ 1.5 × ULN
* In absence of liver metastases, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) \< 2.5 × ULN. If the participant has liver metastases, the participant will be eligible for the study if ALT and AST \< 5 X ULN.
* Serum lipase ≤ 1.5 × ULN Note: no platelet transfusion, packed red blood cell transfusion, or G-CSF will be allowed during the screening phase after ICF signature
* Participant must have the following laboratory values within normal limits or corrected to within normal limits with supplements before the first dose of study medication:
* Potassium
* Magnesium
* Total Calcium (corrected for serum albumin) 12. Participant must be able to swallow capecitabine tablets. 13.

Participant must be able to communicate with the investigator and comply with the requirements of the study procedures.

14a. For Phase I part only Female participant must be in postmenopausal status at the time of starting study treatment.

Postmenopausal status is defined by any of the following (NCCN 2024):

* Prior surgical bilateral oophorectomy (with or without hysterectomy)
* Age ≥ 60 years
* Age \< 60 years and ≥ 12 months of natural (spontaneous) amenorrhea in the absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression with serum Follicle-Stimulating Hormone (FSH) and estradiol in the postmenopausal range per local normal range.
* Aged \< 60 years: chemotherapy-induced amenorrhea for ≥ 12 months with serial measurements of FSH and estradiol in post-menopausal ranges (NCCN V4 2023).
* Aged \< 60 years: on tamoxifen with serial measurements of FSH and estradiol in post-menopausal ranges Note: Ovarian radiation or treatment with a gonadotropin releasing hormone agonist (GnRHas e.g. goserelin acetate) is not permitted for induction of ovarian suppression in the Phase I part.

Male participants, provided that they do not require continued GnRHas while on study treatment 15a. For Phase II part only

• Female participant is post-menopausal as per criteria above at the time of starting study treatment.

OR • Female participant is pre/peri-menopausal at the time of starting study treatment

Pre-menopausal status is defined as either:

* Patient had last menstrual period within the last 12 months OR
* If on tamoxifen or toremifene within the past 14 days, FSH and estradiol in pre-menopausal ranges on serial measurements OR
* In case of therapy induced amenorrhea, FSH and estradiol in pre-menopausal ranges on serial measurements Note: Peri-menopausal status is defined as neither pre-menopausal nor post-menopausal (see definition above)
* Male participants, regardless of their need of GnRHas while on study treatment.

Exclusion Criteria:

1. Participant with symptomatic visceral disease or any disease burden that are at risk of life-threatening complications as per the investigator's judgment.

2a. Participant has received \>1 prior treatment with chemotherapy and/or Antibody Drug-Conjugates (ADCs) in the metastatic setting. Chemotherapy in neoadjuvant/ adjuvant setting is not considered a line of therapy, unless progression or recurrence occurred during or within 12 months after completion of adjuvant chemotherapy.

3. Participant has received prior treatment with capecitabine. 4. History of hypersensitivity or contraindication to any of the study treatments or their excipients or to drugs of similar chemical classes.

5. Participant has inflammatory breast cancer at screening. 6. Participant has had major surgery within 14 days prior to starting study treatment or has not recovered from major side effects.

7. Participant has received any prior treatment with a therapeutic radiopharmaceutical.

8. Prior External Beam Radiation Therapy (EBRT) to more than 25% of the bone marrow.

9. Participant has a concurrent malignancy or malignancy within 3 years of start of study treatment, with the exception of adequately treated, basal or squamous cell carcinoma, non-melanomatous skin cancer, or curatively resected cervical cancer.

10. Participant has impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of the study drugs (e.g., uncontrolled ulcerative diseases, uncontrolled nausea, vomiting, diarrhoea, malabsorption syndrome, or small bowel resection) based on investigator's discretion.

11. Participant has any other concurrent severe and/or uncontrolled medical condition that would, in the investigator's judgment, cause unacceptable safety risks, contraindicate participant participation in the clinical study or compromise compliance with the protocol (e.g., chronic pancreatitis, chronic active hepatitis, active untreated or uncontrolled fungal, bacterial or viral infections, interstitial lung disease (ILD)/ pneumonitis etc.).

12. Participant has a history of or ongoing acute pancreatitis within 1 year of screening.

13. History or current diagnosis of impaired cardiac function, clinically significant cardiac disease or ECG abnormalities indicating significant risk of safety for participants in the study such as:

* Documented myocardial infarction (MI), angina pectoris, cardiomyopathy, symptomatic pericarditis, or coronary artery bypass graft (CABG) within 6 months prior to study entry
* Clinically significant cardiac arrhythmias (e.g., ventricular tachycardia), complete left bundle branch block, high-grade atrioventricular (AV) block (e.g., bifascicular block, Mobitz type II and third-degree AV block)
* Long QT syndrome or family history of idiopathic sudden death or congenital long QT syndrome, or any of the following:
* Risk factors for TdP including uncorrected hypocalcemia, hypokalemia or hypomagnesemia, history of cardiac failure, or history of clinically significant/symptomatic bradycardia
* Inability to determine the Fridericia QT correction formula (QTcF) interval
* Resting QTcF ≥450 msec (male) or ≥460 msec (female) at screening as per standard 12-lead ECG values defined as the mean of the triplicate ECGs and assessed locally
* Left Ventricular Ejection Fraction (LVEF) \< 50% as determined by echocardiogram (ECHO) or MUGA.
* Uncontrolled hypertension defined by a Systolic Blood Pressure (SBP) ≥ 160 mmHg and/or Diastolic Blood Pressure (DBP) ≥ 100 mm Hg, with or without anti-hypertensive medication.

14. Participant is currently receiving brivudine which cannot be discontinued at least 4-week prior to start of capecitabine therapy.

15a. Participant is currently receiving NEP inhibitors (i.e., Entresto®, racecadotril) and images for dosimetry assessments cannot be acquired for this participant as per Section 8.7.3.

16a. Participant with deficiency or family history of deficiency of dihydropyrimidine dehydrogenase.

17. Participant participated in a prior investigational study within 30 days prior to start of study treatment, or within 5 half-lives of the investigational product, whichever is longer; or as required by local regulations.

18. Sexually active male participants unwilling to:
* remain abstinent (refrain from sexual intercourse) or
* use a condom, while taking study treatment and for at least 4 months after the last administration of \[177Lu\]Lu-NeoB, or 3 months after the last dose of capecitabine (or as per locally prescribing information) whichever is longer, in addition to the highly effective method used by the partner who is a female of child-bearing potential.

Note: A condom is required for all sexually active male participants to prevent them from fathering a child and to prevent delivery of study treatment via seminal fluid to their partner. In addition, male participants must not donate sperm for the time period specified above.

19. Participants with legal incapacity to give informed consent, where required by local regulation (e.g. in EU).

20a. For Phase II part only

* Pregnant or breast-feeding women
* Women of childbearing potential, defined as all women physiologically capable of becoming pregnant, are not allowed to participate in this study UNLESS they are using highly effective methods of contraception throughout the study and for up to 7 months after the last administration of \[177Lu\]Lu-NeoB or 6 months after the last dose of capecitabine (or as per locally prescribing information) whichever is longer. Highly effective contraception methods include:
* Total abstinence (when this is in line with the preferred and usual lifestyle of the subject). Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.
* Bilateral oophorectomy with or without hysterectomy, total hysterectomy, or bilateral salpingectomy at least six weeks before taking study treatment. In case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow up hormone level assessment are they not considered to be of childbearing potential.
* Bilateral tubal occlusion, Bilateral tubal ligation (at least six weeks before taking study treatment)..
* Sterilization (vasectomy) of male partner(s) of the female participant at least 6 months prior to screening provided partner(s) has(have) received medical assessment of the surgical success.
* Placement of an intrauterine device (IUD) and concurrent use of barrier methods of contraception: condom or occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/vaginal suppository.

If local regulations deviate from the recommendations provided above, local regulations apply and will be described in the ICF.

Women are considered not of child-bearing potential if they are post- menopausal or have had surgical bilateral oophorectomy (with or without hysterectomy), bilateral salpingectomy or total hysterectomy at least six weeks prior to enrollment on study. In the case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow-up hormone level assessment is she considered to be not of child-bearing potential.

Note: Use of oral (estrogen and progesterone), injected or implanted hormonal methods of contraception or intrauterine system (IUS) or any other form of hormonal contraception for example hormone vaginal ring, or transdermal hormone contraception is not allowed in this study.

21.Participants taking prohibited therapies as listed in Section 6.8.2

Australia

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