IRB APPROVED
AS MODIFIED
Jan 17, 2019

**Hoffman Oncology**
Study# CL- Gedatolisib-001

Informed Consent Form to Participate in Research

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| **TITLE:** | Phase I Dose-Escalation Study of Combination of Gedatolisib (a Dual Inhibitor of PI3-K and mTOR) with Palbociclib and Faslodex in the Neoadjuvant Setting in Previously Untreated Patients with ER+/HER2- Breast Cancer |
| **PROTOCOL NO.:** | CL-Gedatolisib-001<br>WIRB® Protocol #20152600 |
| **SPONSOR:** | Anthony Hoffman, MD |
| **INVESTIGATOR:** | Anthony Hoffman, MD<br>Hoffman Oncology<br>1461 Astor Avenue<br>Bronx, New York 10469<br>United States |
| **STUDY-RELATED PHONE NUMBER(S):** | Anthony Hoffman, MD<br>718-655-1005 (24-hours) |

## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have ER+/HER2- breast cancer and you intend to undergo surgery for the disease (e.g., a mastectomy or lumpectomy) after completion of neoadjuvant chemotherapy (or chemotherapy before the surgery). Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

An investigational drug is one that has not been approved by the U.S. Food and Drug Administration (FDA). Gedatolisib is an investigational drug that has not been approved by the FDA for the treatment of any type of tumor or cancer, and it is currently being studied for the treatment of different types of cancer.

The primary purpose of this study is to test the safety, tolerability and potential effectiveness of Gedatolisib when given at different dose levels in combination with two other anti-cancer drugs (Palbociclib and Faslodex), administered as neoadjuvant chemotherapy in previously untreated patients with a specific type of breast cancer called ER+/HER2- breast cancer. Palbociclib and Faslodex have already been approved by the FDA for the treatment of ER+/HER2- breast cancer. We want to find out what effects, good and/or bad, Gedatolisib has on you and your cancer when given in combination with Palbociclib and Faslodex, as well as find what should be the highest dose level of Gedatolisib used when given in combination with Palbociclib and Faslodex in treating patients with ER+/HER2- breast cancer. Gedatolisib is thought to inhibit the biological process within cancer patients called PI3-K/Akt/mTOR/p-S6 pathway. This pathway has been associated with the development of resistance to cancer treatment in ER+ breast cancer. Inhibition of this biological pathway with Gedatolisib, in combination with the anti-hormonal/anti-cancer drugs Palbociclib and Faslodex, may increase survival beyond the combination of Palbociclib and Faslodex in ER+/HER2- breast cancer patients. The potential advantages of Gedatolisib is its inhibition of the drug treatment resistance biological process (so that patients are less likely to develop resistance to chemotherapy treatment) and that once a week administration used in this study may be as effective, but less toxic, than long-term oral dosing used in other clinical studies. A biopsy sample of your tumor tissue in the breast will be taken before and during investigational neoadjuvant therapy (i.e., Gedatolisib in combination with Palbociclib and Faslodex). The biopsy samples and material from your breast surgery at the end of this trial will be analyzed and tested to evaluate some biomarkers (or biological key molecular or cellular events that link the effectiveness of chemotherapies). We will also want to measure the amount of tumor cells and other biomarkers in your blood.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to eighteen (18) people will take part in the first portion of the study in order to select the highest dose of Gedatolisib that can be used safely. Once the highest safe dose has been found, another nine (9) people will take part in the second portion of the study to further investigate the safety and effectiveness of Gedatolisib. Over the course of the entire study, a maximum of 18 people will take part in this study.

## WHAT IS INVOLVED IN THE STUDY?

After your study doctor has answered all your questions about this study and you have given written consent by signing this form, several tests will be done to be sure you are able to enter this study. Many of the tests are the same as those you have had in the past to diagnose and treat your disease. Some of these same tests will also be done during the study to follow your progress.

Your participation in this study is divided into different visits:

**Pre-Study Screening Tests** (To see if you are eligible to participate in this study)

The following tests will be done in order to determine if you are eligible to participate in this study. These tests may be completed within two weeks, except for imaging scans which will be performed within four weeks, prior to receiving the investigational neoadjuvant chemotherapy (Gedatolisib in combination with Palbociclib and Faslodex).

- The study doctor or study nurse will ask you about your medical history, and obtain a list of all medications that you are currently taking.
- The study doctor or study nurse will ask you about your cancer history (date of diagnosis, current stage of disease, date of diagnosis of the current stage of disease, and cancer-related treatment history)
- A physical examination with your vital signs (heart rate, blood pressure, breathing rate, and body temperature), height, and body weight will be recorded.
- A blood test called Hemoglobin A1c will be performed.
- An ECG will be recorded and examined.
- Blood work (clinical chemistry with renal function, hematology and coagulation)
- Fasting serum glucose, fasting triglycerides, insulin, C-peptide and cholesterol will be assessed in the clinic. You are required to fast overnight (nothing except water and/or medications after midnight or for a minimum of 8 hours before you give a blood sample) for the fasting serum glucose and fasting triglyceride tests.
- Your tumor will be evaluated based on imaging scans.
- Your tumor will also be evaluated based on physical exam of your breast and axilla.
- Tumor tissues are obtained at baseline via needle biopsy, and post-neoadjuvant treatment from tumor excision surgery, to assess pCR (pCR background information at baseline) and genetic information (i.e., genomics) via the Foundation CDx™ test. If extra tumor tissue samples are available, they will be stored for possible future testing.
- Whole blood samples will be obtained to assess genetic information (i.e., genomics) using a test called FoundationOne®Liquid. If extra blood samples are available, they will be stored for possible future testing.
- Approximately 3-4 teaspoons of blood will be drawn for routine lab tests and the biomarker tests.

The following test must be completed within 2 weeks before receiving the investigational neoadjuvant chemotherapy:

- Pregnancy test for female subjects who can become pregnant and at least monthly in premenopausal subjects.

Participants may receive different doses of the investigational drug Gedatolisib, depending on when they are enrolled onto the study. This is because in this study, Gedatolisib will be starting from the lowest dose (180 mg/m$^2$) and then gradually increased to a maximum dose (260 mg/m$^2$). The different doses of Gedatolisib to be tested in this study are expected to be safe, based on interim results from ongoing clinical trials in cancer patients.

You will be given a total of four treatment cycles, and each treatment cycle lasts for 4 weeks. During each of four 4-week treatment cycles, Gedatolisib will be given to you once weekly on the first day for each of the four weeks, Palbociclib will be given to you daily for the first 21 days, and Faslodex will be given to you on the first day of the first and third weeks during Cycle 1 and on the first day of Cycles 2, 3 and 4.

Gedatolisib will be administered as an intravenous infusion over 30 minutes. Palbociclib will be taken by mouth with food. Faslodex will be given by intramuscular (or into the muscle) injection.

If you are pre-menopausal, Zoladex will be given to you by subcutaneous (or under the skin) injection once every 28 days, starting 1 week prior to the start of the investigational neoadjuvant chemotherapy. The study doctor could also use Eligard or Lupron Depot instead of Zoladex. These are approved drugs.

- After completion of 4 cycles of this therapy, you will have surgery to remove the breast cancer.

**Evaluation / Procedures for Each 4-Week Treatment Cycle for a Total of 16 Weeks**

*Week 1, Day 1*

- You will be given Gedatolisib.
- You will be given Palbociclib.
- You will be given Faslodex
- You will have a physical exam. Your vital signs will be measured, and your symptoms will be evaluated, before and after giving Gedatolisib to you.
- Fasting serum glucose as well as clinical chemistry, hematology and coagulation, are assessed in the clinic. You are required to fast overnight (nothing except water and/or medications after midnight or for a minimum of 8 hours before you give a blood sample) for the fasting serum glucose test. (For the first cycle, the results from screening can be used for the tests to be performed on this day.)

*Week 1, Days 2, 3, 4, 5, 6, and 7*

- You will be given Palbociclib.

*Week 2, Day 1*

- You will be given Gedatolisib.
- You will be given Palbociclib.
- You will have a physical exam. Your vital signs will be measured, and your symptoms will be evaluated, before and after giving Gedatolisib to you.
- Clinical chemistry, hematology and coagulation are assessed in the clinic.

Week 2, Days 2, 3, 4, 5, 6, and 7

- You will be given Palbociclib.

*Week 3, Day 1*

- You will be given Gedatolisib.
- You will be given Palbociclib.
- You will be given Faslodex (only during Cycle 1).
- You will have a physical exam. Your vital signs will be measured, and your symptoms will be evaluated, before and after giving Gedatolisib to you.
- Clinical chemistry, hematology and coagulation are assessed in the clinic.

Week 3, Days 2, 3, 4, 5, 6, and 7

- You will be given Palbociclib.

*Week 4, Day 1*

- You will be given Gedatolisib.
- You will have a physical exam. Your vital signs will be measured, and your symptoms will be evaluated, before and after giving Gedatolisib to you.
- Clinical chemistry, hematology and coagulation, are assessed in the clinic.

**Evaluation / Procedures After Each 4-Week Treatment Cycle**

- Your tumor will also be evaluated based on physical exam of your breast and axilla.

**Evaluation / Procedures at the End of Two 4-Week Treatment Cycles**

- Your tumor will be evaluated based on imaging scans.
- Physical exam of your breast and axilla will be performed

After Neoadjuvant Chemotherapy, and Before Surgery

- You will have a physical exam, your vital signs will be measured, and your symptoms will be evaluated.
- Hemoglobin A1c, insulin, C-peptide and cholesterol, as well as clinical chemistry, hematology and coagulation, are assessed in the clinic.

At Surgery

- Tumor tissues from the surgery will be obtained to assess genetic information (i.e., genomics) via the Foundation CDx™ test. If extra tumor tissue samples are available, they will be stored for possible future testing.

After Surgery

- Whole blood samples will be obtained to assess genetic information (i.e., genomics) using a test called FoundationOne®Liquid. If extra blood samples are available, they will be stored for possible future testing.

## HOW LONG WILL I BE IN THE STUDY?

You are expected to be in the study for a maximum of 16 weeks, as you will be receiving a total of four 4-week treatment cycles of the investigational neoadjuvant chemotherapy before surgery. Once you have completed the four 4-week treatment cycles of the investigational neoadjuvant chemotherapy, you will be evaluated for surgery for your cancer. The length of participation in this study may be shorter, if you do not receive all four 4-week treatment cycles.

You can stop participating at any time. It is important to tell the study doctor if you are thinking about stopping so that any risks from the investigational chemotherapy can be evaluated by your study doctor. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

## WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

### Risks of Participating in this Study

Risks Related to Gedatolisib

The study drug is in the early stages of development for use in humans. The main purpose of this study is to learn about the safety and effectiveness of the investigational drug Gedatolisib when used to treat ER+/HER2- breast cancer. Please carefully read the sections on risk and benefits below. Not all of the side effects are known at this time. If you choose to take part in this study, it is very important that you let the study team know of any symptoms you have.

Some potential risks associated with Gedatolisib have been determined from previous clinical studies. These side effects include mucosal inflammation and stomatitis. To avoid these potential side effects, investigators may employ prophylactic measures and treatment options to reduce the incidence and severity of oral complications. Although drug-induced pneumonitis was not reported in clinical trials in which Gedatolisib is used alone, one patient treated with Gedatolisib in combination with dacomitinib experienced Grade 3 drug-induced pneumonitis. To avoid this potential side effect, potential drug-induced pneumonitis and other respiratory events may be monitored by the study personnel.

Many side effects may go away shortly after Gedatolisib is given, but in some cases side effects may be severe, long lasting, or may not go away. Although not yet reported in any human subjects, it remains possible that Gedatolisib might cause your disease to progress. Gedatolisib may also cause side effects that we have not yet seen and cannot predict.

Some common side effects observed in patients taking Gedatolisib may include:

- Nausea
- Mucosal Inflammation
- Vomiting
- Diarrhea
- Stomatitis (mouth sores)
- Dry Mouth
- Asthenia ( Weakness, loss of strength )
- Pyrexia (fever)
- Fatigue
- Aspartate aminotransferase increased which may indicate liver damage
- Alanine aminotransferase increased which may indicate liver damage
- Hyperglycemia (high blood sugar)
- Dehydration
- Dysgeusia (abnormal taste)
- Rash
- Dry skin
- Pruritus (itching)
- Dermatitis acneiform

It is possible that you could experience an allergic reaction to Gedatolisib. An allergic reaction can be mild, or it can be serious, leading to shock with loss of consciousness, or it can be life-threatening.

There may be other, more severe side effects, such as inflammation throughout your body.

Pregnancy Risks

The effects of Gedatolisib on a fetus are unknown. You should not become pregnant while on this study. If you are able to become pregnant, you must use effective birth control methods during the study period. Effective birth control methods are outlined below:

Women subjects can use one of the following methods:

- Abstinence
- A barrier method (diaphragm or condom with a spermicidal foam or jelly) plus hormonal birth control (oral, patch or injectable).
- A barrier method (diaphragm or condom with a spermicidal foam or jelly) plus and intrauterine device (IUD).

If you suspect that you have become pregnant, you must notify the study doctor immediately.

Female subjects should avoid becoming pregnant by one of the above contraceptive methods during the study and for at least 3 months following completion of the study.

Risks Related to Faslodex

Some common side effects observed in patients taking Faslodex include:

- Injection site pain
- Nausea
- Bone pain
- Arthralgia
- Headache
- Back pain
- Fatigue
- Pain in extremity
- Hot flash
- Vomiting
- Anorexia
- Asthenia (loss of strength)
- Musculoskeletal pain
- Cough
- Dyspnea
- Constipation
- Increased hepatic enzymes (ALT, AST, ALP) that may mean liver damage

Risks Related to Palbociclib

Some common side effects observed in patients taking Palbociclib include:

- Low white blood cell counts (Neutropenia)
- Infection
- Leukopenia
- Fatigue
- Nausea
- Stomatitis
- Anemia
- Alopecia
- Diarrhea
- Thrombocytopenia
- Rash
- Vomiting
- Decreased appetite

- Asthenia
- Pyrexia

Risks Related to Zoladex

Some common side effects observed in patients taking Zoladex include:

- Headache
- Abdominal pain
- Pelvic pain
- Back pain
- Vasodilatation (dilation of blood vessels)
- Migraine
- Nausea
- Nervousness
- Depression
- Pharyngitis (inflammation of the pharynx)
- Sinusitis
- Sweating
- Dysmenorrhea (pain in association with menstruation)
- Uterine Hemorrhage
- Vulvovaginitis
- Menorrhagia
- Vaginitis

Risks related to Eligard

Common side effects of Eligard include:

- hot flashes (flushing),
- increased sweating,
- night sweats,
- chills,
- clammy skin,
- tiredness,
- swelling of the ankles or feet,
- increased urination at night,
- mental/mood changes (e.g., depression, mood swings),
- dizziness,
- injection site reactions (redness, stinging, burning, pain, bruising),
- acne,
- increased growth of facial hair,
- breakthrough bleeding in a female child during the first 2 months of Eligard treatment,

- weakness,
- nausea,
- diarrhea,
- constipation,
- stomach pain,
- skin redness/itching/scaling,
- joint or muscle pain,
- vaginal itching or discharge,
- breast swelling or tenderness,
- testicle pain,
- impotence,
- loss of interest in sex,
- sleep problems (insomnia), or
- memory problems.

Tell your doctor if you have serious side effects of Eligard including:

- new or worsening bone pain,
- easily broken bones,
- increased thirst, or
- mental/mood changes (such as depression, thoughts of suicide, mood swings, aggression in children

**This is not a complete list of side effects and others may occur, please feel free to discuss this with your study doctor**

Risks related to Lupron Depot:

Common side effects of Lupron Depot 3.75 include:

- hot flashes (flushing),
- increased sweating,
- night sweats,
- chills,
- clammy skin,
- tiredness,
- headache,
- nausea,
- diarrhea,
- constipation,
- stomach pain,
- upset stomach,
- breast swelling or tenderness,
- acne,

- increased growth of facial hair,
- joint or muscle aches or pain,
- trouble sleeping (insomnia),
- reduced sexual interest,
- vaginal discomfort or dryness,
- vaginal itching or discharge,
- abnormal vaginal bleeding (in girls),
- swelling of the ankles/feet,
- dizziness,
- weakness,
- skin redness/itching/scaling,
- testicle pain,
- impotence,
- depression,
- memory problems

**This is not a complete list of side effects and others may occur, please feel free to discuss this with your study doctor**.

Risks Related to Investigational Treatment

This study involves an investigational treatment. The risk of death from breast cancer may be higher with this investigational treatment compared to standard of care.

**Other Risks**

Certain drugs, when taken together with the study drug, may increase side effects. It is important that you inform your study doctor of any prescription, over-the-counter, or alternative medications you are taking while in this study.

Drawing blood may cause pain, bruising, lightheadedness, or, on rare occasions, infection.

Your condition may not get better or may become worse during this study.

If you have questions about risks and side effects, ask your study doctor. You should talk to your study doctor about any side effects that you have while taking part in this study. The study doctor will take steps to try to treat any side effects, if they appear. If the study drug causes severe side effects or if your disease worsens, the study drug will be discontinued. In that case, your study doctor will discuss treatment options with you.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. Palbociclib and faslodex have benefited some people with breast cancer. It is hoped that gedatolisib will improve the effects of these drugs but this is not guaranteed. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be an improvement in your cancer.

## WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- Other chemotherapies or neoadjuvant chemotherapies. You may also receive palbociclib, faslodex and zoladex without being in this study.
- Comfort care, which is an option if you decide that you do not want any more active treatment for your cancer. Comfort care includes pain medication and other types of support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home. If you think you might prefer comfort care, please discuss this with your family, friends, and your doctor.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: your health history, medical images, how you respond to study procedures, laboratory and other test results, and physical examinations.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Hoffman Oncology who oversee research
2) Other people or laboratories providing services for this research project on behalf of Hoffman Oncology
3) The U.S. FDA and regulatory agencies of other countries

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Anthony Hoffman, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Anthony Hoffman, MD
Hoffman Oncology
1461 Astor Avenue
Bronx, NY 10469

However, if you take away permission to use your Protected Health Information, you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical records at Hoffman Oncology will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Hoffman Oncology. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A Hoffman Oncology medical record will be created for all study participants. Information about your participation in the study will be placed in the Hoffman Oncology medical records, along with any routine medical test results that were obtained at Hoffman Oncology as part of this study.

## WHAT ARE THE COSTS?

The investigational study drug, Gedatolisib, is being provided to you at no cost. However, taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will have to pay for the other drugs and procedures. We will give you an estimate of what the added cost may be based on your particular situation and insurance carrier.

## WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

## WHO IS SPONSORING THIS STUDY?

Anthony Hoffman, MD of Hoffman Oncology is the sponsor of this clinical trial.

## WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

You will not be paid for participating in this study. The study drug, Gedatolisib, will be given to you free of charge as long as you receive treatment on the study.

There will be no costs to you during the study for medical services or laboratory tests which are needed as part of the study.

If you are injured as a consequence of participation in the study due to the administration of the study drug or study procedures, your medical condition will be evaluated and medical care will be provided by one of the investigators or you will be referred for appropriate treatment. If you are injured as a result of participating in this study, the costs of your medical treatment will be paid for by your insurance to the extent that such coverage is available.

No funds have been set aside to compensate you in the event of injury or illness related to study treatment or procedures.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Anthony Hoffman, MD at 718-732-4000.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best interest, you do not follow the study rules, the study is stopped, you do not later consent to any future changes that may be made to the study plan, or your become pregnant.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about the study or in the event of a research-related injury, contact the study investigator, Anthony Hoffman, MD at 718-732-4000.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems, complaints, or concerns, have questions, or want to offer input, or you want to obtain additional information, you should contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

You will be given a copy of this signed consent form.

**Hoffman Oncology**
Study# CL- Gedatolisib-001

**SIGNATURES**

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am/pm

Person Obtaining Consent:_____ Date: _____Time:_____ am/pm