PRINCIPAL INVESTIGATOR: Jung-Min Lee, MD

STUDY TITLE: A Phase II Single Arm Pilot Study of the Chk1/2 Inhibitor (LY2606368) in BRCA1/2 Mutation Associated Breast or Ovarian Cancer, Triple Negative Breast Cancer and High Grade Serous Ovarian Cancer

STUDY SITE: NIH Clinical Center

Cohort: All Study Participants

Consent Version: December 2, 2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

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This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The main purpose of this study is to see whether an investigational drug, LY2606368, will help to shrink tumors in people with certain types of breast and ovarian cancer. LY2606368 is

manufactured by Eli Lilly and is not approved by the United States (U.S.) Food and Drug Administration (FDA) to treat any type of breast or ovarian cancer, or any other type of disease. All cells go through cycles which allow them to divide. Cell division is important because it allows all living things to grow, to heal and to reproduce. In normal cells, there are many proteins which help to make sure that cells are dividing correctly. LY2606368 blocks two of these proteins called Chk1 and Chk2. In normal cells, Chk1/2 stop cell division at various points to allow any damage to DNA to be repaired and to make sure that chromosomes are lined up correctly. When Chk1/2 are not present, cells stop dividing and eventually die. The researchers in this study hope that by blocking these proteins it will cause tumor cells to die, thereby shrinking tumors.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You are being asked to participate in this study because you have been diagnosed with:

1) Breast or ovarian cancer and have a mutation in BRCA1/2 genes (BRCAm)
2) High Grade Serious Ovarian Cancer (HGSOC) OR
3) Triple Negative Breast Cancer (TNBC) OR
4) Recurrent platinum-resistant High Grade Serious Ovarian Cancer (HGSOC) AND
5) All other standard measures have failed to cure your cancer.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 153 people will take part in this research study.

DESCRIPTION OF RESEARCH STUDY

What will happen if you take part in this research study?

This study consists of the following parts:

- A screening period that may last up to 30 days, during which tests will be done to see if you qualify to take part in the study.
- A treatment period consists of 28 day cycles during which you will be given study drug once every 14 days (day 1 and day 15 of every cycle). This treatment period will continue until up to 2 cycles after your cancer goes away, until your cancer gets worse, or if you are withdrawn from the study. If you cannot tolerate LY2606368, it may also be necessary to end your treatment.
- An end of treatment visit (for safety reasons) will be done after the last dose of study drug.
- If your cancer completely goes away, you will be followed every 4 weeks with non-invasive imaging performed every 12 weeks until your cancer returns, gets worse, or if you are withdrawn from the study.

Before you begin the study

Certain standards (criteria) have been established to ensure that you are a medically appropriate candidate for this trial. These criteria also make sure that the results of this study can be used to help make decisions about treating other participants. We will record your medical history and give you a physical examination. We will review slides of a previous biopsy you have had to confirm your diagnosis. You will undergo standard blood tests including a complete blood count, chemistry panel, a pregnancy test, an EKG, and scans and x-rays as part of the NCI Screening Protocol. One test of your immune system will be a blood test that checks for the presence of the human immunodeficiency virus (HIV), the cause of acquired immunodeficiency syndrome (AIDS). HIV infection may disqualify you from this study. If you test positive for HIV, we will tell you what the results mean, how to find care, how to avoid infecting others, and how we report newly diagnosed HIV infection.

If you are eligible to participate in this trial and wish to do so, a CT-assisted biopsy of your tumor will be performed for research purposes before you start treatment. If you are in the one of groups 1-3, an additional CT-assisted biopsy may be performed during Cycle 1 if you agree, after your dose of study drug on Day 15 and at the end of your study treatment. If you are in group 5 and respond to the treatment longer than 4 months, an additional CT-assisted biopsy will be performed when your tumor stops shrinking so that researchers can study what made the tumors stop responding to LY2606368. If you are in group 6, you will not have an additional CT-assited biopsy.

During the study

During the study, the study doctor and staff will monitor you for any side effects and monitor your cancer. You may receive supportive care during this study. Ask the study doctor or staff if you have questions about supportive care. During Cycle 1, you will receive weekly phone calls to ask about whether there have been any changes to your health and about any other medications that you may be taking. For safety, during Cycle 1, you will also have routine laboratory tests done weekly, then every other week for Cycle 2 and beyond. About 3 tablespoons of blood will be drawn for these tests.

<u>Day 1</u>

After all of your baseline tests are complete, you will start treatment. On Day1, the study staff will perform a complete physical exam. They will ask if there have been any changes to your physical health and about any medications you have taken since your screening visit. They will check your vital signs and may do some routine laboratory tests. Laboratory tests that were completed within the last 3 days before Cycle 1 Day 1, will not be repeated. Blood will also be drawn for research tests to assess certain cancer markers (about 2 tablespoons). A CT scan of the chest, abdomen, and pelvis will not be repeated if you had one done within 14 days prior to the start of Cycle 1 Day 1.

<u>LY260368 Therapy</u>

You will receive the study drug LY260368 through an infusion in your vein over approximately one hour on Day 1 and on Day 15 of each 28-day cycle.

Therapy will be continued every 14 days until your cancer goes away, until your cancer gets worse, or until you are withdrawn from the study.

Your vital signs will be assessed 30 minutes before and after you have received the study drug.

An EKG will be done within 1 hour after you have received the study drug.

Day 15

On Day 15, you will be asked about whether there have any been any changes to your physical health and about any medications you have taken. The study staff will perform a complete physical examination and you will have some routine laboratory tests done for safety. About 3 tablespoons of blood will be drawn for these tests. If you are in the one of groups 1-3, you will be asked if you want to have a second biopsy. This second biopsy, which would be assisted by a CT scan, is for research purposes and it is optional. Even if you do not want to do this second biopsy, you can still continue on the study. You will also be required to have an EKG and about 2 tablespoons of blood will be drawn to assess certain cancer markers.

Day 28

On Day 28, the first treatment cycle will end. You will be asked about whether there have been any changes to your health and about any other medications you have taken. You will have a complete physical exam and have about 3 tablespoons of blood drawn for routine laboratory tests. You will also be required to have an EKG.

Cycle 2 and beyond

Some tests will be performed every cycle, some will be performed every other cycle, some will be performed every three cycles, and some will be completed in the first cycle only. If you are in the group 5 and on the treatment longer than 4 months, you will be asked about a second biopsy when your tumors start growing on imaging. This second biopsy, which would be assisted by a CT scan, is for research purposes and it is mandatory for the researchers to study what makes tumors become resistance to the treatment. This mandatory second biopsy will not be done if you (group 5) don't respond to the therapy longer than 4 months. The Study Chart below gives more information about the timing of all of the tests needed for this study.

When you are finished taking the drugs (treatment)

If you or your study doctor decides to stop study treatment, if your cancer has spread, or if you cannot tolerate the study treatment then you will be asked to return for an end of treatment visit. During this visit, the following will be performed:

- You will have a complete physical examination to assess any changes since the last study visit.
- Your vital signs will be measured.
- You will be asked if you want to have another CT-assisted biopsy. It will be your choice whether you want to have this biopsy done.
- Your cancer will be evaluated through CT scans of the chest, pelvis, and abdomen. Male participants may also be evaluated with bone scans. Your tumor will be checked to see if it has grown, shrunk or stayed the same.
- You will have an EKG.

- Blood samples (about 3 tablespoons) will be taken for safety laboratory blood tests, including blood counts, blood clotting ability, and liver, and kidney functions.
- A blood sample (about 2 tablespoons) will be collected to assess certain cancer markers.
- You will be asked about any changes in your health and any changes to the medications that you are taking.

Study Chart

Study Procedures	**Day**	**Blood Samples (amount)**	**Subsequent Cycles and Study Completion**
History and Physical Examination	Each visit and phone follow-up every week during Cycle 1		Day 1 of every cycle; Study Completion
Vital Signs	Before treatment; and 30 minutes before and after each infusion and Day 28		Same for all cycles; Study Completion
Routine Blood Tests	Each Visit	3 tablespoons each	Day 1 and Day 15 of every cycle; plus the every week during Cycle 1 only; Study Completion
CT-assisted Biopsy for Research	Before treatment; Cycle 1 Day 15*		One at Study Completion*
EKG	Before treatment; Cycle 1 Days 1 and 15 within 1 hour after each infusion		Once in Cycle 2 and then once every 3 months before and within 1 hour after each infusion; Study Completion
Blood Tests for Research	Before treatment; Day 15	2 tablespoons each	Once at study Completion
CT Scan of the chest, abdomen, and pelvis (tumor assessment to see if it is shrinking, growing, or staying the same size)	Before treatment or Cycle 1 Day 1 if the screening scan was done more than 14 days prior to Cycle 1 Day 1		Participants with breast or ovarian cancer: at the beginning of every other cycle, starting with Cycle 3 Day 1, , prior to infusion; Study Completion
Pregnancy Test	Before treatment		None
Study Drug Infusion	Day 1, Day 15		Same for all cycles

* Groups 1-3: Biopsies in Cycle 1 Day 15 and at the completion of the study are not necessary for study participation. The post treatment biopsy will only be requested to study why your tumor does not respond the treatment.

Group 5: If you are on LY2606368 treatment longer than 4 months, the post-treatment biopsy will only be requested, to study why your tumor does not respond the treatment. If your tumor briefly responds to LY2606368 less than 4 months, the post treatment biopsy will not be asked.

BIRTH CONTROL

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. All participants of reproductive capability must agree to use both a barrier method and a second method of birth control during the study and for four months after you finish study treatment. If you are a man who is sexually active, you and your female partner must agree to use medically accepted barrier methods of contraception (e.g., male or female condom) during the study and for 4 months after you finish the study treatment, even if oral contraceptives are also used. If you think that you, or your female partner if you're a man, are pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

WHAT TESTS WILL BE DONE ON MY SAMPLES?

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study therapy, we will also collect samples from you for purposes of research only. All of your samples collected for research purposes on this study (such as the tumor and normal tissue) may be used to look for specific changes in the DNA in tumors that could be used to develop new ways of diagnosing and treating cancer. DNA (also called deoxyribonucleic acid) in the cells carries genetic information and passes it from one generation of cells to the next – like an instruction manual. Normal tissue contains the DNA (instructions) that you were born with, DNA in tumor cells has changed – or mutated – and we think that change in the DNA is what causes tumors to form and to grow.

To look at your DNA, we may do what is called "whole genome sequencing." This is where we will do special tests in the lab to look at the entire sequence, or order, of how your DNA is put together. This is what makes you unique.

To determine which parts of the DNA have mutated, we will compare the DNA in your tumor cells to DNA from your normal cells. We will then analyze the results from similar tumors to see if there are any changes in the DNA that are common to a particular type of tumor. To examine the

tumor and normal tissue we may use several different techniques depending on the type of tissue we collect. These could include growing cell lines (cells which keep dividing and growing in the laboratory, sometimes for years allowing us to continually study those cells), xenograft studies (placing or growing cells in another animal, such as mice), and looking in detail at the parts of the genes that produce specific proteins.

However, you should know that the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing or testing for routine clinical care. For these reasons, we will not give you the results of the research tests done on your research samples in most cases. There may be exceptions to what we share with you.

In the unlikely event that we discover a finding that is believed to be clinically important based on medical standards at the time that we first analyze your results, we will contact you. This could be many years in the future. We will ask you to have an additional tube of blood drawn to verify the findings we have seen in our lab. If the results are verified, you will be re-contacted and offered a referral to a genetic healthcare provider to discuss the results. In the event that you are removed from this study before such findings become available, you must be enrolled on a follow-up study in order for us to contact you. This will enable us to maintain updated contact information for you and contact you when such findings become available.

Psychological or Social Risks Associated with Loss of Privacy

The following general points are indirectly related to your participation in the research study:

1. Unanticipated medical information: During the course of this investigation, it is possible (although not likely) that we will obtain unanticipated information about your health or genetic background.
2. Release of genetic information
    - Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
    - Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease.
    - There also may be other privacy risks that we have not foreseen.

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic

information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

Who else besides the investigators on this study will know the results of my sample testing?

Once we obtain any of the samples listed above, the investigators take all your personal information off those samples and label them with a study code number. Only the investigators on this study know who the sample came from. The key linking your personal information with the code number is kept in a secure computer data base, with access only to the 2-3 research staff who will be discussing this study with you. Once the sample has been labeled with a code, it is sent to a variety of NIH laboratories for storage and testing. No one testing your samples will be able to link the results to you personally. Specimens obtained during your participation in this study may be sent for testing to investigators outside of NCI or the NIH. All samples will be coded to protect your privacy and no personal information will be included. Other investigators on this study will have access to limited clinical and biologic data such as age, gender and disease status.

How long will your samples be stored?

The samples collected during this study will be stored for as long as the study is open. When this study is closed, we would like to keep the samples for future research. We will request your permission to do so, later in this consent.

RISKS OR DISCOMFORTS OF PARTICIPATION

What side effects or risks can I expect from being in this study?

LY2606368

As with all treatments, there are several side effects or risks from the treatment provided in this study. However, doctors don't know all the side effects that may happen with this drug, so it is important to report any changes that you notice, even if your study team does not ask specifically about them. Side effects may be mild or severe. Your study team will give you medicines to help lessen side effects. Many side effects go away with those medicines and others may go away soon after you stop treatment. In some cases, side effects can be serious, long-lasting, or may never go away. In very rare instances, they could cause death.

Just over 100 people have been treated with this study drug. Based on what these people reported the possible side effects are described below:

Likely

- Low white blood cell count (which can increase your risk for infections)
- Low red blood cell count
- Low platelet count (increases your risk of bleeding)
- Nausea

- Fatigue (feeling tired)
- Fever

Less Likely

- Vomiting
- Sore mouth
- Blood in stool
- Jaundice (yellowing of the skin)
- Skin infections
- Urinary tract infection
- Fainting
- Nose bleed

Rare but Serious

- Pneumonia

Serotonin Syndrome

There is a potential risk of a condition called serotonin syndrome for participants who use certain medications from a class of drugs known as selective serotonin reuptake inhibitors (SSRIs) at the same time they're taking the study drug LY2606368. Serotonin syndrome is a potentially life-threatening drug reaction that causes the body to have too much serotonin, a chemical produced by nerve cells. Symptoms may include, but are not limited to, agitation or restlessness, severe diarrhea, a fast heartbeat, and high blood pressure. Participants who use SSRIs will be closely monitored by their study doctor for any signs and symptoms of serotonin syndrome, and they should also be monitored for this condition by their home physician. Treatment and supportive care measures are available to manage serotonin syndrome.

QTc prolongation

There is a potential risk of developing irregular heartbeats on EKG, a condition called QTc prolongation, for participants who are taking the study drug LY2606368. This EKG change is a potentially life-threatening event. People who have QTc prolongation on EKG are at risk of fainting and sudden death. Electrolytes abnormalities increase the risk for developing this change on EKG. Your electrolytes and EKG will be closely monitored before and after the study drug LY2606368 during the first two months, and then every 3 months until the end of treatment. Treatment and supportive care measures are available to manage QTc prolongation.

Myelodysplastic Syndrome (MDS)

MDS is a rare but serious group of disorders caused when something disrupts the production of blood cells. Some types have no known cause, while others occur in response to cancer treatments or chemical exposure. Symptoms may include shortness of breath, fatigue, easy bruising, and paleness. Myelodysplastic syndrome may progress to leukemia. Transfusions and medications can help manage symptoms, and medications or bone marrow transplants may

lessen the need for transfusion and slow or prevent progression to leukemia. Although it is not yet known that MDS is a risk of LY2606368, there is a possibility that it could contribute to the development of MDS in high-risk participants such as those who previously received certain types of cancer drugs or radiation therapy.

Tumor Biopsy

If your doctor determines it is safe we will obtain a piece of your tumor (biopsy) using a needle with minimal risk to you. You will be given local anesthesia (numbing medicine) and a sedative prior to the biopsy. The biopsy will be taken through a needle put through the skin into your tumor. Depending upon the location of your tumor, a CT scan may be used to assist the biopsy. After the procedure the nurses will watch your blood pressure and other vital signs. This biopsy is not optional and you cannot participate in this study if you do not agree to the biopsy. If the first biopsy is too difficult or if you experience too much discomfort as a result of it you will be able to continue on the protocol without undergoing the second and third biopsies, which are optional. However, an attempt at the first biopsy is needed to enter this study. There are other studies at NIH which may also be options for you and which do not involve biopsies.

For group 5, the second biopsy at progression is mandatory for those who responded to LY2606368 longer than 4 months.

Risk of Radiation

During your participation in this research study, you will be exposed to radiation from CT scans. The amount of radiation exposure you will receive from these procedures is equal to approximately 10.1 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure of 0.3 rem per year from these sources. This type of radiation is called “background radiation”. This study will expose you to more radiation than you get from everyday background radiation. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT scans that you get in this study will expose you to roughly the same amount of radiation as 33.7 years’ worth of background radiation. Being exposed to too much radiation can cause harmful side effects such as an increase in the risk of cancer. The risk depends on how much radiation you are exposed to. Please be aware that about 40 out of 100 people (40%) will get cancer during their lifetime, and 20 out of 100 (20%) will die from cancer. The risk of getting cancer from the radiation exposure in this study is 1 out of 100 (1%) and of getting a fatal cancer is 0.5 out of 100 (0.5%).

You may not participate in this study if you are pregnant. If you are able to become pregnant, we will perform a pregnancy test before exposing you to radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Blood Sampling

Risks of blood sampling include bruising or bleeding at the needle site; rarely infection. This is treated with bandages, pressure and, if infection, antibiotic medicines. For more information about risks and side effects, ask your study team.

CT Scans:

A CT scan is an X-ray procedure where a high-speed computer is used to make multiple images or pictures of your body. Sometimes, a contrast dye that contains iodine is administered into one of your veins to improve these images. In some cases, people might have an allergic reaction to this dye. You will be asked to lie still on a table and at times may have to hold your breath for a few seconds in order to avoid blurring the pictures. You may hear a slight buzzing, clicking and/or whirring sounds as the CT scanner moves around your body.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to see if this LY2606368 will cause your tumors to shrink. We do not know if you will receive personal, medical benefit from taking part in this study. These potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer. Because there is not much information about the drug's effect on your cancer, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.

ALTERNATIVE APPROACHES OR TREATMENTS

What other choices do I have if I do not take part in this study?

Instead of being in this study, you have these options:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

STOPPING THERAPY

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you

- If the study drug is no longer available

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to Eli Lilly or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases cannot be recalled and destroyed.

CONFLICT OF INTEREST

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a Protocol Review Guide. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

The National Institutes of Health and the research team for this study are using LY2606368 developed by Eli Lilly through a joint study with your researchers and the company. The company also provides financial support for this study.

USE OF SPECIMENS AND DATA FOR FUTURE RESEARCH

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that it may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any

specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

Genomic Data Sharing

As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

Summary information about all of the participants included in this study (including you) is being placed in a database and will be available through open access. That means that researchers and non-researchers will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

On this study, the NCI will cover the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. Someone will work with you to provide more information.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs if they are not covered by your insurance company.

- Medicines that are not part of the study treatment will not be provided or paid for by the NIH Clinical Center.
- Once you have completed taking part in the study, medical care will no longer be provided by the NIH Clinical Center.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor, National Cancer Institute Center for Cancer Research, or their agent(s)
- Qualified representatives from Eli Lilly, the pharmaceutical company who produces LY2606368.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Jung-Min Lee, MD, leej6@mail.nih.gov, 240-760-6128. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only:

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.