Participant Informed Consent for Clinical Research

Study title for participants: Palbociclib and INCMGA00012 in People with Advanced Liposarcoma

Official study title internet search on http://www.ClinicalTrials.gov: A Phase II Study of CDK4/6 Inhibition (Palbociclib) Combined with PD-1 Blockade (INCMGA00012) in Patients with Advanced Well-differentiated/Dedifferentiated Liposarcoma

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Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part in this research study because you have liposarcoma that has gotten worse (progressed), has spread beyond its original location (metastatic), is unable to be removed surgically (unresectable), or your cancer did not respond to standard therapies. . This study will have 2 parts. Part I will determine the safest dose of Palbociclib when combined with INCMGA00012 and Part 2 will determine if it is an effective treatment for advanced liposarcoma.

Palbociclib works by blocking proteins that are commonly found in liposarcoma cells that are known to contribute to cancer cell growth. INCMGA00012 is an immunotherapy drug (therapy that boosts the body's natural defenses to fight cancer). In another research study, INCMGA00012 was tested in people with other types of cancers and the drug showed some benefit without severe side effects.

The Food and Drug Administration (FDA) has approved palbociclib for the treatment of some types of breast cancer. The FDA has not approved the drug for the treatment of liposarcoma, although it is listed in the treatment guidelines of the National Comprehensive Cancer Network for the treatment of advanced liposarcoma. This study involves an investigational use of the drug.

The FDA has not approved INCMGA00012 for the treatment of liposarcoma or any other condition. INCMGA00012 is an investigational drug.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to my advanced liposarcoma?

People who are not in a study may be treated with chemotherapy agents. Surgery and radiation therapy may also be used to relieve symptoms in some patients. The chemotherapy drugs doxorubicin,

trabectedin, and eribulin have been approved by the FDA and are commonly used. The effectiveness of these FDA-approved drugs varies between different types of liposarcoma.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available
- You may choose not to be treated for cancer
- You may choose not to be treated for cancer, but to receive comfort care to help relieve your symptoms

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive treatment with the study drugs, palbociclib and INCMGA00012 for up to 2 years, or until your disease gets worse (progresses), or the side effects of the study treatment become too severe.

Within 30 days of stopping the study treatment (for any reason), you will come to the clinic for an End-of-Treatment visit. After this visit, the study doctor or a member of the study team will call you every 3 months for up to 1 year after your last dose of study drug to check on your overall health.

If your cancer has not gotten worse (progressed) by the time you stop the study treatment, the study doctor may ask you to come back to the clinic every 3 months for CT or MRI scans to monitor your cancer.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the study drugs. These side effects may be worse, and they may be different than you would have with the usual approach for your cancer.

Some of the most common side effects of the combination that the study doctors know about are:

- Fatigue
- Musculoskeletal pain
- Rash
- Nausea and/or vomiting
- Diarrhea
- Low blood cell count
- Infection
- Decreased appetite
- Infusion reaction (similar to an allergic reaction)

- Cough
- Shortness of breath

There may be some risks that the study doctors do not yet know about.

Benefits

In pre-clinical studies, a similar drug combination has been shown to shrink or stabilize cancer. . It is not possible to know now if the study drugs will be more effective against your disease than the usual approach to managing liposarcoma. Palbociclib in combination with INCMGA00012 may help your cancer, or your cancer may stay the same, or even get worse. However, what we learn from this research will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely. This may mean slowly stopping the study drugs to avoid a sudden unsafe change or risk to your health.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- For women who are able to have children: You become pregnant while you are in the study
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

We are doing this study to find out whether combining the study drugs palbociclib and INCMGA00012 is an effective and safe treatment for advanced liposarcoma. This study will have 2 parts: Part I and Part 2. Part I will determine the safest dose of Palbociclib when combined with INCMGA00012 and Part 2 will determine if it is an effective treatment for advanced liposarcoma.

Researchers think the study drug combination may be effective against liposarcoma because of the way each drug works.

INCMGA00012 is a type of medication called an antibody. It is similar to the antibodies made by the immune system to protect the body from harm. INCMGA00012 blocks the protein PD-1 (programmed cell death receptor 1), which usually acts as a brake on the immune system. Blocking this protein is like releasing the brakes, so the immune system can target cancer cells and destroy them.

Palbociclib regulates proteins that control cell growth. In a normal cell, controller proteins make sure the cell is healthy and ready to divide, which is how cells grow and increase in number. But this process does not work well in cancer cells, which divide and grow uncontrollably. By regulating proteins, palbociclib can help prevent cancer cell growth.

The FDA has approved palbociclib as a treatment for some types of breast cancer, but not for liposarcoma. This study involves an investigational use of the drug. INCMGA00012 is an investigational drug. The FDA has not approved INCMGA00012 for the treatment of liposarcoma or any other disease.

The INCMGA00012 will be provided by Incyte Pharmaceuticals.

About 42 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

This study has several parts: Part I, Part II Arm A, and Part II Arm B. Part I and Part II Arm A are closed to enrollment.

During Part I, 6 study participants received Palbociclib once a day starting on Day 1 and then received INCMGA00012 starting on Day 15.

In Part II Arm A, 6 study participants were enrolled at the same dosing scheduling used in Part I. If you were previously enrolled on study and started treatment, you will continue to receive Palbociclib 125 mg once daily starting on cycle 1 day 1 for 21 days, followed by 7 days off, plus 500 mg of INCMGA00012 on Cycle 1 Day 15 and every 28 days thereafter as long as clinically tolerated.

Part II Arm B, will enroll an additional 30 participants. You will receive Palbociclib 125 mg once daily starting on cycle 1 day 1 for 21 days, followed by 7 days off, plus 500 mg of INCMGA00012 on Cycle 1 Day 1 and every 28 days thereafter at the start of each cycle.

If, while you are receiving the study treatment, your cancer shows some signs of growth, but you and the study doctor think that you are benefitting from the study treatment, or if your cancer has shrunk, you may be eligible to continue to receive the study treatment. Your study doctor will discuss your treatment options with you, and you will be asked to sign an additional informed consent form if you agree to continue receiving the study treatment.

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

The tests and procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- A sample of your tumor tissue will be collected for biomarker and genetic research testing. The doctor doing the biopsy will explain what will happen, including any risks or possible side effects that may result from collecting the sample. You will sign a separate consent document before you undergo this procedure.
- If you have stored (archival) samples from an earlier biopsy or surgical procedure, the study doctor will request a portion of the stored tissue from the hospital or medical center where the procedure was performed.
    - We will study your samples to improve our understanding of the way changes in genes can affect the risk of cancer and other diseases. Genes are the “blueprints” for our bodies. Sometimes genes may have changes that occur during your lifetime that can affect the way a gene works. These changes (mutations) may cause cells to grow rapidly and abnormally, and become a cancer that you cannot pass on to your family members (somatic mutation).
    - We will look for changes in your genes using a test called Whole Genome Sequencing or Whole Exome Sequencing (WGS/WES). Your data may be used to learn more about cancer and other diseases. Data from large numbers of people can help researchers learn how changes in the order (sequence) of genes might affect a disease or a person’s response to treatment, identify possible links between diseases, and provide new ideas for drug development and personalized therapies.
    - Neither you nor your doctor will be given the results of any genetic research testing done on your samples. If you or your family are interested in learning more about inherited risk factors for cancer, ask your study doctor for a referral to MSK’s Clinical Genetics Service.
- Blood collection (2.5 tablespoons) for biomarker research testing. A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.
- Blood collection to check for infection with HIV, and hepatitis B or C
- CT or MRI scan, performed earlier than it would be for your usual care, to check on the presence of your disease

During the study:

You will receive study drugs during treatment Cycles. Each Cycle lasts 28 days.

You will start taking Palbociclib on Day 1 of each cycle. Palbociclib is a pill you will take by mouth every day on Days 1-21. You will not take palbociclib on Days 22-28. You will receive INCMGA00012 as an intravenous (IV) infusion given into a vein in your arm every 4 weeks, starting on Cycle 1, Day 1. The infusion will take about 1 hour.

If you previously started INCMGA00012 on Cycle 1 Day 15, you will continue to receive INCMGA00012 every 28 days per the previous schedule.

A member of the study team will give you a pill diary, so that you can write down, every day, when you take palbociclib. Instructions about how to take the study drug are included in the pill diary. Palbociclib will be prescribed to you as a capsule (in a bottle) or as a tablet (in a blister pack). Bring your completed diary to all your study appointments, and bring your medication bottles or blister packs even if the bottle or blister pack is empty.

Exams, Tests, and/or Procedures
You will have exams, tests, and/or procedures during the main study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- A sample of your tumor tissue will be collected for biomarker and genetic research testing. You will have a biopsy on Cycle 3 Day 1. will sign a separate consent document before you have this procedure.
- Blood collection (2.5 tablespoons) for genetic and biomarker research testing.

End-of-Treatment and follow-up visits:
We would like to keep track of your medical condition after you stop receiving treatment with palbociclib and INCMGA00012. Staying in touch with you and checking on your condition helps us learn more about the long-term effects of the study drugs.

You will come to the clinic for an End-of-Treatment visit within 30 days of when you stop receiving the study treatment so the study team can check on your health and see if you are having any side effects. If your cancer has gotten worse, you will have the option to undergo a biopsy procedure. More information about this procedure is in the *Optional Study* section of this consent form. After this visit, the study doctor or a member of the study team will contact you by phone every 3 months for up to 1 year after your last dose of study drug to check on your health.

If your cancer has not gotten worse (progressed) by the time you stop the study treatment, the study doctor may ask you to come back to the clinic every 3 months for CT or MRI scans to monitor your cancer.

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?
Neither you nor your doctor will receive the results of any tests done for research purposes during this study.

What risks can I expect from taking part in this study?
If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss
- There may be a risk in finding out new genetic information about yourself.

The drugs used in this study may affect how different parts of your body work, such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood throughout the study, and he or she will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drugs/study approach.

Important information about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it difficult for you to have children.
- Some side effects may be mild. Others may be very serious, and may even result in death.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce your side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of INCMGA00012:

Common, some may be serious In 100 people receiving INCMGA00012, more than 10 and as many as 100 may have:
• Tiredness (fatigue) • Feeling weak • Decreased number of red blood cells (anemia), which causes tiredness and shortness of breath • Nausea • Diarrhea • Fever • Decreased appetite

Occasional, some may be serious In 100 people receiving INCMGA00012, between 4 and 10 may have:
• Vomiting • Cough • Joint Pain • Abdominal Pain • Back Pain • Weight decreased

Occasional, some may be serious In 100 people receiving INCMGA00012, between 4 and 10 may have:
• Inflammation of the lungs; symptoms include coughing, difficulty breathing, shortness of breath, and chest pain. This condition can be life-threatening; tell the study doctor right away if you have any of these symptoms (pneumonitis) • Inflammation of the bowels/gut, which may cause pain in your belly and loose or watery stools; left untreated, in rare cases, this condition may lead to a tear in the wall of the intestine, which can be serious and life-threatening (colitis) • The thyroid gland produces too much hormone (hyperthyroidism), causing weight loss, rapid heartbeat, sweating, sensitivity to heat, and nervousness. This condition may require medical treatment. • Decrease in white blood cells, which may increase your risk of infection (leukopenia) • Decreased number of red blood cells (anemia), which causes tiredness and shortness of breath • Low number of platelets (thrombocytopenia), which may increase your risk of bleeding or bruising, and delay clotting • Shortness of breath • Blood test result associated with liver disease or bone disorders (increased alkaline phosphatase) • Laboratory test result associated with decreased kidney function and/or kidney failure (increased creatinine) • Urinary tract infection; symptoms may include blood in urine, burning when peeing, lower back pain • Constipation • Pain in arms or legs • Skin rash • Dehydration; symptoms may include feeling thirsty, dark-colored urine, dry mouth • Low levels of potassium in the blood, causing changes in heart rhythm and muscle weakness (hypokalemia)

In studies with drugs similar to INCMGA00012, the following rare and serious side effects were seen:

- Inflammation of the nerves, which may cause pain, weakness or tingling in your hands and feet, and may spread to your legs, arms, and upper body, leading to severe muscle weakness and possible temporary paralysis
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels), which may cause severe pain in the top part of your belly, and the pain may move to your back; you may feel sick to your stomach, and experience vomiting that gets worse when you eat
- Inflammation of the liver, which may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, have a pain in the right side of your belly, yellow eyes and skin, and dark urine
- Inflammation of the pituitary gland (a gland in the head), which may make you feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting, and dizziness or fainting
- Adrenal glands (glands on top of the kidneys) may not make enough hormone, which could cause tiredness; weight loss; muscle weakness; feeling faint; joint, muscle, and belly aches;

nausea; vomiting; and loose or watery stools; fever; salt craving; and sometimes darkening of the skin like a suntan
- Type 1 diabetes, a condition that can result in too much sugar in your blood, making you feel thirstier than usual, with frequent urination, and weight loss. You are likely to need regular insulin shots to treat this condition.
- Inflammation of the kidney, which may make you pass less urine or have cloudy or bloody urine, swelling, and low back pain
- Inflammation of the middle layer of your heart wall, which may make it difficult for your heart to pump blood through your body, causing chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting.
- Inflammation of the thyroid gland, which may lead to changes in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy
- Inflammation of the brain, with confusion and fever. Symptoms may include disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness
- IRR (similar to an allergic reaction) that occurs during or shortly after the infusion; symptoms include fever and chills, skin rash or swelling at the infusion site, nausea, vomiting, headache, cold-like symptoms, difficulty breathing, and low blood pressure

Possible side effects of palbociclib:

Common, some may be serious In 100 people receiving palbociclib, more than 20 and as many as 100 may have:
• Decrease in white blood cells, which may increase your risk of infection (leukopenia) • Decreased number of red blood cells (anemia), which causes tiredness and shortness of breath • Low number of platelets (thrombocytopenia), which may increase your risk of bleeding or bruising, and delay clotting • Inflammation of the mouth or lips (stomatitis) • Nausea • Diarrhea • Rash • Hair loss • Fatigue

Occasional, some may be serious In 100 people receiving palbociclib, between 4 and 20 may have:
• Weakness or low energy • Fever • Decreased appetite • Vomiting • Blurred vision • Trouble sleeping (insomnia) • Cough • Constipation

Occasional, some may be serious In 100 people receiving palbociclib, between 4 and 20 may have:
• Watery eyes • Shortness of breath • Change in sense of taste • Nose bleeds • Dry skin • Laboratory test results associated with abnormal liver function • Dry eye • Low number of white blood cells (neutrophils) and fever (temperature greater than 103.3 degrees), which increases the risk of infection (febrile neutropenia)

Possible risks and discomfort associated with research biopsies: Risks associated with biopsies include pain, redness, swelling, bleeding, bruising, infection, and, rarely, death. The doctor performing the biopsy will explain the details and risks of the procedure, which may vary, depending on how the biopsy sample will be obtained. You will sign a separate consent document before you undergo this procedure.

Possible risks of radiation-based diagnostic imaging: The above section *What extra tests and procedures will I have if I take part in this study?* describes the CT scans you will have during this study. The study team may also use CT scans to guide a needle to the tumor site for any tumor biopsies you have.

You will be exposed to low amounts of radiation from the scans performed during this research study. The CT scans provide detailed pictures of the inside of the body using radiation, like an x-ray. Every day, people are exposed to low levels of radiation that comes from the sun and the environment. Scientists think that exposure to too much radiation can be harmful.

The amounts of radiation associated with the scans included in this study are similar to those from standard-of-care imaging procedures. Each year, many thousands of patients routinely undergo similar scans and receive similar doses of radiation with no short- or long-term adverse effects.

Possible risks of contrast materials: Contrast materials, also called contrast agents or contrast media, are injected into a vein in the arm to improve the pictures produced by CT and MRI scans. Contrast materials are generally very safe, but adverse reactions ranging from mild to severe may occur. Serious allergic reactions or other reactions are rare. A small percentage of patients may develop a delayed allergic reaction, with a rash that can occur hours to days after the injection of the contrast agent. Most of these rashes are mild, but severe rashes may require medication; please discuss any reactions the study doctor.

Reproductive risks: You should not get pregnant, breastfeed, father a baby, or donate sperm while you are in this study. The drugs used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control or pregnancy prevention to use while you are in this study. You must continue to use these methods for at least 90 days after completing the study treatment.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

If you or your partner become pregnant during the study, tell the study doctor right away. Female study participants who become pregnant during the study will stop receiving the study treatment immediately. The study doctor will advise you about your medical care. The study doctor and the study funder, Incyte, may ask you to provide information about the outcome of your pregnancy.

The study funder would also like to collect information from the pregnant partners of male study participants. If your partner becomes pregnant while you are participating in this study, we will give you the funder's contact information. Your partner will decide whether to contact the funder and provide the requested information about her pregnancy.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study
- Remember to bring your completed pill diary to all your clinic appointments, along with your medication blister packs, even if the blister pack is empty.

Is there a conflict of interest for this study?

This study is sponsored by MSK. The study is being funded by Incyte and Pfizer. There are no known conflicts of interest for either the institution or the investigator(s) in this study.

What are the costs of taking part in this study?

You will not have to pay for the INCMGA00012 or for tests and procedures done only for research purposes, including:

- Biopsy procedure at screening and Cycle 3 Day 1
- Optional biopsy procedure if your cancer gets worse (progresses)
- Collection and testing of blood for research purposes

It is possible that INCMGA00012 may not continue to be supplied while you are in the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

You and/or your health plan/insurance company will have to pay for all the other costs of treating your cancer while you are in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Although you do not have to pay for INCMGA00012, the cost of getting the study drug ready and giving it to you is not paid by the study sponsor, so you or your insurance company may have to pay for this.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

Your biospecimens (blood, tissue) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many

safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

A Federal law, the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or if you are a member of the military.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Optional Study:

This part of the consent form describes an optional study that you can choose to take part in. You will not get health benefits from this study. The doctors leading this research hope that the results of this study will help other people with cancer in the future.

The results of this study will not be added to your medical records, and you and/or your study doctor will not be informed of the test results.

You will not be billed for this optional study. You can still take part in the main study even if you do not participate in the optional study. If you sign up for but cannot complete the optional study for any reason, you can still take part in the main study.

Optional collection of tissue for research testing

If you choose to take part in this study, you will have a biopsy procedure if your cancer gets worse (progresses). Researchers will use the information from tests on this new biopsy sample for biomarker and genetic testing, and to study changes in your cancer after receiving study treatment.

Information about genetic research can be found in *What extra tests and procedures will I have if I take part in this study?* section of this consent form.

You will sign a separate consent form for the biopsy procedure. The doctor doing the biopsy will explain what will happen, including any risks or possible side effects. The risks could include pain, redness, swelling, bleeding, bruising, infection and, rarely, death.

The results of testing your tissue sample will be used only for research, and not to guide your medical care.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to have the optional biopsy procedure if my cancer gets worse:

❑ Yes ❑ No

Optional contact questions:

Please indicate below whether you wish to be contacted if genetic testing on your tumor done during the study suggests that you may have inherited a genetic change (mutation) that increases your risk and/or your family's risk for cancer or another disease. We will also ask you to provide the name of a family member (or caregiver) to inform about your test results if you are unable to receive the results, either because you have died or you are otherwise incapacitated.

Please read each sentence below and think about your choice; then choose Yes or No. No matter what you decide, your choice will not affect your care. You will still be allowed to participate in this research study even if you do not want to be re-contacted in the future. If you have any questions about future contact regarding the results of your genetic testing, please speak with your doctor.

1. Someone may contact me in the future to discuss the research findings that may come from tests on my sample.

❑ Yes ❑ No

If you checked Yes to Question 1, please answer Question 2:

2. If I am unavailable, I give permission to my health care provider to discuss the results of my research tests with a family member or caregiver.

❑ Yes ❑ No

Designated contact:

Name: _____

Address: _____

Telephone: _____

Relationship: _____

This is the end of the section about the Optional Study.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

Palbociclib and INCMGA00012 in People with Advanced Liposarcoma

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Sandra D'Angelo, MD and William Tap, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- The companies or organizations that provide the funding for the study, Pfizer and Incyte Corporation.
- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study drugs.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the

study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to your medical record at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent
I have fully explained this clinical research study to the participant. In my judgment, and in that of the participant, sufficient information, including risks and benefits, was provided for the participant to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's statement
I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant must personally sign and date		
Participant signature		**Date:**
Participant name (Print)		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's language, and I confirm that the consent discussion was appropriately interpreted for the participant.
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____
(The name of the witness must be documented in the EMR.)

Interpreter (if required)
Name of interpreter (if present): _____
ID number (if phone interpreter): _____
(The interpreter's name or ID number must be documented in the EMR.)

The participant must be provided with a **signed copy** of this form.

Memorial Sloan Kettering Cancer Center
IRB Number: 20-062 A(14)
Approval date: 19-Mar-2024

Study Calendar:

This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

	Screening		Cycle 1		Cycle 2		Cycle 3+		End of treatment	Follow-up
Exam/test/ procedure	**Within 28 days of treatment**	**Day 1**	**Day 14**	**Day 15**	**Day 1**	**Day 15**	**Day 1**	**Day 15**	**Within 28 days of last dose**	**Every 3 months for up to 1 year**
Physical exam	X	X			X		X		X	
Blood for routine tests	X	X		X	X	X	X	As clinically indicated	X	
Blood to test your thyroid function	X						X C3 and every odd cycle			
Blood for HIV and hepatitis B and C tests	X									
Pregnancy test	X									
Urine for routine tests	X									
ECG	X									
Echocardiogram	X									
CT and/or MRI scan	X	X							X	
Blood for research tests	X	X			X		X		X	
Research biopsy	X						X (Cycle 3 Day 1 only)		X (Optional at time of progression)	
Review of side effects and medications you are taking	X	X		X	X	X	X	X	X	
Take palbociclib and fill out pill diary			X Once a day, Days 1-21 (Do not take Days 22-28)							
INCMGA00012 infusion		X			X		X			

Phone call to check on your health										X