THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase II Study of Futibatinib and Pembrolizumab in Metastatic Microsatellite Stable Endometrial Carcinoma
2020-0776

Subtitle: NCCN Futibatinib and Pembrolizumab

Study Chair: Siqing Fu

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if the combination of futibatinib and pembrolizumab can help to control metastatic microsatellite stable endometrial carcinoma in patients who have not received a type of treatment called immune checkpoint blockade therapy. The safety of this drug combination will also be studied.

This is the first study of futibatinib and pembrolizumab in humans.

This is an investigational study. Futibatinib is not FDA approved or commercially available. It is currently being used for research purposes only. Pembrolizumab is FDA approved and commercially available for the treatment of several types of cancer, including endometrial carcinoma. The combination of pembrolizumab and futibatinib to treat microsatellite stable endometrial carcinoma is investigational.

The study doctor can describe how the drugs are designed to work.

The study drugs may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may need to stay in the Houston area for a prolonged amount of time after the first dose of study drugs and then return to the clinic several times over the course of the study.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may receive the study drugs for up to 2 years, or for as long as the study doctor thinks you are benefitting from it.

Futibatinib will be provided at no cost to you on this study. You and/or your insurance providers will be responsible for the cost of pembrolizumab. If you stay in the hospital, you and/or your insurance provider will be responsible for the costs of hospitalization.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive other procedures or treatment options. Your doctor will discuss other treatment options with you. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor determine if you are eligible:

- You will have a complete physical exam.
- You will have an eye exam performed by an eye doctor.
- You will have an EKG and either an echocardiogram (ECHO) or MUGA scan to check your heart function.
- Blood (about 2½ tablespoons) will be drawn for routine, tumor marker, and biomarker testing. Tumor markers may be related to the status of the disease. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs and/or may help predict your response to the study drugs. If you can become pregnant, part of this blood sample will include a pregnancy test. To take part in this study, you must not be pregnant.
- Urine will be collected for routine tests.
- You will have an MRI, PET, or CT scan to check the status of the disease.
- Leftover tumor tissue from a previous procedure will be collected and tested for genetic biomarkers. If you do not have leftover tissue available, you will have a tumor biopsy. The study doctor will tell you what type of biopsy you will have.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Up to 30 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

If you are found to be eligible to take part in this study, you will receive futibatinib and pembrolizumab. You will receive the study drugs in cycles. Each study cycle is 21 days (about 3 weeks).

You will take **futibatinib** tablets by mouth 1 time every day with a glass (about 8 ounces) of water. You must fast (have nothing to eat or drink except water) for at least 2 hours before and 1 hour after each dose.

If you miss a dose of futibatinib and it has been less than 12 hours since your scheduled dose, you may take it as soon as you remember. If it has been more than 12 hours or if you vomit a dose, wait and take your next dose as scheduled.

You will receive **pembrolizumab** by vein over about 30-60 minutes on Day 1 of all cycles. You will stay in the clinic for 30-60 minutes after your dose so the study team can watch you for side effects.

You will be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Study Visits

On **Day 1 of all cycles:**

- You will have a physical exam.
- You will have an EKG and either an ECHO or MUGA scan. Starting at Cycle 2, this will only be done if the doctor thinks it is needed.
- You will have an eye exam before Cycle 3. After Cycle 3, this will be done only if the doctor thinks it is needed.
- Urine will be collected for routine tests.
- Blood (about 3½ tablespoons) will be drawn for routine and tumor marker tests. If you can become pregnant, part of the blood sample will be used for a pregnancy test.
- Blood (about 1½ tablespoons) will be drawn for biomarker testing. During this study, researchers will also look at genetic biomarkers. If you continue taking the study drugs beyond Cycle 13, blood (about 1½ tablespoons) will be drawn before Cycle 13 for biomarker testing.

On **Days 8 and 15 of Cycle 1**:

- You will have a physical exam.

- Blood (about 1 tablespoon) will be drawn for routine tests.

On **Day 22 of Cycle 1 or Day 1 of Cycle 2**, blood (about 1½ tablespoons) will be drawn for biomarker testing.

Before Cycle 3 and Cycle 5, and then every 9 weeks after that, you will have an MRI, CT, or PET scan. If the doctor thinks it is needed, you may have this scan more often.

End-of-Dosing Visit

Within 30 days after your last dose of study drugs:

- You will have a physical exam.
- Blood (about 1½ tablespoons) will be drawn for routine and tumor marker testing. If you can become pregnant, part of the blood sample will be used for a pregnancy test. If you stopped taking the study drugs before Cycle 13, blood (about 1½ tablespoons) will be drawn for biomarker testing.
- Urine will be drawn for routine and research tests.
- You will have an EKG and either an ECHO or MUGA scan.
- Depending on when your last scan was done, you may have an MRI, PET, or CT scan.

Follow-Up

You will be called every 3 months for up to 2 years after the end-of-dosing visit and asked about how you are doing and about any other treatments you may be receiving. Each call should last about 5-10 minutes.

Other Instructions

- Do not donate blood while on study and for 3 months after your last dose of study drug.
- Tell your study doctor about your current medical conditions.
- Tell your study doctor about all prescription and non-prescription medications and supplements you may be taking, including vitamins and herbals, and check with your study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the study drugs.
- Tell your study doctor if you are thinking about taking part in another research study.
- Tell your study doctor if you are considering receiving vaccination with a live vaccine.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away

shortly after the treatment, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects that you may have, even if you do not think they are related to the treatment.

Futibatinib and pembrolizumab may each cause low blood cell counts (red blood cells, platelets, and white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Futibatinib Side Effects

This is one of the early studies of futibatinib in humans, so the side effects are not well known. Based on limited early testing in humans, futibatinib may cause the following side effects:

• abnormal EKG • fatigue • dizziness • weakness • chills/fever • headache • temporary stroke symptoms • mental status change (such as memory loss or impaired thinking) • depression • skin rash/blisters/ dryness • hives • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • hair loss (partial or total)	• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) • dehydration • nausea/vomiting • loss of appetite • abnormal taste • dry mouth • constipation/ diarrhea • abdominal pain • weight loss • esophageal sores and/or mouth blisters/sores	• loss of full control of bodily movements • nerve damage (possible numbness, pain, and/or loss of motor function and/or reduced sense of touch or sensation) • muscle damage and/or muscle breakdown • muscle spasms • blurry vision and other vision problems • dry eyes • disorders of the eye cornea (possible cloudy vision) • cataracts (clouding of the lens of the eye) • painful red eyes

• nail changes	• mouth pain • inflammation of the digestive system • intestinal blockage • uterine and/or vaginal bleeding • low blood cell counts (red, platelets, white) • liver damage • difficulty walking	• retinal detachment or other damages to the eye that may lead to decreased vision or even blindness • kidney damage • nosebleed • pharyngitis • infection

Based on studies in animals, futibatinib may cause the following additional side effects:

• build-up of bone-like crystals (calcium phosphate) or lesions in different parts of the body (possibly leading to bone or joint cartilage disorders, eye disorders, heart failure, kidney failure, and/or liver failure)	• stunted growth • birth defects	• miscarriage

Based on the side effects seen with similar drugs, TAS-120 also may cause:

• fever	• pain in back, joints, arms/legs, and/or bones	• kidney failure

<u>Pembrolizumab Side Effects</u>

Common (occurring in more than 20% of patients)

• fatigue • fever • skin rash and/or itching • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke) • loss of appetite • nausea • constipation • diarrhea • abdominal pain • low blood cell count (white/red/platelets)	• abnormal liver test (possible liver damage) • pain • abnormal kidney test (possible kidney damage) • cough • difficulty breathing

Occasional (occurring in 3-20% of patients)

• swelling (face/arm/leg) • inflammation of the tissue around the heart (possible chest pain) • irregular heartbeat • headache • confusion • patches of skin color loss • underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating) • low blood sugar • weight loss • fluid in the abdomen • blood in the urine • vomiting • abnormal liver test (possible yellowing of the skin and/or eyes)	• weakness • nerve damage (possible numbness, pain, and/or loss of motor function) • difficulty breathing (possibly due to lung inflammation) • flu-like symptoms • infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing

Frequency Unknown

• heart failure • heart attack • build-up of fluid around the heart (possible heart failure)	• abnormal connections or passageways between organs or vessels • bleeding in the rectum and/or uterus	• blockage in the lung (possible pain and/or shortness of breath) • nosebleed • coughing up blood

Rare but serious (occurring in fewer than 3% of patients)

• low blood pressure (possible dizziness/fainting) • heart inflammation • build-up of fluid in the tissue around the heart • blood vessel inflammation (possible bleeding and/or bruising) • seizure • immune system damage to the nervous system (causing muscle weakness, numbness and/or paralysis) • spinal cord inflammation (possible pain, weakness, loss of feeling or movement, and/or paralysis) • brain inflammation (possible paralysis and/or coma) • shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids) • large skin blisters • very severe blistering skin disease (loss of large portion of skin and/or with ulcers of the skin and digestive tract)	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress • pituitary gland inflammation (possible headaches) • inflammation of the thyroid gland (possible tenderness in the neck) • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • liver damage (hepatitis)	• inflammation inside the eye (possible vision problems) • kidney inflammation (possible kidney damage/failure) • kidney failure • build-up of fluid around the lungs • immune response that causes the body to attack itself (possible organ damage) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • immune response (causing muscle weakness) • immune system reaction (possible fever, jaundice, liver/spleen enlargement, irritability, and/or seizures) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)

If you have a solid tumor type and you have an organ transplant, pembrolizumab may increase your risk for the transplant to be rejected by your body.

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue. These side effects can affect more than one of your normal organs and tissues at the same time.

Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

EKGs and ECHOs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

MUGA scans may cause allergic reactions to the radioactive tracer, injection site soreness, and/or swelling. They may cause damage to cells or tissue from being exposed to the radiation used in the scan. These side effects may occur in less than 10% of patients.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped.

Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.
This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. If you can become pregnant, you must use 2 methods of birth control during the study and for 180 days after the last dose of study drugs. If your partner can father a child, they must also use birth control.

You must use either 2 barrier methods or 1 barrier and 1 hormonal method. The following birth control methods are allowed during the study:

- Barrier Methods: intrauterine device (IUD), diaphragm, birth control sponge (only for women who have not given birth), condom, cervical cap with spermicide (only for women who have not given birth)
- Hormonal Method: Birth control pill, injection, or patch

If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant during or within 120 days after completing the study, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree and depending on when you enroll in the study, you will have a tumor biopsy within one week before Day 1 of Cycle 2 for biomarker testing. They type of biopsy will be described to you by your doctor. If you are not one of the participants that this biopsy applies to, you will circle "NO" below. This will be discussed with you.

Optional Procedure #2: If you the tumor responds to the study drugs and then comes back/gets worse and you agree, you will have a tumor biopsy for biomarker testing. They type of biopsy will be described to you by your doctor.

Optional Procedure #3: If you agree, you will complete 2 questionnaires about your symptoms and how you are feeling. The questionnaires should take about 15 minutes to complete. You may be asked to complete this once every week for 6 weeks, and then once before each subsequent cycle of therapy.

There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have a tumor biopsy for biomarker testing within 1 week before Day 1 of Cycle 2?

YES **NO**

Optional Procedure #2: If the disease gets better (responds) and then comes back/gets worse, do you agree to have a tumor biopsy for biomarker testing?

YES **NO**

Optional Procedure #3: Do you agree to complete questionnaires about your symptoms/feelings during the study?

YES **NO**

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

If you become injured or ill as a direct result of taking part in this study, the sponsor may pay for the treatment of the injury or illness. MD Anderson cannot determine at this time what you may be reimbursed for. A financial counselor will be made available to you after the injury or illness is reported.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

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

Additional Information

4. You may ask the study chair (Dr. Siqing Fu, at 713-792-4318) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, MD Anderson IND office, Taiho Pharmaceutical Co., Ltd., NCCN (National Comprehensive Cancer Network), the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is supported by: Taiho Pharmaceutical Co., Ltd. through a NCCN Oncology Research Program.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Personal information being collected as part of this study are gender, month and year of birth, race, and ethnicity. These data may be used by researchers at MD Anderson, NCCN, Taiho, and/or shared with other researchers and/or institutions for use in future research.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Samples
Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. The sponsor will not receive samples for future use.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

You have the right to withdraw your consent to use/store your research samples (including requesting the destruction of the sample), without explaining the reasons for your decision, if the link to your identity still exits. If you no longer want your blood or tissue samples to be used in this research or future research, you should tell your study doctor, who will ensure that the samples are destroyed. If tests have already been done on your samples, it will not be possible to withdraw permission for those tests, but no further testing will be done.

Genetic Research
Research samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

A federal law, called 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 deciding 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, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

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

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Taiho Pharmaceutical Co., Ltd. and NCCN, who are supporters of this study, and/or any future sponsors/supporters of the study
   - MOCLIA for data management
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION