MC1788 / 17-010349

A Phase II, Open-label, Single-Arm Trial Using KEYTRUDA (pembrolizumab) as Initial Systemic Therapy in the Treatment of Advanced Mycosis Fungoides

NCT03695471

Document Date: 08/18/2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 18, 2023**
Not to be used after: **August 17, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1788: A Phase II, Open-label, Single-Arm trial Using KEYTRUDA (pembrolizumab) as Initial Systemic Therapy in the Treatment of Advanced Mycosis Fungoides

IRB#: 17-010349

Principal Investigator: Dr. Jason Sluzevich and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Jason Sluzevich	**Phone:** (904) 953-2000 **Institution Name and Address:** Mayo Clinic Jacksonville 4500 San Pablo Rd Jacksonville, FL 32224	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Participant Advocate (The RPA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

Other Information:
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.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with Mycosis Fungoides (MF). The plan is to have about 10 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to test the safety, tolerability, and anti-tumor activity of pembrolizumab (MK-3475) in subjects with MF.

Pembrolizumab (MK-3475), also known as KEYTRUDA®, has been approved by the Food and Drug Administration (FDA) to treat several different cancers, but may not be approved to treat your type of cancer. Pembrolizumab works by helping your immune system to fight your cancer.

3. Information you should know

Who is Funding the Study?
Merck Sharp & Dohme Corp., (a subsidiary of Merck & Co. Inc.) is funding the study. Merck Sharp & Dohme Corporation will pay the institution to cover costs related to running the study.

4. How long will you be in this research study?

You will be in the study for about 1.5 years.

5. What will happen to you while you are in this research study?

Screening
During this visit, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. If you aren't eligible, the Principal Investigator will tell you why. At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates
- Draw a blood sample
- Test your blood and/or urine for pregnancy if you are a female able to become pregnant
- Dermatology Exam
- Take clinical photos
- Collect a skin cancer sample from a previous procedure (called "archival tumor tissue") OR collect a newly obtained skin biopsy sample before the start of the trial.
- Tumor Evaluation

These exams, tests, or procedures are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to the Principal Investigator.

Study Visit Day 1, Cycle 1
At this visit we will:

- Physical and Dermatology (Skin) Exams
- Draw a blood sample
- Administer the study drug

Study Visit Day 1, Cycles 2-4
At these visits we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rate)
- Physical and Dermatology (Skin) Exams
- Take clinical photos
- Draw a blood sample
- Study drug administration

Study Visit Day 15, Cycle 2

At this visit we will:

- Perform a research skin biopsy

Study Visit 1 week after the end of Cycle 4

- Tumor Evaluation (Whole Body PET Scan)
- Research Blood draw

Study Visit Day 1, Cycles 5 and beyond

At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates
- Physical and Dermatology (Skin) Exams
- Take clinical photos
- Draw a blood sample
- Study Drug Administration

End of Treatment Visit (3 weeks after your last dose of treatment)

At this visit we will:

- Physical and Dermatology (Skin) Exams
- Take clinical photos
- Draw a blood sample
- Study drug administration
- Tumor Evaluation (Whole Body PET Scan)
- Research Blood draw

Safety Follow-up Visit (30 days after the End of Treatment visit)

At this visit we will:

- Ask you about your medical history
- Draw a blood sample
- Dermatology (Skin) Exams
- Take clinical photos

Clinical Follow-up visit (8 weeks after the safety follow-up visit)

At this visit we will:

- Dermatology (Skin) Exams
- Take clinical photos

Research Blood Draw
An additional blood sample will be collected at the end of Cycle 4 and at the end of treatment visit to detect if there is any blood involvement with your mycosis fungoides.

Study Drug Administration
You will be given pembrolizumab every 3 weeks at a dose of 200 mg. Pembrolizumab is administered as a 30 minute intravenous (IV) infusion on Day 1 of each treatment cycle. Your body's response to the study drug will be calculated using a Modified Skin Severity Assessment (mSWAT). If there is no response within 3 weeks of the study drug administration, you will no longer receive the study drug. You will be asked to complete an end of Treatment visit.

Tumor Evaluation
A radiographic assessment of your cancer by Whole-Body PET/CT will be performed. A PET/CT scan uses radioactive sugar water and a special scanning camera to visualize the body. A PET scan uses these materials to create images of your internal organs. A CT scan uses X-rays to create images of the bones and internal organs within your body. The PET/CT will be done before you start the study treatment, 1 week after Cycle 4, and at the end of treatment. A pregnancy test will be performed, as clinically indicated, prior to any radiation procedure that exposes your abdominal/pelvic region to radiation for females of childbearing potential.

If the radiographic assessment of your cancer shows that your cancer may have worsened, you may be asked to have another, repeat, radiographic assessment later to confirm. If your study doctor thinks you are healthy enough to continue study treatment, you will continue in the study until after your repeated scan. If your repeated PET/CT scan shows that the size of your tumor has not increased further, you may be eligible to continue on the study after a discussion with the investigator. However, if your repeat CT scan shows disease progression, you will be discontinued from study treatment.

Punch Skin Biopsy
A punch skin biopsy is a procedure to remove a core of skin. The skin sample is examined in the laboratory to provide information about your medical condition. A punch skin biopsy is done at the site of the involved skin. For a punch skin biopsy, the area of skin to be biopsied is cleaned and then numbed with an injection of local anesthetic. The health care provider then uses a punch instrument similar to a tiny circular cookie cutter to cut out a core of tissue.
This instrument, which is usually no larger than a pencil eraser, is pressed down onto the skin and rotated until the circular incision goes to the desired depth. The instrument is removed. The health care provider pulls up the core of skin tissue and cuts it off at the base.

Clinical Photos

A dermatologist will complete a check for skin, hair and eye color abnormalities. Digital pictures of your face from the eyes downward and hairline will be taken for this study to monitor changes over time in skin and eye color and/or the color of hair and facial hair. If you sign this form, the dermatologist will take a picture of your face from the eyes downward and hairline during the study.

- You cannot be in the study if you do not want your picture taken. The pictures will be used to monitor for any changes you may experience while taking the study drug. Your pictures may be used and shared in the same ways as your other study records.

6. What are the possible risks or discomforts from being in this research study?

Side effects of pembrolizumab (MK-3475) therapy:

Pembrolizumab may cause one or more of the side effects listed below. This information is based on data from cancer subjects in other clinical trials with pembrolizumab. It is important to understand that the risk associated with a combination of any of these agents with pembrolizumab is currently unknown due to limited data. This includes side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects that you experience.

Very common side effects (>10%) seen in people taking MK-3475 include the following:

- Itching of the skin
- Loose or watery stools
- Cough
- Irregular heartbeat and swelling of your lower legs or hands
- Itching, skin rash, loss of skin color
- A low level of bicarbonate in your blood may cause a condition called metabolic acidosis, or too much acid in the body. A wide range of conditions, including diarrhea, kidney disease, and liver failure, can cause metabolic acidosis
- A condition in which the blood has too little calcium (Hypocalcemia).It can also signal a condition of the four small glands in the neck (parathyroid glands), the kidneys, or the pancreas. Most cases have no symptoms. In severe cases, symptoms include muscle cramps, confusion, and tingling in the lips and fingers.
- A condition in which there is too much calcium in the blood (Hypercalcemia) is most often caused by overactivity in the four tiny glands in the neck (parathyroid glands) or from cancer. Extra calcium in the blood affects many body systems. Symptoms of hypercalcemia range from mild to severe. They may include increased thirst and urination, belly pain, nausea, bone pain, muscle weakness, confusion, and fatigue

- An increase (hyperkalemia) or decrease potassium (hypokalemia) symptoms may include belly pain, diarrhea, chest pain, irregular heartbeat, and nausea
- Low magnesium (hypomagnesemia) symptoms may include nausea, vomiting, weakness, and decreased appetite
- Low sodium (hyponatremia) is a condition that the body holds onto too much water. This dilutes the amount of sodium in the blood and causes levels to be low. Symptoms include nausea, headache, confusion, and fatigue.
- Low phosphate (hypophosphatemia) symptoms may include muscle weakness, fatigue, bone pain, bone fractures, loss of appetite, irritability
- Mild decreased release of thyroid hormone. Symptoms may include feeling tired, weight gain, feeling cold easily, or bowel movements occurring less often than usual
- High blood cholesterol, triglycerides, high blood sugar
- Presences of blood in urine, urinary tract infection
- Lack of blood, bleeding, longer time for your blood to clot, decreased in disease-fighting cells (leukocytes) in your blood, decreased in white blood cells and neutrophils (lymphocytes) that protect your body from infection
- Increased bilirubin causing yellow discoloration of eyes and skin, liver damage that may include hepatitis, cirrhosis or other liver diseases
- Fatigue, headache, pain, weakness, numbness in hands and feet
- Joint stiffness, lack of energy, pain in the back, muscles, bones, ligaments, tendons, and nerves
- Cough, dyspnea, flu-like symptoms, pneumonia, pneumonitis, upper respiratory tract infection
- Mild Fever

<u>Common side effects (1-10%) seen in people taking MK-3475 include the following:</u>

- Decreased release of thyroid hormone. Symptoms may include feeling tired, weight gain, feeling cold easily, or bowel movements occurring less often than usual
- Joint Pain
- Rash
- Fever
- Back Pain
- Loss of skin color
- Pain or uncomfortable feeling in the belly
- Low levels of salt in the blood that may cause you to feel tired, confused, have headache, muscle cramps and/or feel sick to your stomach
- Mild buildup of fluid in space around the heart, facial swelling, heart disease, inflammation of heart muscles

- Mild inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. Too much thyroid hormone so you may feel anxious, angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools
- This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy
- Inflammation of the colon, difficulty swallowing, inflamed and sore mouth
- Increase in size and/or tenderness of lymph nodes
- Fluid in the spaces within your abdomen, inflammation of your liver
- Herpes virus, shingles
- Body's extreme response to an infection called sepsis
- Altered mental status, confusion, dizziness, insomnia
- Arthritis, muscle weakness, neck pain
- Mild redness, pain, or light sensitivity in eyes
- Kidney failure
- Common cold, respiratory failure
- Mild infusion related reaction

Uncommon, but some may be serious side effects (1-5%) seen in people taking MK-3475 include the following:

- Moderate inflammation of the blood vessels (vasculitis)
- Bodies inability to produce hormones, diabetes, and complications from diabetes such as thirst, frequent urination, nausea, fruity-scented breath
- Changes in your red blood cells that may cause shortness of breath and fatigue
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis
- A rare, benign, (noncancerous, nonmalignant) disorder of the lymph nodes of young adults, predominantly of young women. Affected individuals may develop mild fever, night sweats, muscle pain (myalgia) and a rash. Less common symptoms include headaches, fatigue, joint pain (arthralgia), and nausea and vomiting. In some cases, affected individuals may experience abnormal enlargement of the liver or spleen ([Kikuchi lymphadenitis])
- Mild formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs
- Severe, potentially life-threatening allergic reaction (anaphylaxis)
- Organ transplant rejection (solid)
- Infection

- Moderate inflammation of the nerves that 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 (Myelitis)
- Moderate inflammation of the brain with confusion and fever. This may also 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
- A rare disorder where the body's immune system damages nerve. The damage to the nerves causes muscle weakness and sometimes paralysis. While its cause is not fully understood, the syndrome often follows infection with a virus or bacteria (Guillain-Barre syndrome)
- Redness, pain, or light sensitivity in eyes Inflammation of the lungs so you may feel short of breath and cough. Sometimes this might lead to death
- Too much thyroid hormone so you may feel anxious, angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools
- Moderate infusion reactions, where you may feel dizzy or faint, flushed, get a rash, have a fever, feel short of breath at the time of receiving your infusion (IV) or just after, or pain at the site of infusion
- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus
- Inflammation of the skin so you may have peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e. peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body which can cause severe infection. These severe conditions can sometimes lead to death

Rare, but some may be serious side effects (<1%) seen in people taking MK-3475 include the following:

- Severe inflammation of the nerves that 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 (Guillain-Barré syndrome)
- Severe inflammation of the muscles so you may feel week or have pain in your muscles (myositis)
- Severe inflammation of the pancreas (a gland in your abdomen that controls sugar levels) so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and vomiting that gets worse when you eat (pancreatitis)
- Severe inflammation of the eye so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters or have headaches (uveitis)

- Severe inflammation of the liver that 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 (hepatitis)
- Severe inflammation of the pituitary gland (a gland in the head), which may cause you to 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 (hypophysitis)
- Adrenal glands (glands on top of the kidneys) that may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, joint, muscle and belly aches, nausea, vomiting, lose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)
- Type 1 Diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination and weight loss. You are likely to need regular insulin shots
- Inflammation of the kidney so you may pass less urine or have cloudy or bloody urine, swelling and low back pain (nephritis)
- Severe inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting. (myocarditis)
- Severe inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy (thyroiditis)
- A condition that may make you feel weak and tired and might have drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- Extensive formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs (sarcoidosis)
- Severe inflammation of the brain with confusion and fever. This may also 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 (encephalitis)
- Severe inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation (myelitis)
- Severe inflammation of the blood vessels (vasculitis). Symptoms will depend on the particular blood vessels that are involved in the inflammatory process, for example, if it is your skin, you may get a rash. If your nerves are not getting enough blood, you could have numbness and weakness. You may also experience fever, weight loss, and fatigue.

- Low levels of parathyroid hormone (a hormone made by 4 tiny glands in your neck) which may result in low blood calcium and cause muscle cramps or spasms; fatigue or weakness; numbness, tingling or burning in your fingertips, toes, or lips (hypoparathyroidism)

Additionally, since pembrolizumab was approved in September 2014, the following side effects have been reported by people receiving pembrolizumab. These side effects were voluntary reported from a group of people of unknown size. It is not possible to estimate the frequency of these side effect:

- Inflammation of the joints which may include joint pain, stiffness and/or swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis)
- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This may cause symptoms similar to those seen with inflammation of the liver (hepatitis) such as pain in right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- Inflammation or swelling of the nerve fibers of the eye which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis).

In addition to the above, if you have had an allogeneic stem cell transplant (a procedure in which a person receives blood-forming stem cells from a donor), you may experience graft versus host disease (GvHD), which may include diarrhea, skin rashes, and liver damage, after receiving pembrolizumab. Sometimes this condition can lead to death.

Other Risks

Risk with Intravenous (IV) Drug Administration

Temporary irritation and bruising may occur at the infusion site. There may also be discomfort, pain, or bruising from the needle puncture. In rare cases, an infection may also occur at the site of the needle stick.

Blood Draw Risks
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Skin Biopsy Risks
Scarring, infection, or bleeding under the skin at the biopsy site may occur.

Pregnancy Risks
The effect of pembrolizumab on a fetus (developing baby still in the womb), or on a breastfeeding infant, is known to cause harm. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.
Because of the possible risks to an unborn child, if you are a female who can become pregnant, you will be asked to take a pregnancy test at screening, within 72 hours prior to starting study treatment to ensure you are not pregnant. You must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.

Birth Control Requirements for Female Participants:

If you are sexually active and able to become pregnant, you and your partner must agree to use the birth control methods listed below:

- Single Method (One of the following is acceptable):
  - Intrauterine device (IUD)
  - Tubal Ligation
  - Contraceptive rod implanted into the skin
- Combination Method (requires use of two of the following):
  - Diaphragm with spermicide
  - Cervical cap with spermicide (only if you have never given birth)
  - Contraceptive sponge (only if you have never given birth)
  - Female condom (cannot be used with a male condom)
  - Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Unacceptable contraception methods:
  - Vaginal sponge
  - Withdrawal
  - Rhythm Method
  - Any barrier method without spermicide
  - Spermicide only
  - Progestin-only pills (also called “mini-pills”)
  - Concomitant use of female and male condom

You must use birth control without interruption for the entire study and for at least 120 days after your last dose of the study drug.

Birth control is not required if you meet one of the following:

- Postmenopausal (12 months without a period)
- History of hysterectomy and/or bilateral oophorectomy, salpingectomy, or bilateral tubal ligation at least 6 weeks before screening
- Has a congenital or acquired condition that prevents childbearing
- Abstinence (only if this is your preferred and usual lifestyle. Must remain abstinent for the entire study.)

Women must not breast feed while on treatment. If you miss a period, or think you might be pregnant during the study, you must tell the Principal Investigator immediately.

Birth Control Requirements for Male Participants:

If you are sexually active and able to father a child, you and your partner must agree to use the birth control methods listed below:

- Single Method (One of the following is acceptable):
    - Intrauterine device (IUD)
    - Tubal Ligation
    - Contraceptive rod implanted into the skin
    - Abstinence (only if this is your preferred and usual lifestyle. Must remain abstinent for the entire study)
- Combination Method (requires use of two of the following):
    - Diaphragm with spermicide
    - Cervical cap with spermicide (only if you have never given birth)
    - Contraceptive sponge (only if you have never given birth)
    - Female condom (cannot be used with a male condom)
    - Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Unacceptable contraception methods:
    - Vaginal sponge
    - Withdrawal
    - Rhythm Method
    - Any barrier method without spermicide
    - Spermicide only
    - Progestin-only pills (also called “mini-pills”)
    - Concomitant use of female and male condom

You and your partner must use birth control without interruption for the entire study and for at least 120 days after your last dose of study drug. You must agree to complete abstinence from heterosexual contact or use a condom during sexual contact with a female of childbearing potential while receiving study medication and within 120 days after last dose of study medication. If your partner becomes pregnant while you are receiving study medication or within 120 days after you took your last dose of study medication, you must tell the study doctor right away.

The Principal Investigator may ask for your partner's permission to collect information about the outcome of her pregnancy and her newborn. You won't have to stop taking the study drug or stop taking part in the study if your partner becomes pregnant.

Unforeseeable Risks Related to Pembrolizumab
Pembrolizumab works by boosting your immune system to attack your cancer cells more effectively; however, this may have an adverse effect on your immune system causing your condition to worsen. You will be monitored carefully during the study to make sure the treatment is working as expected. If your disease progresses, the study doctor may decide to remove you from the study.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator, the sponsor (Merck Sharp & Dohme Corp.) or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment, and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

Taking part in this study may not make your health better. However, the information collected during this study may help doctors learn more about the study treatment that may benefit you and other people with Mycosis Fungoides.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. You have other available systemic options including oral retinoids, chemotherapy, interferions, and in some cases, extracorporeal photopheresis. Your other choices for treatment will depend on the following:

- The stage of the cancer
- The type of lesion (patches, plaques, or tumors).
- Your age and gender.

Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Study drug and administration (pembrolizumab)
- Skin biopsy (at Cycle 2, Day 15)
- Clinical Photography
- Research blood draw (1 week after Cycle 4 and at the End of Treatment visit)

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- Physical and Skin Exams
- Skin Biopsy (at screening)
- Whole body PET/CT
- Routine blood and/or urine testing
- Pregnancy test for women of childbearing potential

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the "Contact Information" section of this form.

12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. What will happen to your samples?

Your samples will be used for this study. When the study is done, they will be destroyed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. To protect the confidentiality of your data, a code will be used as an identifier. The code will be a registration number assigned specifically to you by the Mayo Clinic Cancer Center Registration Office. The correlating Mayo Clinic number and your name for reference will be maintained in a secure database accessible by Mayo Clinic assigned research staff.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- Merck & Co., Inc.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

Approval Date: **August 18, 2023**
Not to be used after: **August 17, 2024**

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 18, 2023**
Not to be used after: **August 17, 2024**

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature