Study Title for Participants: Testing whether the Combination of Two Immunotherapy Drugs have activity in Recurrent or Persistent Clear Cell Ovarian Cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: NRG-GY016 - A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epacadostat (NSC #766086) in Recurrent Clear Cell Carcinoma of the Ovary. (NCT # TBD)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. 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 study because you have *clear cell ovarian* cancer, which has recurred or has not responded to standard therapy.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also 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 has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to test if the combination of two drugs (MK-3475 (pembrolizumab) and epacadostat) can stop your cancer from growing. We are doing this study because we want to find out if this approach is better or worse than the usual approach for your clear cell ovarian cancer. The usual approach is defined as care most people get for clear cell ovarian cancer.

What is the usual approach to my clear cell ovarian cancer?

The usual approach for people who are not in a study is treatment with either surgery, radiation, or cytotoxic chemotherapy with physician agent of choice. Sometimes, combinations are used

and your doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

What are my 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 study, if one is available
- You may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

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

If you decide to take part in this study, you will get the study drugs MK-3475 (pembrolizumab) and epacadostat until your disease gets worse or the side effects become too severe.

After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 3 months for 2 years after treatment. After that, they will check you every 6 months for 3 years. This means you will keep seeing your doctor for 5 years after treatment, unless you decide to stop this study early. The chance of developing side effects from the study drugs after 5 years is extremely low, but can be treated by your doctor if this were to occur.

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 for you to think carefully about these as you make your decision.

Risks

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

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 your cancer at preventing your cancer from coming back.

Benefits

This study has only a small chance of helping you because we do not know if the study drug/study approach is effective. It is unlikely that it will work in everyone with your cancer or help you live longer. This study may help the study doctors learn things that may help other people in the future.

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

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

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

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.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor NRG Oncology. The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

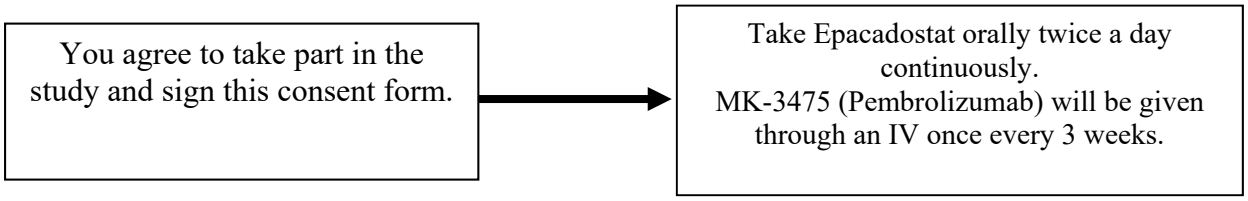
The purpose of this study is to test any good and bad effects of the combination of two study drugs called MK-3475 (pembrolizumab) and epacadostat in the treatment of clear cell ovarian cancer. MK-3475 (Pembrolizumab) and epacadostat could shrink your cancer but they could also cause side effects. Researchers hope to learn if the study drug will shrink the cancer by at least one-third compared to its present size. MK-3475 (pembrolizumab) is FDA-approved for certain cancers, while epacadostat is not FDA-approved. The combination of both MK-3475 (pembrolizumab) and epacadostat is considered experimental and not FDA-approved. There will be about 23 people taking part in this study.

What are the study groups?

All study participants will get the same study drugs, MK-3475 (pembrolizumab) and epacadostat. Epacadostat should be taken orally twice a day continuously with or without food. If you forget to take your scheduled dose, the missed pills will not be taken later. MK-3475 (Pembrolizumab) will be given through a vein (intravenous) once every 3 weeks. Every 3 weeks

is 1 cycle. Epacadostat has the potential to interact with other medications. You will be given a drug information handout and wallet card as a resource for yourself, caregivers and other health care providers.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right following the lines and arrows.



What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests and procedures to monitor your safety and health are:

- You will receive a pill diary to document dates and times of doses of Epacadostat
- If you are taking Warfarin, you will require more frequent blood testing

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- Three additional research blood samples will be taken before you begin study drug, before you begin the second cycle of study drug, and at the end of the study. Your doctors will ask that you do not eat before these blood samples are collected. If you agree, these samples will be used for the optional future research testing described in the "Optional studies" section at the end of this consent. You and your study doctor will not get the results of this testing.
- Your study doctor will need to use some of the tissue left over from your previous biopsy or surgery. This sample is a required part of the study. If you agree, this sample will be used for the optional future research testing described in the

"Optional studies" section at the end of this consent. You and your study doctor will not get the results of this testing.

- **A patient study calendar is attached at the end of this document. It shows how often these tests will be done.**

What risks can I expect from taking part in this study?

General Risks

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 your cancer at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- May not be able to take part in future studies.
- Discomfort from having required blood samples drawn for optional future research

Reproductive risks: In the pre-treatment period (28 days prior to starting treatment) you should plan to prevent pregnancy if you are of childbearing potential. Women of childbearing potential must agree to use adequate contraception (barrier method of birth control or abstinence) before registering to this study and for the duration of study participation through 120 days after receiving the last dose of treatment. If you become pregnant while receiving treatment on this study, you should inform your doctor immediately and stop the MK-3475 (pembrolizumab) and epacadostat. You should check with your doctor before receiving any live vaccines. You should not plan on breast-feeding anytime during the study period.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue from a previous surgery. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Side Effect Risks

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 test your blood and let you know if changes occur that may affect your health.

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

Here are important things to know 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 be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.
- The study doctor will provide you with information about other drugs you may need to avoid while receiving the study drug.

This study is looking at a combination of two drugs to treat this type of cancer. This different combination of drugs may increase your side effects or may cause new side effects.

Drug Risks

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

Risk Profile for MK-3475

COMMON, SOME MAY BE SERIOUS In 100 people receiving MK-3475 (pembrolizumab), more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving MK-3475 (pembrolizumab), from 4 to 20 may have:

- Nausea
- Infection
- Loss of appetite
- Pain in back
- Joint stiffness
- Cough
- Swelling and redness of the skin

MK-3475 (pembrolizumab) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Anemia which may require blood transfusion
- Pain in lymph nodes
- Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness
- Hormone gland problems (especially the thyroid, pituitary and adrenal glands, and pancreas). Signs and symptoms may include: headaches that will not go away or unusual headaches, extreme tiredness or changes in mood or behavior; decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting
- Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea or increase in bowel movements, blood in your stools or dark, tarry, sticky stools, severe belly pain or tenderness
- Diarrhea
- Sores in the mouth which may cause difficulty swallowing
- Pain in belly
- Sores in the bowels
- Chills, fever
- Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly
- Pain or swelling of the joints
- Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Fluid in the joints
- Pain in chest
- Lung problems (pneumonitis and other conditions). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Skin: itching; acne; rash (can be severe); blisters and peeling on the skin, mouth; skin changes; hives

RARE, AND SERIOUS

In 100 people receiving MK-3475 (pembrolizumab), 3 or fewer may have:

- Feeling of "pins and needles" in arms and legs
- Redness, pain or peeling of palms and soles

MK-3475 (pembrolizumab) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Heart problems including swelling and heart failure. Symptoms and signs of heart problems may include: Shortness of breath, swelling of the ankles and body.
- Swelling and redness of the eye
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Reaction during or following a drug infusion which may cause fever, chills, rash
- Damage to organs in the body when donor cells attack host organs which may cause yellowing of eyes and skin, itchy dry skin
- Damage to organs in the body when the body produces too many white cells
- A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in a coma
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs.
- Swelling of the brain (encephalitis/meningitis) which may cause headache, confusion, sleepiness, seizures, and stiff neck
- Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling.
- Swelling or tenderness of blood vessels

Risk Profile for Epacadostat (INCB024360) (CAEPR Version 1.2, November 21, 2018)

POSSIBLE, SOME MAY BE SERIOUS
• Bloating, constipation, diarrhea, nausea, vomiting • Pain • Swelling of arms, legs • Tiredness, fever • Damage to the body by own immune system • Weight loss, loss of appetite • Dehydration • Dizziness, headache • Changes in taste • Numbness, tingling or pain of the arms and legs • Difficulty sleeping • Cough, shortness of breath • Rash • Low blood pressure which may cause feeling faint

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

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 your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.
- Write down in your pill calendar when you take the study drug at home.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- Your insurance co-pays and deductibles.

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

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The three additional research blood draws.
- Submission of a sample of your tissue.

You and/or your insurance provider will not have to pay for the MK-3475 (pembrolizumab) and epacadostat will be supplied at no charge by NCI while you take part in this study. However, you and/or your insurance will be responsible for the cost of getting the MK-3475 (pembrolizumab) ready and giving it to you.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. Contact information for your study doctor is listed on the consent cover page. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor, NCI and any drug company supporting the study now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research, including NRG Oncology.
- The NRG Oncology Biospecimen Bank-Columbus (Biobank) and laboratories designated by NRG Oncology to perform testing as part of the study.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with

older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or 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 you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, you may contact the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading this optional study hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say NO to any or all of these studies. There is no penalty for saying NO. You and your insurance company will not be billed for these optional studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of YES or NO for each of the following studies.

Optional known laboratory studies and storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will use the blood and tissue collected as part of the main study for research on certain proteins in your blood and tumor sample.

Unknown future studies

If you choose to take part in this optional study, blood and tissue will be stored. Storing samples for future studies is called "biobanking." The biobank is being run by NRG Oncology and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your blood and tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

What is involved in these optional studies?

If you agree to take part, here is what will happen next:

1. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
2. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
3. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in these optional studies?

- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance.

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.

3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in these optional studies?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to these optional studies?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about these optional studies?

If you decide you no longer want your samples to be used, you can call the study doctor, who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about these optional studies?

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies
I agree that my samples and related health information may be used for the laboratory study described above.

YES NO

Samples for unknown future studies
I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

Signature:

This study has been explained to me, and I have been told what my enrollment in the study involves. I have read all pages of this consent and have had my questions answered to my satisfaction at this time. I consent to participate in this study and any additional studies where I circled 'yes'. I understand that by signing this form I have not given up any of my legal rights. I will be given a copy of this consent form. I may also request a copy of the protocol (full study plan).

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)

NRG-GY016: A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epacadostat (NSC #766086) in Recurrent Clear Cell Carcinoma of the Ovary.

Study Calendar

Visit	Patient Activities
Prior to Cycle 1	
Before starting study drugs (within 4 weeks of start of treatment)	• routine blood tests • pregnancy test (if you could become pregnant) • history and physical examination • electrocardiogram (ECG) • imaging (CT or MRI; same method to be used at future visits)
Cycle 1 and Beyond	
Week 1: Day 1	• history and physical examination if they have not been completed within 28 days • routine blood tests if they have not been completed within 14 days • fasting blood test prior to taking study drugs • Begin taking Epacadostat *daily* • MK-3475 (Pembrolizumab) will be administered *every 3 weeks*
Week 3: Day 21 (+/- 3 days)	• history and physical examination • routine blood tests • fasting blood sample • return pills and patient pill calendar
Week 6: (and onwards) Day 42 (+/- 3 days)	Every 3 weeks: • history and physical examination • routine blood tests • return pills and patient pill calendar

Week 12: Day 1 (+/- 7 days)	• history and physical examination • routine blood tests • imaging (CT or MRI; by same method as screening) • return pills and patient pill calendar
Week 18: (and onwards) Day 1 (+/- 7 days) for 49 weeks	Every 6 weeks (while you are on study): • Imaging (CT or MRI; by same method as screening)
Week 63: (and onwards) Day 1 (+/- 7 days)	Every 12 weeks (while you are on study): • Imaging (CT or MRI; by same method as screening)
After Completion of Treatment	
End of treatment or at disease progression	• side effects assessment • return pills and patient pill calendar • fasting blood sample
Follow up (unless consent is withdrawn): Every three months for two years and every six months for three years (either in person or by phone), then annually (unless otherwise indicated based on symptoms or physical signs suggestive of progressive disease)	• history and physical examination • side effects assessment, if clinically necessary • routine blood tests, if clinically necessary • Imaging (CT or MRI; by same method as screening), if clinically necessary