To: CTEP Protocol and Information Office

From: Rohit Jain, M.D.

Date: February 06, 2025

Re: Protocol **#10483: "Phase Ib trial of Erdafitinib combined with Enfortumab Vedotin following platinum and PD1/L1 inhibitors for metastatic urothelial carcinoma with FGFR2/3 genetic alterations."**

SUMMARY OF CHANGES – ICF

I. Changes from the PIO

#	Section	Summary
1	Protocol Version Date	Updates to Protocol Version Date in Header to align with new Protocol.
2	Possible Side Effects of erdafitinib (JNJ-42756493)	Added New Risk: • Occasional: Heartburn; Bruising, bleeding • Rare, And Serious: Excess mineral deposits in tissues which may cause stiffness Increase in Risk Attribution: • Changed to Common from Occasional: Anemia which may require blood transfusion; Dry eye; Constipation • Changed to Occasional from Also reported on Erdafitinib Trials But With Insufficient Evidence for Attribution (i.e. added to the Risk Profile): Kidney damage which may require dialysis; Rash Provided Further Clarification: • "A hole or tear in the skin which may cause bleeding" previously reported (under Occasional) is now reported as, "A hole or tear in the skin" (under Occasional).

Research Study Informed Consent Document

Study Title for Participants: Testing combination erdafitinib and enfortumab vedotin in metastatic bladder cancer after treatment with chemotherapy and immunotherapy

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol 10483: "Phase Ib trial of Erdafitinib combined with Enfortumab Vedotin following platinum and PD1/L1 inhibitors for metastatic urothelial carcinoma with FGFR2/3 genetic alterations" (NCT# NCT04963153)

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.

We are asking you to take part in this research study because you have advanced urothelial carcinoma (bladder cancer) that has an alteration in the genes called the FGFR (fibroblast growth factor receptor) 2/3 genes.

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 answer the following question:

What is the safest and most tolerable dose of enfortumab vedotin that can be taken in combination with the standard dose of erdafitinib?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your metastatic bladder cancer. The usual approach is defined as care most people get for metastatic bladder cancer.

What is the usual approach to my metastatic bladder cancer?

The usual approach for patients who have received prior treatment with chemotherapy and/or immunotherapy but are not in a study is treatment with either enfortumab vedotin or erdafitinib. These drugs are not given together in usual practice. These drugs have been individually approved by the FDA for the treatment for metastatic bladder cancer.

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 research study if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

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

If you decide to take part in this study, you will get enfortumab vedotin and erdafitinib in combination for up to 2 years, or until one of the following occurs:

- Your disease gets worse
- The side effects become too severe
- Your doctor believes it is no longer safe for you
- You want to discontinue the study drugs

After you finish study treatment your doctor will continue to follow your condition for up to 2 years and watch you for side effects and check on the status of your disease. Follow up will occur with clinic visits every 3 months for 2 years.

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 combination of erdafitinib and enfortumab vedotin may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the erdafitinib and enfortumab vedotin. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

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

- Transient blurred vision, dry eyes
- Skin rash
- Peripheral neuropathy
- Dry mouth, skin
- Sores in the mouth which may cause difficulty swallowing
- Diarrhea
- Tiredness
- Changes in taste
- Redness, pain or peeling of palms and soles

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

Benefits

There is some evidence in patients with bladder cancer that combination treatment with similar drugs can shrink or stabilize cancer with alterations in FGFR 2/3 genes, but we do not know if this will happen in people with the study drugs. It is unlikely that this treatment with the combination of erdafitinib and enfortumab vedotin will 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.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (NCI). 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 the safety and tolerability of enfortumab vedotin at different doses in combination with a standard dose of the study drug erdafitinib. "Dose" is defined as the amount of drug you get. Both drugs have been tested in people, but not in combination. The combination of erdafitinib and enfortumab vedotin is not approved by the FDA. The dose escalation part of this study tests different doses of enfortumab vedotin to see what is the highest dose that most people in the study can tolerate in combination with erdafitinib. There will be up to 18 people taking part in this part of the study.

The purpose of the dose expansion part of the study is to further test the safety and tolerability of the dose combination of erdafitinib and enfortumab vedotin established in the dose escalation part of the study. There will be up to 12 people taking part in this part of the study.

What are the study groups?

This study has a screening step. The purpose of this step is to test your tumor to find out if it has a specific alteration in the FGFR 2/3 genes. If it does and you meet all the study requirements, then we can assign you to treatment on this study. If we find that your tumor or blood does not have the genetic changes that are needed for this study, then your doctor will discuss other options for your care. This screening is considered as standard of care for all patients to check for this mutation. The drug erdafitinib is only FDA-approved in patients with mutations in the FGFR 2/3 gene.

There are two parts in this study, a dose escalation part and a dose expansion part. Your doctor will tell you which part you are in.

In the dose escalation part of this study, different people will get different doses of enfortumab vedotin in combination with the study drug, erdafitinib.

The first 3 people taking part in this study will get the initial dose. If the drug does not cause serious side effects, the next group of people in the study will get the higher dose. The study doctor will watch each group carefully as they increase the dose. If the new group of people on the higher dose don't have serious side effects that require the dose to be lower, then the dose

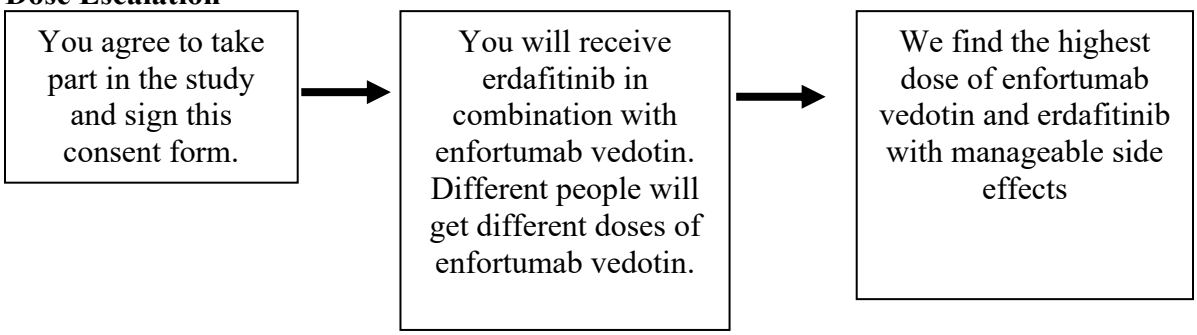
escalation is stopped. Once this dose is found, the study will move to second stage enrolling 12 more patients.

In the dose expansion part of this study, the highest dose of enfortumab vedotin in combination with erdafitinib with manageable side effects will be given to 12 more people. This will help study doctors better understand the side effects that may happen with this drug combination.

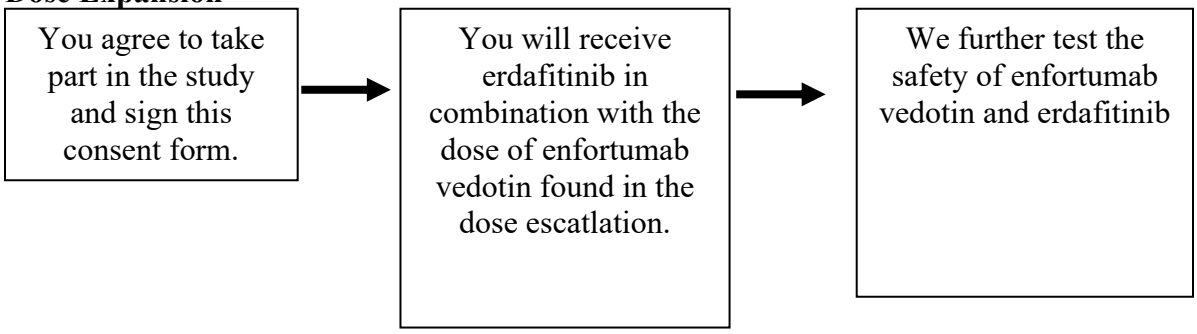
Treatment schedule: You will take erdafitinib tablets by mouth once a day. You should bring your dose with you to the clinic on Days 15 and 17 of Cycle 1 and Day 1 of Cycle 2. Erdafitinib tablets should be taken whole, do not crush or chew the tablets. Erdafitinib is dispensed in the original 30 count container and you will have more tablets than you need. You should bring the extra tablets with you to the clinic. You will receive enfortumab vedotin through a vein in your arm over 30 minutes on Days 1, 8, and 15 of each cycle. Each cycle lasts 28 days. See the study calendar for more information.

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.

Dose Escalation



Dose Expansion



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 include:

- Eye exams monthly for the first 4 months of treatment and then every 3 months after.
    - Patients on Enfortumab Vedotin (EV) monotherapy are not required to continue monthly or every three month ophthalmologic examination once all eye toxicities are resolved. If on EV monotherapy, eye exam can be completed as clinically indicated
- Blood counts done weekly during the treatment.
- Physical exams done with every cycle.
- Electrocardiogram (ECG) at the end of the study.
- Pregnancy tests will be done if required while on treatment.
- Imaging will be done on treatment to assess response

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.

You will need to have mandatory blood samples taken for the study. You will have blood collections (about 1 teaspoon of blood) before taking your dose of erdafitinib and your enfortumab vedotin infusion on Day 15 of Cycle 1 and Day 1 of Cycle 2. You will also have a blood collection (about 1 teaspoon of blood) before taking your dose of erdafitinib on Day 17 of Cycle 1. Researchers will determine the level of the study drugs in your blood. 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 exams, tests, and/or procedures 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 combination of erdafitinib and enfortumab vedotin may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor’s office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The erdafitinib and enfortumab vedotin used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 3 months (for women) and 5 months (for men) after you have completed the study treatment.

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:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. 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.

This study is looking at a combination of two usual drugs used to treat this type of cancer but given in combination with each other. 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 most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of erdafitinib (JNJ-42756493)
(Table Version Date: November 12, 2024)

COMMON, SOME MAY BE SERIOUS In 100 people receiving erdafitinib (JNJ-42756493), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion • Dry eye, mouth, skin • Blurred vision or blindness • Constipation, diarrhea • Sores in the mouth which may cause difficulty swallowing • Tiredness • Loss of appetite • Changes in taste • Redness, pain or peeling of palms and soles • Change in or loss of some or all of the finger or toenails

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving erdafitinib (JNJ-42756493), from 4 to 20 may have:
• Red, itchy eyes with increased watering • Swelling and redness of the eye • Pain • Heartburn, nausea, vomiting • Fever • Infection which may cause painful and frequent urination • Bruising, bleeding • Weight loss • Kidney damage which may require dialysis • Cough, shortness of breath • Nose bleed • Dryness in the nose • Hair loss, itching, rash • A hole or tear in the skin

RARE, AND SERIOUS In 100 people receiving erdafitinib (JNJ-42756493), 3 or fewer may have:
• Excess mineral deposits in tissues which may cause stiffness

Possible Side Effects of Enfortumab Vedotin
(Table Version Date: July 2, 2024)

COMMON, SOME MAY BE SERIOUS In 100 people receiving enfortumab vedotin, more than 20 and up to 100 may have:
• Tiredness • Numbness, tingling or pain of the arms and legs • Itching, rash

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving enfortumab vedotin, from 4 to 20 may have:
• Anemia which may require blood transfusion • Dry eye, mouth, skin • Watering eyes • Constipation, diarrhea, nausea, vomiting • Sores in the mouth which may cause difficulty swallowing • Swelling of arms, legs • Fever • Weight loss, loss of appetite • Infection, especially when white blood cell count is low • Changes in taste • Skin changes

RARE, AND SERIOUS In 100 people receiving enfortumab vedotin, 3 or fewer may have:
• Blurred vision • Tear on the surface of the eye • Pain • Problem with eyelid • Swelling and redness of the eye • Swelling and redness at the site of the medication injection • Reaction during or following a drug infusion which may cause chills, low blood pressure • A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in coma • Muscle weakness • Damage to nerves that may interfere with walking or organ function which may cause weakness or pain in muscles • Damage to the lungs which may cause shortness of breath • Blisters on the skin • Swelling and redness of the skin • Redness, pain or peeling of palms and soles • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Rash on buttocks and skin folds, caused by certain drugs

Additional Drug Risks

The study drug could interact with over-the-counter drugs (including herbal supplements) and prescription drugs such as digoxin. Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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

Other Risks and Precautions

You may experience dry mouth and dry skin from the study drugs. If you agree to participate in this study, you will receive instructions on how to manage dry mouth and dry skin, including guidelines for good oral hygiene, dietary changes, and bathing practices.

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 medication diary when you take the study drug at home.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study or donate sperm while taking part in this study and for 3 months after your last dose of study treatment. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 months (for women) or 5 months (for men) after your last dose of study treatment.

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 bladder 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.
- the cost of enfortumab vedotin
- 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:

- Blood collection for research purposes on Days 15 and 17 of Cycle 1 and on Day 1 of Cycle 2.

You or your insurance provider will not have to pay for the erdafitinib while you take part in this study.

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. 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.

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. 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 or receive copies of some of the information in 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:

- The study sponsor and any company supporting the study drug 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 trial site at which you will be receiving your treatment

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 or some 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 the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*)

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

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 these optional studies hope the results will help other people with your condition 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 these 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 sample collections for known laboratory studies

Researchers are trying to learn more about cancer and other health problems using 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 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 collect tumor tissue for research to see if your tumor expresses different proteins. This will help with research to associate your response to treatment to these samples.

What is involved in this optional sample collection?

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

1. A sample from the tissue that was collected at the time of your procedure to check your cancer will be collected.

2. 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.
3. 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.
4. 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 this optional sample collection?

- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- 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. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers. 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 this optional sample collection?

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 this optional sample collection?

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 this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial *), who will let the biobank know. 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 this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial *).

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

Samples for known future studies:

I agree that my tissue sample and related health information may be used for the laboratory studies described above.

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.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature

Patient Study Calendar

		Cycle 1					Cycles 2+				After You Finish Study Treatment	
	Before you begin Study Treatment	Day 1	Day 8	Day 15	Day 17	Day 28	Day 1	Day 8	Day 15	Day 28	When You finish Study Treatment (4 weeks after your last dose)	Follow-up Every 12 weeks for 2 years after you finish study treatment
Enfortumab Vedotin[A]		X	X	X			X	X	X			
Erdafitinib[B]		X----------X					X----------X					
Pre-study procedures including informed consent, demographics, height, medical history, and assessment of how you perform everyday tasks and activities	X											
Check of medications you are taking	X	X					X				X	X
Physical Exam	X	X					X					
Vital signs and weight	X	X	X	X			X	X	X		X	
Blood test to check your average blood sugar levels	X											
Blood draws for complete blood count and general health status	X	X	X	X			X	X	X		X	
Blood or urine collection for pregnancy test for women of childbearing potential	X	X					X				X	
ECG	X										X	

Assessment of the size, shape, and position of the heart	X											
Eye exam	X	An eye exam will be done on Day 1 of Cycle 1 and additional checks of your vision will be done monthly for 4 months, then one every 3 months thereafter or as clinically indicated. Additional assessments will be taken as your doctor indicates it is necessary[F]									X	
Side effect assessment	X	X	X	X			X	X	X		X	
Medical imaging scans for tumor measurement	X	Measurements are repeated every 8 weeks.									X	X
Bone scan (only if your doctor indicates it is necessary)	X											
Mandatory Blood collection for research purposes to check the levels of Erdafitinib in your blood[C]				X	X		X[D]					
Optional collection of leftover tumor tissue from your previous biopsy	X											
ctDNA blood collection[E]	X										X	
Follow-up visits to assess your disease and side effects												X

A: Enfortumab Vedotin: Dose as assigned on Day 1, 8, and 15 of every 28-day cycle.
B: Erdafitinib: Dose as assigned on Day 1 through Day 28 of every 28-day cycle.
C: Blood collection will be done 30-60 minutes after your infusion of Enfortumab Vedotin
D: Day 1 of Cycles 2 only.
E: ctDNA blood collection will be done if physician orders it as standard of care (not mandatory).
F: Patients on Enfortumab Vedotin (EV) monotherapy are not required to continue monthly or every three month ophthalmologic examination once all eye toxicities are resolved. If on EV monotherapy, eye exam can be completed as clinically indicated.