A Study of Pemigatinib in Non-muscle Invasive Bladder Cancer Patients With Recurrent Low- or Intermediate-Risk Tumors

NCT03914794

9/9/2020

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Phase 2 Window of Opportunity Study of Pemigatinib in Non-muscle Invasive Bladder Cancer Patients with Recurrent Low- or Intermediate-Risk Tumors**

Application No.: **IRB00194271**

Supporter: **Incyte Corporation**

Principal Investigator: **Noah Hahn, M.D.**
Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
The Bunting-Blaustein Cancer Research Building 1, Room 1M42
1650 Orleans Street
Baltimore, MD 21287
Phone:
Fax: 410-367-2668

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to study the effects, safety, and tolerability of the study drug, Pemigatinib, when given to people with recurrent bladder tumors and a prior history of low or intermediate risk of non-muscle invasive bladder cancer.

In many cancers including bladder cancer, alterations (changes) in genes within an individual's cancer are frequently noted. Genes comprise the building blocks that define the biological code responsible for many unique characteristics of each individual such as hair color, eye color, etc. In cancer, alterations in genes that contribute to the initiation, growth, and spread of the cancer are common.

Fibroblast growth factor receptor (FGFR) genes are an example of genes that, when altered, can lead to and promote the growth of cancer in patients. To date, several FGFR genes have been discovered and described including fibroblast growth factor receptors 1, 2, 3, and 4 (FGFR 1/2/3/4). In non-muscle invasive bladder cancer, alterations in the fibroblast growth factor receptor 3 (FGFR3) gene are noted in 60-80% of patients with recurrent bladder tumors and a prior history of low or intermediate risk tumors. In contrast, alterations in the FGFR3 gene occur in only about 15% of patients with bladder cancer that has invaded into the muscle wall of the bladder or spread beyond the bladder.

Pemigatinib is an orally administered drug that inhibits fibroblast growth factor receptors 1, 2, and 3 (FGFR 1/2/3). In bladder cancer patients with advanced disease that has spread throughout the body and whose tumor demonstrated a change in the FGFR3 gene, use of pemigatinib has resulted in reduction of tumor size in 25% of patients in ongoing clinical trials. Pemigatinib has not previously been studied in patients with non-muscle invasive bladder cancer. Therefore, the rate of reduction or complete disappearance of tumors in non-muscle invasive bladder cancer patients with or without FGFR3 gene alterations is unknown. In studies of drugs similar to pemigatinib, the potential for FGFR inhibition to enhance the function of immune cells near the patients' tumor regardless of FGFR gene alteration status has also been suggested.

The use of Pemigatinib in this research study is investigational. The word "investigational" means that Pemigatinib is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of Pemigatinib in this study.

People with recurrent bladder tumors with a prior history of low or intermediate risk non-muscle invasive bladder cancer may join.

How many people will be in this study?

About 43 people are expected to take part in this study. About 20 of these people are expected to be enrolled at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Screening

You will have the following tests and procedures to make sure that you are eligible to enroll in this study. This process is called "screening".

The following tests and procedures will be performed by the study staff to determine if you qualify and if it is safe for you to participate in this study. Some of these tests and procedures are likely to be part of your regular cancer care and may be done even if you do not take part in the research study. If you have had some of these tests or procedures within 28 days of starting the study drug, they may or may not have to be repeated:

- Review of your medical history
- Review of medications you are currently taking and have taken in the past including herbal medications.
- A physical examination including measurement of your height, weight and vital signs (temperature, blood pressure, heart rate and respiratory rate).
- An evaluation of your ability to carry out daily activities will be performed.
- You will be asked about the symptoms you are having from your disease.
- An examination of your eyes by an eye specialist (ophthalmologist). The exam will include visual acuity test, slit-lamp examination, fundoscopic exams, and optical coherence tomography (OCT).
- Collection of a blood sample (about 4 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets, and measure the amount of cholesterol and fats in your blood.
- Collection of a urine sample for cytology exam, an exam of cells from the body under a microscope to see how they look and function.
- A Cystoscopic exam: A cystoscopy procedure allows the study doctor to look at the inside of the bladder and the urethra using a cystoscope (thin, lighted instrument, used by the urologist). The overall procedure, which is normally performed in less than 10 minutes, will **not** require general anesthesia (you will not go to sleep for this procedure). During the cystoscopy procedure, the bladder lining will be inspected. Your study doctor will also take pictures of the bladder during these bladder inspections.
- Collection of the most recent archival tissue sample of your tumor.
- Collection of a blood sample (about 8 teaspoons) for research.
- Collection of a urine sample for research.

Study Drug Administration Period:

If you are eligible to continue to participate in the study, you will return to the clinic to begin taking the study drug. You will visit the study doctor as instructed.

The administration of Pemigatinib will be divided into "cycles" of 28 days duration. Pemigatinib will be taken by mouth once a day. Pemigatinib regimen will be planned for at least 1 cycle (28 days) in all participants followed by your usual care cystoscopy, cytology, and transurethral resection of bladder tumor (TURBT). The exact number of cycles you receive will depend on local TURBT scheduling practices, how well your cancer responds to Pemigatinib, how well you tolerate Pemigatinib and your overall condition.

At the TURBT evaluation, if no detectable disease is found, you will be considered a "Complete Response" participant, and continue with the study as below. Administration of Pemigatinib may continue for a maximum of 13 cycles.

If the disease reoccurs, you will stop the study drug and your study doctor may treat you with any standard of care treatment.

Cycle 1:
You will return to the clinic on Day 1, and Day 15 of Cycle 1, where study staff will have you complete the following:

***Cycle 1 Day 1 visit*:**
- Review of your medical history
- A physical examination including measurement of your height, weight and vital signs (temperature, blood pressure, heart rate and respiratory rate).
- An evaluation of your ability to carry out daily activities.
- You will be asked about the symptoms and health problems you have and any new medications or changes in existing medications that you are taking.
- Collection of a blood sample (about 4 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets, and measure the amount of cholesterol and fats in your blood.

Cycle 1 Day 15 visit:
- Collection of a blood sample (about 4 teaspoons) for laboratory tests, which measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets.

You will continue taking Pemigatinib for at least 1 cycle (28 days) prior to your Transurethral Resection of Bladder Tumor (TURBT) visit. The exact duration of drug administration beyond your cycle 1 will be dependent upon TURBT scheduling with your doctor. You should continue taking Pemigatinib up until you undergo TURBT.

Prior to your planned standard of care TURBT, your doctor will consent you for that procedure utilizing a standard hospital consent. The following will be performed on the day of your on study TURBT visit-
- A Cystoscopic exam, which allows the study doctor to look at the inside of the bladder and the urethra (urine channel) using a cystoscope (thin, lighted instrument, used by the urologist). The overall procedure, which is normally performed in less than 10 minutes, will **not** require general anesthesia (you will not go to sleep for this procedure). During the cystoscopy procedure, the bladder lining will be inspected. Your study doctor will also take pictures of the bladder during these bladder inspections.
- A Transurethral Resection of Bladder Tumor (TURBT) procedure: This will be performed using a rigid telescope-like instrument called a cystoscope. During the TURBT procedure, tumor(s) in your bladder will be removed. Your doctor will look at the tumor sample from TURBT and decide if you whether you should continue on Pemigatinib.
- Collection of a urine sample for cytology exam, an exam of cells from the body under a microscope to see how they look and function.
- Collection of a blood sample (about 8 teaspoons) for research.
- Collection of a urine sample for research.

If your doctor decides you should continue on Pemigatinib once a day, you will return on Day 1 and Day 15 of all cycles (maximum of 13 cycles), where study staff will have you complete the following:

***Day 1 of Cycle 2 and thereafter*:**

- Review of your medical history
- A physical examination including measurement of your height, weight and vital signs (temperature, blood pressure, heart rate and respiratory rate).
- An evaluation of your ability to carry out daily activities.
- You will be asked about the symptoms and health problems you have and any new medications or changes in existing medications that you are taking.
- Collection of a blood sample (about 4 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets, and measure the amount of cholesterol and fats in your blood.

If you achieve a complete response at TURBT and remain on Pemigatinib post-TURBT, an eye exam will be performed including a visual acuity test, slit-lamp examination, fundoscopic exams, and optical coherence tomography (OCT) within 14 days of Cycle 4 Day 1, Cycle 7 Day 1, Cycle 10 Day 1, and Cycle 13 Day 1.

Day 15 of Cycle 2 and thereafter:

- Collection of a blood sample (about 4 teaspoons) for laboratory tests, which measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets.

Cystoscopy, TURBT and urine cytology assessments beyond Cycle 1 may be performed at the discretion of your doctor.

End of study/safety Follow up

You will be asked about the symptoms and health problems you have within 1 month (give or take 7 days) of your last study-related therapy. You will be followed up for up to 2 years.

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information. The law provides that health insurance companies and group health plans:

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

Request to collect and store biospecimens for future research

As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research. This research could include other diseases.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*

Will you allow us to store the biospecimens we collect for this study for use in future research?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

How long will you be in the study?
If you are eligible to participate in the study, you will receive the study drug for up to 13 cycles, each about 28 days. Then you will be followed for up to 2 years from the date of your on-study TURBT visit.

4. What are the risks or discomforts of the study?

Risks and Inconveniences
While taking the study drug, you are at risk for side effects. Risks are possible side effects of study drug, or another medicine, coming from study procedures such as drawing blood for laboratory tests. These side effects will vary from person to person. You should discuss these risks and any other side effects that may not be listed in the form with the doctor. Many side effects go away shortly after the drug is stopped, but in some cases side effects may be serious, long lasting, and/or permanent, and may even cause death.

If you experience any of the described symptoms or have any other problems, you must immediately tell the appropriate study staff member or the doctor.

With all medicines or procedures, there may be risks that we do not know about. You will be given any new information that may affect your willingness to start or continue in this study.

There is no information available on the potential interaction between sunlight and Pemigatinib. As a precaution, you are advised to protect yourself from the sun/ultraviolet light wearing long sleeves, long trousers, hats and sunglasses.

Side Effects of Pemigatinib
Based on the patients that have been given the study drug (Pemigatinib) and data collected to date, there is a risk of the following side effects:

- Hyperphosphatemia - an increase in phosphate levels in the blood and the kidney's inability to get rid of the increased levels of phosphate (a component of bone and other tissues). Please report any symptoms of hyperphosphatemia such as muscle cramps, twitching, or mouth numbness or tingling.
- Fatigue or Weakness
- Dry mouth
- Hair loss and/or thinning
- Diarrhea
- Redness and sores in your mouth and/or throat
- Anemia (low red blood cell count)
- Dehydration
- Decreased appetite
- Off sense of taste
- Blurred vision
- Weight loss
- Constipation
- Cough
- Nausea
- Abdominal pain
- Increase in liver enzymes
- Back pain
- Dry eye
- Hypophosphatemia (low phosphate level in the blood)
- Vomiting
- Urinary tract infection
- Abnormal kidney function
- Dry skin
- Pain in joints
- Hypercalcemia (high calcium level in the blood)
- Edema peripheral (fluid accumulation in legs or arms)
- Fever
- Hyponatremia (low sodium levels in blood)
- Fluid accumulation in the retina
- Soft tissue mineralization (calcium/phosphate in your tissues like skin muscles, tendons, fat, or blood vessels)

You will have blood tests and physical exams to monitor for these side effects. If the safety tests show a decrease in these test values listed above, your dose of study drug may be stopped, re-started upon resolution, or discontinued permanently.

Risks of cystoscopy and TURBT procedures:

- Infection. Rarely, the procedures can introduce germs into your urinary tract, causing an infection.
- Bleeding. The procedures might cause some blood in your urine.
- Pain. You might experience abdominal pain and a burning sensation when urinating.

Risks of Eye Exams:

- You might experience light sensitivity, trouble focusing on close objects, eye irritation and temporary blurring of vision due to the eye exams.

Other Risks

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- having a hard time breathing
- wheezing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- a fast pulse
- sweating

You should get medical help and contact the doctor or appropriate staff member if you have any of these or any other side effects during the study.

Blood Draw:

Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Confidentiality:

There is the risk that information about you may become known to people outside this study.

Genetic information is unique to you and your family, even without your name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

There may be side effects and discomforts that are not yet known.

5. Are there risks related to pregnancy?

This research may hurt an embryo or fetus in ways we do not currently know. You must avoid becoming pregnant while participating in this study. If you are pregnant, plan to become pregnant, or are breast-feeding, you cannot take part in this study.

By signing this consent form, you confirm to the best of your knowledge that you are not pregnant now, you are not currently breast-feeding and you do not intend to become pregnant or start breast-feeding during the study or for 8 weeks following the last dose of study drug. If at any time during this study you think you might be pregnant, or later learn that you were pregnant during the study or wish to start breast-feeding, you must contact the study doctor immediately for further instructions regarding your participation in this study and follow-up.

If you are a woman capable of becoming pregnant (that is, not surgically sterile or have not gone through menopause), you must have a negative blood or urine pregnancy test at screening before you can enter the study. In addition, if you are a woman capable of becoming pregnant, you must be willing to use maximally effective birth control for the duration of the study and for at least 8 weeks following the last study drug. Your study doctor will advise you on which types of birth control are appropriate for you during your participation in the study.

If you are a man, you must be surgically sterile or willing to use double barrier contraception method upon enrollment, during the course of the study, and for 8 weeks following the last study drug. Your study doctor will advise you on which types of double barrier contraception are appropriate for your participation in the study.

6. Are there benefits to being in the study?

You may or may not benefit from being in this study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. These options include, but are not limited to: surgical resection of your bladder tumor by TURBT without any other therapy, instillation of treatments within the bladder such as a weakened bacterial strain called BCG, instillation of chemotherapy treatments within the bladder, or participation in a different clinical trial. You do not have to join this study to get treatment. The study doctor can recommend other treatments. You may choose not to participate in this study and instead receive an approved drug(s), if one is available.

It is possible that if you have a certain type of cancer, your condition may improve without being part of the study, or using the study drug.

If you have questions about alternate treatments and their potential benefits and risks, ask the study doctor for additional information.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

No.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Noah Hahn at 410-955-8893. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.
If you are taking part at Sibley Memorial Hospital, call Dr. Jean Hoffman-Censits at insert 202-650-6600 or 202-841-2707 for Sibley Research Office.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Noah Hahn at 410-955-8893 during regular office hours.
If you are taking part at Sibley Memorial Hospital, call Dr. Jean Hoffman-Censits at insert 202-650-6600 or 202-841-2707 for Sibley Research Office.

If you have an urgent medical problem related to your taking part in this study, call Dr. Noah Hahn at 410-955-8893 during regular office hours or the medical oncologist on call at 410-955-4331 during regular office hours, after hours, and on weekends.
If you are taking part at Sibley Memorial Hospital, call Dr. Jean Hoffman-Censits at insert 202-650-6600 or 202-841-2707 for Sibley Research Office.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

eIRB uploaded 9/15/2020
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MEDICINE

Insurance and Research Participant Financial Responsibility Information Sheet

Clinical Research Study Title: Phase 2 Window of Opportunity Study of Pemigatinib in Non-muscle Invasive Bladder Cancer Patients with Recurrent Low- or Intermediate-Risk Tumors

Principal Investigator: Dr. Noah Hahn

eIRB #: IRB00194271

Date: 08/15/2019

PRA Review Date: CIR00061910 09/15/2020

The following procedures, tests, drugs or devices are part of this research and will be supplied free of charge by the study:

- Ophthalmology Examination
- Vitamin D3, Parathyroid Hormone
- Lipid Profile (Total Cholesterol, HDL, LDL) and Triglycerides
- Pemigatinib (oral)

You and/or your health insurer will be responsible for all other procedures, tests, drugs or devices that are part of this study such as the following:

- Physical examination including BP, height and weight
- CBC w/differential
- CMP w/Calcium and Phosphate
- Serum pregnancy test
- Cystoscopy
- TURBT
- Urine cytology diagnostic sample

If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

For questions about your bill, including payment plans, financial assistance or information changes, please call:

1-855-662-3017