INFORMED CONSENT

TITLE: A Double-blind Randomized Parallel Group Study of the Efficacy and Safety of Tesevatinib in Subjects with Autosomal Dominant Polycystic Kidney Disease

PROTOCOL NO.: KD019-211
WIRB® Protocol #20171613

SPONSOR: Kadmon Corporation, LLC

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1. INTRODUCTION

You have been diagnosed with a medical condition called autosomal dominant polycystic kidney disease (ADPKD). As a result, you are being asked to participate in a clinical trial or research study that is sponsored by Kadmon Corporation, LLC (the "Sponsor") and is being conducted in collaboration with the research center where you are receiving medical care.

The study is being conducted under U.S. laws, regulations and guidelines that direct clinical research. Your participation in this study is entirely voluntary. Before agreeing to participate in this research, please take time to review this document carefully and ask questions about anything you do not understand before deciding whether or not to participate. Before you can decide whether or not to volunteer for this research study, you need to understand the possible risks and benefits and what will be asked of you. This process is called informed consent. This consent form will give you information about the study and your rights so that you can know as much as possible about the study and the experimental drug, tesevatinib (also called KD019), before you make a decision. No promises can be made about the results following the use of tesevatinib for ADPKD.

If you decide to take part in the study, you will be asked to sign and date this consent form. If you decide to sign this form and agree to be tested (screened) to see if you qualify, you will be

given a copy of the signed and dated form to keep and to show to your personal doctor.

If you decide not to participate, your decision will not change the care you receive. Also, if you join the study and later decide to drop out or withdraw, your decision will not change the care that you receive. You are free to withdraw from the study at any time.

Please know that your relationship with the study doctor (Investigator) is different from the relationship that you have with your personal doctor. Your personal doctor chooses the medical treatment for a specific health problem that you have with the thought that the treatment will benefit you as his/her patient. The research study doctor cares for all subjects using a specific research plan (protocol) to collect knowledge about a possible new therapy, and also with the understanding that subjects may or may not benefit from taking part in the study. Each research study subject must have exactly the same procedures for the results to be meaningful. Be sure to ask questions of the study doctor if you have questions about this relationship.

It is very important that you are completely truthful about your health and medical history and any symptoms or reactions you may experience during the study. Also, it is important to tell the study doctor what other medications, supplements, herbal therapies, over-the-counter products, or medications given to you by a doctor that you are taking, because they may cause a reaction with the study drug. If you are not truthful, you may harm yourself by being in the study.

Tesevatinib is an investigational drug, which means that the U.S. Food and Drug Administration (FDA) has not approved it for sale or marketing.

DO NOT SIGN THIS FORM UNLESS YOU UNDERSTAND WHAT THE STUDY IS ABOUT AND THE POTENTIAL RISKS AND BENEFITS OF PARTICIPATING.

2. PURPOSE

The purpose of this study is to find out if the experimental study drug, tesevatinib, works as a treatment for ADPKD and if it is safe. Tesevatinib is made by the Sponsor, who provides funding to this facility for the conduct of this study.

Tesevatinib is an experimental drug that stops a protein (enzyme) and may slow down or stop uncontrolled growth of kidney cells as a treatment for ADPKD. To date, over 350 people have been enrolled in studies using tesevatinib. In the first studies, subjects received doses up to 350 mg per day. In some studies, subjects received tesevatinib continuously and in others they received tesevatinib for 5 days in a row followed by a 9-day break.

This is a Phase 2b study. Phase 1 is the first and earliest stage of drug research for people, after scientists have carefully studied tesevatinib in laboratory animals and found the results encouraging. The Phase 1 study looked to see how safe tesevatinib is in subjects with ADPKD and tried to find out the best dose. In the Phase 2b study you will be participating in, scientists want to see how effective tesevatinib is at treating ADPKD.

We have determined that the highest dose of tesevatinib that can safely be given to subjects with ADPKD (also called the maximum tolerated dose or MTD) is 100 mg daily. Five subjects who received a dose of 150 mg of tesevatinib in the Phase 1 study developed some degree of rash, and 2 of these subjects stopped the study because of these rashes, so this dose was considered to be too high. Some subjects receiving the 100 mg daily dose had changes in the electrocardiogram (ECG), a test that measures the activity of the heart, and those subjects had the dose of tesevatinib lowered. In that study, 37 subjects received 50 mg doses of tesevatinib daily. There were no severe side effects in subjects who received tesevatinib at that dose. Therefore, the best tolerated dose of tesevatinib in subjects with ADPKD was determined to be 50 mg daily. This is the dose you will be receiving if you decide to participate in the current study.

During the study, you will be monitored for side effects, including changes in the ECG, to be certain that ECG changes do not occur at the dose of study drug you receive. You will also be monitored by echocardiogram to look at heart function and laboratory tests will be used to measure your kidney and thyroid function.

This study is designed so that you will receive study drug (tesevatinib or placebo) for up to 24 months. Obviously, this is subject to your study doctor and the Sponsor, who may decide to take you out of the study and/or to stop the study if your ADPKD gets worse, if the study drug is thought to be unsafe, if you have side effects or for other reasons.

About 100 subjects will participate in this study across the U.S. Half the subjects (50 subjects) will receive tesevatinib, and the other half (50 subjects) will receive placebo. Placebo is a substance that looks like the study drug but contains no active ingredient. The group that you are placed in is decided by chance.

3. STUDY PROCEDURES

This research study consists of 2 time periods, the screening period and treatment period, and a final visit to the clinic. During the screening period, you will be asked questions and be given tests that will determine whether you are eligible to participate in the study. If the evaluation shows that you are not eligible to participate in the study, you will not be able to continue and your doctor will discuss alternative care options with you. If you qualify, you will take tesevatinib or placebo for up to 24 months. Your last visit will be about 30 days after your last dose of tesevatinib or placebo.

You will take the very first dose of study drug at the study site, and study personnel will give you the remaining doses to take at home on days that you do not visit the study site. You may take the study drug with or without food. You should drink an 8-ounce glass of water immediately after taking the study drug. You should avoid grapefruit or grapefruit juice the entire time you are taking study drug. You will be asked to complete a study drug diary each day to record the time you take the study drug and any necessary comment.

During the time that you are receiving study drug, you will be asked not to receive any other treatment for your condition or be on any other clinical studies. If you believe that you should receive another treatment for your ADPKD, you should not participate in this study.

3.1 Screening Period

Within 42 days before the first dose of study drug, you will be asked to visit the study center once or twice to answer questions about your medical history, any prescription or nonprescription medications you have taken, the history of your ADPKD, and how well you are able to care for yourself. You will have a physical examination, which will include measurements of your height, weight, and vital signs (body temperature, blood pressure, heart rate, breathing rate). A tracing of the electrical activity of your heart will be taken using an ECG instrument. In addition, an echocardiogram will be performed to see how well your heart is pumping blood to the rest of your body. You will have a type of scan called a magnetic resonance imaging (MRI) to measure the size of your kidneys. You will have an eye exam performed to look at the health of your eyes and assess your vision. You will also be asked to provide a urine sample and a blood sample. The total amount of blood taken for this screening is approximately 2¾ teaspoons.

If you are a woman who can have children (ie, of childbearing potential), a urine pregnancy test will be done and the test must be negative for you to be allowed to be in the study. Because it is unknown if tesevatinib affects mother's milk or a developing baby (fetus), women who are pregnant or breastfeeding will not be allowed to be in the study. In animal studies, tesevatinib has caused birth defects in developing babies (fetuses), and has decreased the number of babies surviving until birth. Your study drug treatment will be stopped if you are female and become pregnant during this study. If you are a female of childbearing potential or a male subject with a partner of childbearing potential and you are sexually active, you must agree to use 2 reliable methods of contraception to prevent pregnancy. These include any of the following combinations: an intrauterine device with a barrier method (eg, condoms with spermicide, diaphragm), hormonal birth control (pills or injections) for at least 3 months before the start of the study with a barrier method, or 2 barrier methods. You must agree to use contraception, throughout the time you are receiving study drug and for 6 months afterwards.

If you are a woman who has completed menopause 2 or more years ago and who has not had a menstrual period during the past 12 months, or if you had a total hysterectomy, you are not considered to be of childbearing potential.

If you are a male subject and have had vasectomy, you are also not considered to be of reproductive potential.

If the pretreatment evaluation shows that you are not eligible to participate in the study, you will not be able to continue and your doctor will discuss alternative care options with you.

3.2 Treatment Period

You will visit the study site on Day 1, Day 14, and Day 28 of the first month. On days that you are at the study site, the study personnel will dispense study drug to you. You will be given study drug to take at home for the other days of each cycle.

3.2.1 Month 1 (Days 1, 14, and 28)

Before you take your dose of study drug, you will be asked how you are feeling. Clinical study personnel will measure your vital signs (sitting blood pressure, heart rate, breathing rate and temperature) and perform an ECG (3 times within 30 minutes, on each visit) before you take your dose of study drug. You will have a physical examination (including weight), blood and urine samples will be taken, and a pregnancy test will be performed (if applicable). Blood samples will be taken to check your blood counts, blood minerals, and liver, kidney, and thyroid hormone function. The amount of blood to be taken for these blood tests for most subjects will be approximately 2 teaspoons. At any time during any of your visits, you should immediately report any changes in how you are feeling to the study staff.

In addition to the above, clinical study personnel will measure vital signs 1 and 4 hours after taking study drug on Day 1 and perform additional ECGs at 1, 4, and 8 hours after taking study drug on Days 1 and 14.

On Day 28, another echocardiogram will be performed, and a pregnancy test will be done.

3.2.2 Treatment Period Month 2 to Month 12

If both you and the study doctor decide that you should continue this study following the first 28 days, you will visit the study site approximately every 28 days. The following assessments will be made at each visit: physical exam, vital signs (sitting blood pressure, heart rate, breathing rate, and temperature), ECG (3 times in 30 minutes), blood and urine samples will be collected taken to check your blood counts, blood minerals, and liver, kidney, and thyroid function. The total amount of blood to be taken during each of these visits for most subjects will be approximately 2 ½ teaspoons. A pregnancy test will be done every 3 months (if applicable). An echocardiogram will be performed on your Month 3, 6 and 12 visits. An MRI will be performed at the Month 12 visit. In order to make sure there are no changes in your eye health or vision, an eye exam by an eye specialist will be performed at the Month 3, 6, 9 and 12 visits.

You will be asked how well you are able to care for yourself, how you are feeling, what medications you have taken and what symptoms you are having, and if you have taken all doses of study drug.

3.2.3 Treatment Period Month 12 to Month 24

You will visit the study site every 2 months. The following assessments will be made at each visit: physical exam, vital signs (sitting blood pressure, heart rate, breathing rate, and temperature), ECG (3 times in 30 minutes), pregnancy test (if applicable), blood and urine samples will be taken to check your blood counts, blood minerals, and liver, kidney, and thyroid function. The total amount of blood to be taken during each of these visits for most subjects will be approximately 2 ½ teaspoons. An echocardiogram and MRI will be performed every 6 months as long as you are on study. An eye exam by an eye specialist will also be performed every 6 months.

You will be asked how well you are able to care for yourself, how you are feeling, what medications you have taken and what symptoms you are having, and if you have taken all doses of study drug.

3.3 Last Visit

Approximately 30 days after your last dose of study drug you will be asked how you are feeling, what medicines you have been taking, and how well you are able to take care of yourself. You will have a physical examination (including your weight), your vital signs will be measured, and urine and blood samples will be taken. You will have another ECG, and MRI if they were not done within the last 3 months, an echocardiogram and eye exam will also be performed. If you are a woman of childbearing potential, you will have a urine pregnancy test

4. POTENTIAL RISKS AND DISCOMFORTS

4.1 Potential Risks of Tesevatinib

Over 350 adult subjects have received tesevatinib in clinical studies including at least 232 adult patients with cancer, 66 healthy adult volunteers, and 73 subjects with ADPKD. Study subjects in cancer studies often received higher doses of tesevatinib (up to 350 mg daily) than subjects with ADPKD (up to 150 mg daily).

Certain study subjects who have received tesevatinib have experienced common side effects and some less common side effects that are described below.

4.1.1 Common Side Effects

The most common side effects seen in 73 patients with ADPKD who have received tesevatinib are (in order of most common to least common) diarrhea (28/73, 38%), nausea (22/73, 30%), rash (21/73, 29%), acne (19/73, 26%), creatine phosphokinase increased (18/73, 25%), common cold (15/73, 21%), muscle spasms (14/73, 19%), vomiting (13/73, 18%), creatinine increased (11/73, 15%), headache (11/73, 15%), increased liver enzymes (11/73, 15%), fatigue (10/73,

14%), upper respiratory tract infection (10/73, 14%), amylase increased (9/73, 12%), and back pain (8/73, 11%).

Diarrhea and rash are common side effects of all drugs that, like tesevatinib, inhibit a protein called epidermal growth factor receptor. The rash can look like acne, and treatment may include steroid cream. You should notify the study doctor about any rashes you may have. You should contact your study doctor immediately if you develop frequent diarrhea because this could lead to low levels of blood minerals such as magnesium and potassium, which could affect the electrical activity of the heart. Your study doctor may want to check these levels.

Elevations of a muscle protein called creatinine phosphokinase have been reported in ADPKD subjects receiving tesevatinib. Creatine phosphokinase will be monitored regularly in this study. You should contact your study doctor if any symptoms involving muscle pain or muscle strength occur.

An increase has been seen in serum creatinine, a blood test that measures how well your kidneys are functioning, in subjects with ADPKD who have received tesevatinib. This increase happens in the first several days after receiving tesevatinib, and does not increase anymore after that. Another laboratory test that measures how well your kidneys are functioning (cystatin C) does not change. The increased creatinine levels may mean that your kidneys are not working as well as they were before taking tesevatinib. However, it may instead mean that less creatinine is going into the urine since tesevatinib blocks creatinine release into the urine. Blood creatinine will be closely monitored at each of your visits to the study site.

Some subjects with ADPKD given tesevatinib have had higher levels of a pancreas blood test (called amylase) without any symptoms. This may indicate inflammation of the pancreas, which could result in abdominal discomfort and abdominal pain and could require hospitalization and intravenous treatment. No subjects have had symptoms of abdominal pain, but you should contact your study doctor if any abdominal discomfort or abdominal pain occurs. Your amylase levels will be checked at each visit during the study.

Of the subjects with ADPKD who have received tesevatinib, there were 11 of 73 subjects who had reversible elevations in liver enzyme proteins that indicated liver damage. One subject on a metastatic lung cancer study treated daily with tesevatinib (KD019) experienced a life-threatening liver injury. The subject was taking tesevatinib (KD019) in combination with another medication that has been associated with liver impairment. The subject stopped taking both medications and the liver function tests showed improvement. Possible symptoms of liver injury or liver failure are fatigue and yellowing of the skin and eyes.

Subjects taking study drug will have monitoring of liver tests to detect evidence of liver damage at every visit, and study drug will be discontinued in any subject who has increases in liver enzyme proteins that the study doctor considers clinically significant.

4.1.2 Less Common Side Effects

Less common side effects seen in more than 5 of the 73 patients with ADPKD include (in order of most common to least common) urinary tract infection (7/73, 10%), abdominal pain (6/73, 8%), anxiety (6/73, 8%), cough (6/73, 8%), abnormal ECGs (called QTc prolongation) (6/73, 8%), hypertension (6/73, 8%), sore throat (6/73, 8%), and protein in the urine (6/73, 8%).

Tesevatinib can cause abnormal conduction of electrical signals through the heart, called QTc prolongation. These abnormal heart signals can potentially cause your heart rhythm to be abnormal, and can potentially lead to death. Abnormal heart rhythms caused by QTc prolongation have not been observed with tesevatinib in any of the clinical trials to date. The electrical signals in the heart will be monitored by ECGs during the study in order to detect QTc prolongation if it occurs.

Other medications in the same class as tesevatinib have been known to cause fluid accumulation between the heart and the sac that surrounds the heart and fluid in the tissue that surrounds the lungs. One subject with ADPKD developed a small amount of fluid between the heart and the sac that surrounds the heart. Therefore, echocardiograms will be performed to monitor for this condition.

Other medications in this class of drugs have occasionally caused injury to the heart muscle when given for long periods of time. This may affect how well the heart can pump blood to the rest of the body. Therefore, your heart function will be monitored regularly during this study.

You will be monitored very closely for any side effects, including changes in heart function or blood tests. Other effects may occur that have not yet been seen in studies with tesevatinib, so you should report all changes in how you are feeling to your study doctor. Tesevatinib may involve risks that are currently not known, including the possibility of serious side effects or death.

4.1.3 Other Potential Risks

Based on laboratory and/or animal studies, tesevatinib has the potential to cause skin and eye damage when sun exposure occurs. You should notify your doctor about any skin rashes that present during the study. In addition, you will be monitored for eye toxicity. Eye monitoring will include a number of tests that evaluate how good your vision is, and your eyes will be evaluated for any changes.

When taking tesevatinib you should use UVA ocular protection (eg, sunglasses with UVA filtering) when outside. In addition, you should avoid sun when possible and use sunscreen (with a minimum sun protection factor (SPF) of 30 (preferably titanium dioxide or zinc oxide)) in advance of exposure to the sun.

Before taking study drug, your study doctor will also make sure that you are not taking any medications that may be harmful if taken with tesevatinib. For the same reason, you should not have grapefruit or grapefruit juice when taking study drug - since these may interact with tesevatinib to cause other side effects, and the study doctor will not know whether you are receiving tesevatinib or placebo.

4.2 Potential Risks of Blood Draws

During the course of this study, you will be asked to have blood samples drawn on several occasions. Possible side effects of having your blood drawn may include minimal discomfort and bruising at the site from where the blood is drawn. Rare instances of fainting, blood clots, excess bleeding, or infection have occurred.

4.3 Electrocardiogram

An ECG is a test that records the electrical activity of the heart. An ECG will be used to measure the rate and frequency of your heartbeats as well as the size and position of the heart, and to see if there has been any damage to the heart. You will be asked to lie down, and electrodes (small wires) will be placed on your arms, legs and chest. The skin may be cleaned beforehand and the hair shaved or clipped. The usual number of leads (wires) that will be attached is 12 wires. You will be asked to remain still and may also be asked to hold your breath for short periods during the procedure while the results are recorded on graph paper. Drinking cold water immediately before an ECG may cause changes in one of the waveforms recorded (the T wave). Exercise (such as climbing stairs) right before an ECG may increase your heart rate. You may be asked to remove all jewelry and to wear a hospital gown. There is no risk of shock because this procedure only records electrical impulses and does not give off electricity. Sometimes there is a mild skin reaction or rash to the sticky material on the soft pads that are used to place the wires (leads) on the skin.

4.4 Potential Risks of Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of various parts of the body. Having an MRI test done involves lying flat upon a narrow moving surface. People who have fear of closed spaces (claustrophobia) may experience anxiety and nervousness when inside the machine. Medication may be given to lessen any fear and discomfort during the procedure. If sedative medication is used there is the risk of too much sedation. Since this technique uses strong magnets, you must remove all metal from your pockets or clothing. No metal will be allowed in the room where you will have the MRI, because the magnet may pull the objects toward the MRI machine, which may harm you. You may not have an MRI if you have any metal joint replacements (knee, hip, etc.), artificial heart valves, an implanted heart defibrillator, a pacemaker, metal aneurysm clips inside the brain, cochlear implant, a bullet, shrapnel or any other type of metal fragment in your body. You must tell the study doctor if you have any of the above MRI risks prior to enrolling in the study.

4.5 Potential Reproductive Risks

In animal studies tesevatinib has caused birth defects in developing babies (fetuses), and has decreased the number of babies surviving until birth. You should not become pregnant or father a baby while on this study because it is not known whether the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important that you understand that you need to use 2 forms of birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

5. PAYMENT FOR PARTICIPATION

You will be paid $150 each for Screening visit, Month 12, Month 18 and Month 24 visits. You will be paid $50 each for Day 1, Day 14, Day 28, Month 2, Month 4, Month 5, Month 7, Month 8, Month 10, Month 11, Month 14, Month 16, Month 20, Month 22 and EOS visits. You will be paid $100 each for Month 3, Month 6 and Month 9 visits.

You will receive a study stipend every quarter for study visits completed per protocol during that time.

How does participating affect my yearly tax return?

The IRS requires study, cumulative payments of $600 or more in a calendar year to be reported on tax returns. Our site will request that every participant complete a W-9 form at the same time as signing the informed consent. If your study stipends are $600 or more for the calendar year, you will receive a 1099-MISC to report on your tax return. If your stipends are less than $600 per calendar year, you will not receive a 1099-MISC.

6. BIOLOGICAL SAMPLES

In the course of the study, you may be asked to provide samples of tissue (such as blood cells) and body fluids (blood plasma or urine samples). By agreeing to participate in this study, you understand that you have no claim or ownership on the body tissues and fluids that you donate. It is possible that samples you have donated, which are used in research, may result in new products, tests, or discoveries. In some instances, these may have value and may be developed and owned by the study sponsor or others. Participation in this research means that you or your relatives waive the right to any money profits and new material or process developed through this research.

The samples collected to study tesevatinib may be stored for up to 5 years. Only your initials and your study subject number will identify samples. If, at any time, you withdraw your permission to be in this study or your permission to use and share of your health information, the samples will be destroyed.

7. ANTICIPATED BENEFITS

There may be no direct benefit to you from this study, whether you receive tesevatinib or placebo. While it is possible that tesevatinib may slow down the overgrowth of kidney cells, there may still be no beneficial effect on your illness. If tesevatinib works, and this is the study drug you are receiving, you may have some benefit, however, this cannot be guaranteed. The information gained from this study will help doctors learn more about tesevatinib as a possible new treatment for ADPKD and could help future patients.

8. ALTERNATIVES TO PARTICIPATION

You are under no obligation to participate in this study and other treatment options may be available. Your study doctor will explain to you options available to you. Other treatments may include:

- Getting treatment or care for your condition without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices and those risks and benefits of the choices before you decide if you will take part in this study. If you are asked to be in another research study after you agree to take part in this one, you will need to tell the study doctor before you join in the other study. Being in several experimental research studies at the same time may be harmful to you.

9. PRIVACY AND CONFIDENTIALITY

If you decide to participate in this study, and give your consent by signing your name on the last page of this document, information about you will be recorded. In the context of the clinical study, medical data on your case, including information on your sex, age, body weight and height will be documented in an anonymous form (without using your name but only your initials and study specific subject number). This data will be made available to the sponsor of the study for the purposes of scientific evaluation.

In order to verify that the study is being conducted correctly, authorized representatives of the sponsor, the contract research organization commissioned by the sponsor, Institutional Review Board (IRB), your insurance company and representatives of the official regulatory authorities (for example, the FDA) will be allowed to inspect your personal records held by the study doctor. In exceptional circumstances and in accordance with legal requirements, the regulatory authorities may also require that personal data be passed on. The authority will verify that the study is being conducted correctly, in particular that data are being correctly collected and documented. The authorized representatives are obligated to observe the rules of professional medical confidentiality. They are permitted to pass on the data of subjects in anonymous form only.

With your permission, your general practitioner (personal doctor) may be informed about your participation in this study.

All reasonable measures to protect the confidentiality of your study records and your identity will be taken to the extent permitted by the applicable laws and/or regulations, and will not be made publicly available. U.S. federal privacy regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, the Institution, and the sponsor. In order to analyze the data collected during this research study, all of the health information generated or collected about you during the study may be inspected by the study sponsor or the authorized agents of the sponsor, the FDA, the Department of Health and Human Services (DHHS) other government regulatory agencies from other countries, the study center ethics committee, Western Institutional Review Board® (WIRB®), as well by representatives of the Sponsor or their designee. Once we have shared your information with the individuals and organizations listed on this form, they may be able to share your information again, if they are not subject to laws that protect your privacy. Therefore, total confidentiality cannot be guaranteed.

The results of this study may be presented at meetings or in publications; however, your identity will not be disclosed in these presentations. By signing this informed consent form, you are authorizing such access to your medical records. This authorization will not have an expiration date.

You have the right to review and/or copy any of your protected health information that has been disclosed. This right may be suspended during the course of the trial, but will be reinstated at the conclusion of the trial.

10. PARTICIPATION AND WITHDRAWAL

Your participation in this research study is voluntary. You can choose not to participate in this study either at the beginning or at any time during the study. Your choice will not have an adverse impact on your present or future health care. Whatever your decision, there will be no penalty or loss of benefits to which you are otherwise entitled. To ensure your safety, you will be asked to undergo a final evaluation visit. If you wish to withdraw from the study, you should contact:

Kianoosh Kaveh, DO at 941-258-3556

You may also revoke the authorization to use or disclose personal information about your health. If you choose to withdraw your authorization, you must notify the study doctor in writing. This means you will no longer be on the study. The study doctor's mailing address is:

Volunteer Medical Research
3221 Tamiami Trail, 2nd Floor
Port Charlotte, Florida 33952

It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study and you will not receive the study drug (tesevatinib or placebo) that was described to you. Your health care outside the study will not be affected. The payment for your health care or your health care benefits will not be affected.

The study doctor will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been sent to the study sponsor cannot be withdrawn.

Your participation in this study may be discontinued without your consent by the study doctor or the Sponsor if you fail to follow the study doctor's instructions. You may also be withdrawn from the study if, in the study doctor's opinion, tesevatinib is ineffective, is harmful, has medically unacceptable side effects or for other reasons at the discretion of the Sponsor or study doctor. If you are withdrawn from the study, you will be asked to have the appropriate medical tests and follow-up to evaluate your health and safety.

11. NEW FINDINGS

The study doctor will provide any important new findings or information that becomes available during the study that may affect your willingness to continue in the study. You will be able to discuss the new information with the study doctor and will be asked if you want to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your care to continue. If the study doctor decides that it would be in your best interest for you to withdraw, the study doctor will explain the reasons for stopping and arrange for your care to continue. If you continue to be in the study, you may be asked to sign a new consent form that contains the new information.

12. RIGHTS AND RESPONSIBILITIES

As a study subject, it will be your responsibility to do the following:

- Keep your scheduled office visits with the study doctor. If you can't go to one of your planned office visits, call the study doctor's office and reschedule the visit.
- Take your medication and the study drug as prescribed by the study doctor.
- Keep a record of the study drug you take each day on the study drug diary card.
- Keep study drug out of the reach of children.

You are not waiving any legal claims, rights, or remedies because of your participation in this research study. You will be given a copy of this consent after you have signed and dated it. If you have questions regarding your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

13. CLINICAL TRIAL REGISTRY

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.

14. TRIAL-RELATED INJURY

You may experience problems or side effects. If complications occur, Volunteer Medical Research will provide immediate necessary care for adverse reactions or side effects that could potentially be caused by your participation in the study. You will not be responsible for the cost of treatment for such potential side effects and Volunteer Medical Research will not require proof of medical causation before it provides such care; however, neither Volunteer Medical Research nor the sponsor will provide cost-free care for medical conditions or side effects for which there is a clear alternative cause or which is the result of noncompliance. There will also be no payment of money lost from taking time away from your work to be in the study.

In the event you become injured as a result of participating in the trial, immediately contact:

Kianoosh Kaveh, DO at 941-764-5458 (24 hours)

ARE YOU CURRENTLY PARTICIPATING IN ANY OTHER RESEARCH STUDY?

☐ YES ☐ NO

INFORMED CONSENT AND AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH PURPOSES SIGNATURE OF RESEARCH SUBJECT

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I understand the following: I may stop or withdraw at any time without any penalty or loss of benefits and will be informed of any new findings that might affect my willingness to continue to be in the study. I recognize that there are no plans to provide any payments to me, or my family/relatives for any patents, discoveries or commercial products that may result from my participation in this study. If I suffer injury as a result of being in this study, the study center will provide reasonable medical care. I cannot expect to receive payment of expenses or financial compensation from the study center

for this injury. My partner and I must practice effective double birth control during the time and for as long as I receive tesevatinib and for 6 months after my last dose of tesevatinib. If I am female, I should not breastfeed my baby. If I become pregnant, or suspect that I am pregnant, I must notify the study doctor immediately, and I am aware that getting pregnant may result in removal from the study.

I understand that I will receive a signed and dated copy of this consent form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES AND AUTHORIZE THE USE AND DISCLOSURE OF MY INFORMATION IN CONNECTION WITH THE STUDY.

_____
Printed Name of Subject

_____
Signature of Subject

_____/_____AM/PM
Date/Time

SIGNATURE OF INVESTIGATOR/DELEGATE
The nature of the above study has been carefully explained to the above-named subject and the subject's study partner, or family member (if applicable). I have discussed this clinical research study with the subject using a language that is understandable and appropriate. The subject has been given ample opportunity to ask questions and all questions have been answered. I believe that I have fully informed this subject of the nature of this study, and its possible benefits and risks, and I believe the subject has understood the explanation. A copy of this completed informed consent has been provided to the subject.

_____
Printed Name of Investigator/Delegate

_____
Signature of Investigator/Delegate

_____/_____AM/PM
Date/Time