STANFORD CONSENT FORM

Are you participating in any other research studies? _____ Yes _____No

CONCISE SUMMARY

This section includes important information about the research study to assist you with understanding the purpose and procedures of the study before you decide if you want to participate. It is a summary of the research study, and is not a replacement for the full informed consent form which provides detailed information after this section that is important for you to understand in order to make an informed decision about participating in this study.

You may discuss any and all questions you have about this study with members of the study team. If you wish, you can also discuss this study and your role with your family doctor or medical provider.

Study Purposes - As you know, you have a cancer associated with Epstein-Barr virus. The cancer is now advanced, and we don't have good options for additional treatment.

Cells infected with Epstein Barr have a protein called Epstein Barr Nuclear Antigen. This is a protein that helps maintain the genes of the Epstein Barr Virus inside your cells. We are testing whether drugs that inhibit this protein will halt the growth of the cancer. The drug, VK-2019, is known to inhibit this protein, and thus could help to slow down the growth of your cancer.

This study consists of 2 parts:
Dose Escalation: The first part of the study where planned different doses of VK-2019 will be given to the participants to determine the optimal dose of VK-2019.
Dose Expansion: The second part of the study where the recommended dose of the study drug from dose escalation will be further evaluated to confirm it is safe and effective.

VK-2019 is an “investigational” drug, which means it has not been approved by US Food and Drug Administration (FDA). Whether or not the administration of VK-2019 stops the growth of your cancer is not known. It is possible that the cancer cells may go away. It is also possible that VK-2019 will have little or no effect on the cancer. We just don't know, which is why we are doing this study.

Study Procedures- This study consists of 3 phases:
Screening: You will be checked the eligibility of this study. Screening procedures will last up to 28 days.
Treatment: You will be asked to take VK-2019 by mouth once or twice daily. How many cycles of treatment you would receive depends on how well you are doing. Cycles are defined as 28 days of treatment.
Follow-Up: Your disease status, progression, and survival will be evaluated.

Length of Time in Study – The study will be complete when the last study data, including all follow up data, has been collected, and analysis is complete. If you sign this consent form, you will first undergo screening which takes up to 28 days. Then, you will have a treatment period, followed by Follow-Up period.

Risks – As of May 2024, a total 24 people have been treated with VK-2019. One patient experienced severe allergic reaction and recovered within one day. Several patients experienced diarrhea, nausea, fatigue, rash and increase in blood bilirubin (Bilirubin is a byproduct of broken-down old red blood cells. High bilirubin level in blood might indicate if your liver is having trouble processing bilirubin into bile).

The details are described under "POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES below in this consent form.

Benefits - You may or may not have a direct benefit from this study. However, it would help doctors learn more about EBV- associated cancers and their treatments in the future.

Voluntary Participation –

- Taking part in the study is voluntary. It is up to you whether or not you want to take part.
- You may discontinue your participation at any point during this study.
- Deciding not to take part in this study or discontinuing participation in this study will not affect your right to receive any other treatments or any other benefits.

PURPOSE OF RESEARCH

Your doctors have determined that your cancer is now at a stage for which there are no known curative options, although you may still continue to receive treatment to slow disease advancement (disease progression). Standard care of patients in this situation usually involves supportive care measures such as

palliative radiation to tumors causing symptoms, or systemic treatments with chemotherapy, targeted therapy, or immunotherapy, with the goal of preventing or delaying further symptoms. This study does not include these treatments.

VK-2019 is being developed at Stanford for future use in the treatment of recurrent or metastatic Epstein-Barr-positive (EBV) nasopharyngeal cancer, or EBV lymphoma or post-transplant lymphoproliferative disorder (PTLD).
VK-2019 is an oral drug with known anti-viral properties. It has the potential to slow down the replication of the EBV virus, which is responsible for the development and growth of EBV related cancers.

The primary purpose of this research study is to determine the optimal dose of VK-2019 and to evaluate the anti-cancer effect of VK-2019 in patients with EBV-related NPC for whom there is no other standard treatment available. We will also include patients with EBV lymphoma and PTLD for exploratory research to further study these EBV-driven tumors.

If you decide to terminate your participation in this study, you should notify Dr. Colevas at 650-498-6000.

This research study is looking for up to 61 people with EBV-related cancers (49 NPC, 6 lymphoma, and 6 PTLD). Stanford University will be the only site to enroll research participants for this study.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research estimates study completion for 54 months from the time the study opens to accrual. If you decide to participate in this study and sign this consent form, you will undergo screening which takes up to 28 days. The length of time that you receive study treatment will depend on how well you tolerate the treatment and the effect it has on your cancer. You may continue to receive treatment until your disease gets worse, you experience serious side effects, withdraw your consent, or the study is stopped. After completion of the study treatment, you will be asked to have an End-of Treatment Visit and enter the

Follow-up Period. During follow-up, you will be contacted every 12 weeks to see how you are doing until after completion of or removal from study or until death, whichever comes first.

PROCEDURES

If you are interested in this study, the Protocol Director and his research study staff will go over the study procedures with you before you sign this consent form. Once you have signed the consent form, you will be asked to come to the clinic to be examined if you are suitable to participate in this study. Here is the full description for the study procedures:

Table 1 summarizes all tests and procedures throughout the study.

SCREENING PERIOD (28 DAYS)

If you choose to participate, after you sign the consent form, the first activity will be screening. The purpose of the Screening Period is to see if you qualify for this study. During the Screening Visit, you will be asked to have the following tests and procedures:

- Medical/Cancer history
- Eastern Cooperative Oncology Group (ECOG) Performance Status: You will be asked how well you are able to perform normal daily living activities such as bathing, driving, shopping, working, etc.
- Vital signs (heart rate, blood pressure, and temperature)
- Height and weight will be measured.
- A complete physical examination will be performed, including:
  - General examination of your body systems, such as heart and lungs; ear, nose, and throat; skin; muscles and joints; stomach and gastrointestinal tract; and nervous system.
  - If you are female, the Protocol Director will ask about your ability to have children and use of birth control. You must be on an approved method of birth control to be in this study if you are able to have a child. The Protocol Director will discuss approved methods with you.
- Collection of Blood: Approximately 5 ml of blood samples for plasma EBV DNA analysis will be drawn for correlative study to explore whether VK-2019 has any impact on the EBV DNA.
  Approximately a total of 20ml of blood samples will be collected throughout this study (5ml each at every time point).
- You will be asked to provide a urine sample to check your overall health (urinalysis).

- Pregnancy Test: If you are a woman who can become pregnant, you will be tested to see if you are pregnant. This test may either be a blood or urine pregnancy test. The pregnancy test must be negative before you receive your 1st dose of the VK-2019.
- An electrocardiogram (ECG) will be performed to record the electrical activity of your heart. Wires will be placed on your skin near your heart, and at your wrists/arms and ankles/legs using adhesive pads. You will be asked to lie still during the procedure while the ECG is done three times in a row.
- Adverse Events: You will be asked questions about your cancer and any medical symptoms you are having.
- Concomitant Medications: Review of medications you are currently taking and have taken in the past including herbal medications
- Tumor assessment: Perform computed tomography (CT), positron emission tomography (PET)/CT, or magnetic resonance imaging (MRI). You may receive contrast for imaging scan. If you have a history of severe allergies, or have previously had a reaction to contrast agents, be sure to tell your Protocol Director and/or study staff.
- Optional Tumor Biopsy: You may be asked to provide tumor biopsy for the assessment of EBNA 1 activity before and after treatment. The biopsy samples will also be used to further investigate the presence and/or identity of additional biomarkers and/or mechanisms of activity.
- Assessment of ability to swallow pills reliably and safely (optional). If there is a question about your ability to swallow pills reliably and safely, you will be asked to ingest empty capsules under care provider supervision . These empty capsules have no active drug in them and are made from hypromellulose, a substance made from a natural fiber known to be safe for human consumption.

STUDY TREATMENT PERIOD

Once all of the test results from the screening period have been completed, the Protocol Director will review your results and determine if you qualify to enter the Study Treatment Period. If you do not qualify for this study, the Protocol Director will explain the reasons why and discuss alternatives with you.

At the study visits, you will have the following tests and procedures. See Table 1 for exact scheduling of each event:

- ECOG Performance Status
- Vital signs
- Weight
- Physical examination

- Blood collection:
  - Approximately 5ml of blood samples will be drawn for PK (Pharmacokinetics) analysis at each time through Cycle 3 Day 0.
  - Approximately 5ml blood samples for plasma EBV DNA analysis will be drawn at each time point (Day 0 of Cycles 2 and 3) for correlative study to explore whether VK-2019 has any impact on the EBV DNA.
  - If you undergo a lumbar puncture while on trial as part of standard of care, if possible, an additional sample of cerebro-spinal fluid (CSF) will be collected for the purposes of exploratory study. If feasible, unscheduled plasma PK sample will be collected at approximately the same time.
- Urine sample (urinalysis)
- ECG
- Adverse Events: You will be asked about any symptoms you may be experiencing. The Protocol Director will monitor you for any potential side effects. If the side effects are severe, the Protocol Director may temporarily stop study drug; change the dosage of your study drug; or withdraw your study drug completely.
- Concomitant Medications: You will be asked if you have started any new medications or changed the dose of existing medications.
- Optional tumor biopsy will be done at Day 0, Cycle 2 (in addition to tumor biopsy done at Screening).
- Tumor assessment: Imaging scans will be repeated on Day 0 of every odd cycle beginning at Cycle 3.
- You will be provided with a study drug diary to help you keep track of your dosing. The study staff will review how to complete this diary. The study drug diary should be returned at each visit and will be reviewed by the study staff with you.

STUDY DRUG ADMINISTRATION:

All participants in this study will receive VK-2019. You will be asked to take 1200mg twice daily or 1800mg once/twice daily of the study drug by mouth with each cycle lasting 28 days. You might be asked to swallow test pills in order to assess if you can take VK-2019 safely. You will be provided sufficient supply to last until the next study visit or for an entire cycle, depending on the study team's discretion. You will be given a diary to record the administration of study drug. Your study doctor or study staff will explain more details about the instruction on how to take the study drug.

END-OF-TREATMENT VISIT

When you stop taking the study drug, you may be asked to complete the following tests and procedures within 7 days of the last dose of study drug.

- ECOG Performance Status
- Vital signs
- Weight
- Physical examination
- Blood collection:
  - Approximately 5 ml of blood samples for plasma EBV DNA analysis will be drawn for correlative study to explore whether VK-2019 has any impact on the EBV DNA.
- Urine sample (urinalysis)
- ECG
- Adverse Events
- Concomitant Medications
- Tumor assessment: Imaging Scans - only if not done within four weeks of the End of Treatment Visit.

FOLLOW-UP

The first safety follow-up visit will occur 28 days after the End-of-Treatment Visit and include a repeat of some of the tests from the End of Treatment Visit.

Thereafter, you will be followed every 12 weeks for long term follow-up to see how you are doing until after completion of or removal from study or until death, whichever comes first. You may be asked to have your tumor assessed after the last treatment visit unless you have disease progression or the Protocol Director decides not to do any further tumor assessments for this study during the long-term follow-up period. The follow up will be conducted by clinic visit (either at the study site or outside facility), telephone or video-telephoning.

This research will not include whole genome sequencing.
Your specimens will be sent outside of Stanford for analysis. Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Future Use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

You may be asked to provide blood and tumor samples for the future studies. Those samples may be used for cerebro-spinal fluid (CSF) analysis, plasma EBV DNA analysis, EBNA1 activity assessment, and additional analysis.

Genetic Testing and Future Research

As part of the analysis on your specimens, the investigators will do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease. The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Optional Biopsy Samples for Future Study

You will be asked to allow us to use your tumor samples for EBNA1 activity assessment. You have the right to refuse to allow your tissues to be saved for future study. You do not have to agree for your biopsy sample for these additional studies. You can change your mind later and ask that any identifiable samples be destroyed to prevent future use.

Please mark your choice by placing your initial:

_____ I consent to provide optional tumor biopsies for research test at Screening and Cycle 2 D0.

_____ I do **not** consent to provide optional tumor biopsies for research test at Screening and Cycle 2 D0.

Table 1: Study Calendar

Assessment	Screening	Cycle 1		Cycle 2	Cycle 3 and Odd Cycles	Cycle 4 and Even Cycles	EOT	Safety FU	LTFU
	Within 28 days of Cycle 1 Day 0	Day 0	Day 14	Day 0	Day 0	Day 0	7 days post-last dose	28 days post-last dose	Every 12 weeks post-last dose
Informed consent	X								
Medical/Cancer History	X								
ECOG Performance Status	X						X		
Vital Signs	X	X	X	X	X	X	X	X	
Height & Weight	X	X		X	X	X	X	X	
Physical Examination	X	X		X	X	X	X	X	
Blood samples for Hematology labs	X	X	X	X	X	X	X	X	
Blood samples for Chemistry labs	X	X	X	X	X	X	X	X	
Urine sample (Urinalysis)	X	X		X	X	X	X	X	
Blood samples for blood clots	X	X		X	X	X	X	X	
Pregnancy Test (if applicable)	X								
ECG	X	X	X	X			X	X	
Adverse Events	X	X	X	X	X	X	X	X	
Concomitant Medication Review	X	X	X	X	X	X	X	X	
VK-2019 Administration		X	X	X	X	X			
PK		X	X	X	X (C3 only)				
Plasma EBV DNA	X			X	X (C3 only)		X		
Optional tumor biopsy	X			X					
Tumor Assessments (Imaging scans)	X				X		X		X
Survival									X
Swallowing evaluation (optional)	X								

EOT = End of Treatment Visit; FU = Follow-up; LTFU = Long Term Follow-up

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Colevas at 650-498-6000.

If you withdraw from the study, you may also ask your samples to be destroyed. However, any data that are already generated from your samples will be kept and used for the purposes described in this document.

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.

- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- Disease progression
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Your Protocol Director may give you medications to try to help lessen some of the side effects.

Risks Associated With Study Drug: VK-2019

There may be risks that are not yet known ("unforeseeable"), including a risk of death due to unknown risks.

As of May 2024, 24 people have been treated with VK-2019. One patient experienced severe allergic reaction and recovered within one day. Several patients experienced diarrhea, nausea, fatigue, rash and blood bilirubin increased.

Everyone taking part in the study will be watched carefully for any side effects. However, because this is the first study when VK 2019 is administered to humans, the Protocol Directors and researchers do not know all of the side effects that may happen. Side effects may be mild or very severe and lead to death. In some cases, side effects can be serious, long lasting, or may never go away. The study drug may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The Protocol Director will be testing your blood at regular interval during treatment and will let you know if changes occur that may affect your health. You should talk to your Protocol Director about any side effects that you have while taking part in the study.

Studies in dogs found low toxicity of VK 2019. Increased risk of vomiting was noted at higher doses with no other drug related effects in dogs. Some damage

to liver and kidney as well as lowering of blood counts was observed in rats treated at a dose much higher than planned in the study. The Protocol Director

will monitor your blood counts, liver and kidney function through the course of the study and after completion of the study to detect if any abnormalities occur.

Allergic reactions: All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the Protocol Directors right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters increased heart rate, wheezing or difficulty breathing, dizziness and fainting.

Reproductive Risks:

In this consent form, the terms "man/ or male" and "woman or female" refer to the sex a participant was assigned at birth.

If You Are A Woman of Childbearing Potential:

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk during treatment and for 18 weeks after your last dose of VK-2019. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If You Are A Man:

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception during

treatment and for 18 weeks after your last dose of VK-2019. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your Protocol Director if your partner becomes pregnant.

Risks Associated With Procedures:

Blood draws: The collection of a blood sample may cause some discomfort. Obtaining blood may cause pain/discomfort at the site where the blood is drawn, bruising, bleeding, occasional lightheadedness, and, rarely, infection or fainting.

ECG: Risks from an ECG can include skin irritation and/or a rash from the gel, or from wearing or removing the patches.

Tumor biopsy: A biopsy is a procedure that involves removing small samples of tissue. For this study, a small piece of tumor tissue will be removed for research purposes. Your doctor will explain the details and risks of the procedure, which may vary depending on how the biopsy will be obtained.

Biopsies can cause pain, redness, swelling, excessive bleeding, bruising, or draining at the needle site. Abnormal wound healing, fever, infection, and allergic reaction to the medicine used to numb the skin over the biopsy site can also occur.

CT Scan Risks: A CT scan, also called CT or computerized tomography, is an X-ray procedure where a computer is used to make multiple images or pictures of your body. You will be asked to lie still on a table and at times may have to hold your breath for a few seconds in order to avoid blurring the pictures. You may hear a slight buzzing, clicking, and/or whirring sounds as the CT scanner moves around your body.

A contrast agent or dye will be injected for the CT scans. If you have a history of severe allergies (e.g., bee-sting reaction, food, shellfish, or nut reactions), or have previously had a reaction to medications, iodine or contrast agents, tape or latex**,** tell the study team or technician before the scan.

PET Scan Risks: In the PET, a small amount of radioactive chemical (tracer) is injected into your veins and travels through the bloodstream. The PET scanner works by detecting the radioactive substance inside the body and making images that show where the radiation is concentrated. There is a risk of allergic reaction to the chemical used in the test. You could also have swelling, soreness, or infection at the site where the tracer is injected into your vein. The injection of the

radiotracer may cause some discomfort. Allergic reactions to the radiotracer are rare.
You may experience discomfort related to lying still in an enclosed space for a long period.

Additional PET and CT Risks: This research study involves exposure to radiation from PET/CT or CT scans. Your radiation exposure will be about 66 mSv. This amount of radiation has an estimated risk of fatal cancer of about 0.4 percent. If randomly selected members of the general population were exposed to the radiation exposure from this research, the extra lifetime risk of dying from fatal cancer may be about 4 in 1,000. Statistics represent averages and do not predict what is going to happen to you. They do not take into consideration individual risk factors including lifestyle (smoking, diet, exercise, etc), family history (genetics) or radiation exposure. The majority of cancers occur later in life and the average lifetime risk of dying from cancer is 25% (1 in 4).

MRI (Magnetic Resonance Imaging)
MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. During the scan you will be asked to lie on a long narrow couch for a certain amount of time (approximately 30 minutes) while the machine gathers information. During this time you will not be exposed to x-ra ys, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

MRI Risks:
Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury

involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member. There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. Dizziness or nausea may occur if you move your head rapidly within the magnet.

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator. If you have kidney problems, please tell the operator. It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the Protocol Director if you have any questions about the use of GBCAs with MRIs.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

POTENTIAL BENEFITS

There is no guarantee that you will receive any benefit from taking part in this study. Your condition may remain the same, improve, or could get worse. However, information learned from this study may help other people in the future or in the development of better treatment for your type of cancer.
We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You do not have to be in this study to receive treatment for your nasopharyngeal cancer. Instead of taking part in this study, you may choose to:

- Take part in another study
- Getting no treatment
- Getting comfort care, also called palliative care

If you have questions about alternates and their potential benefits and risks, ask the Protocol Director for additional information.
You do not have to join this study. If you do not join, your care at Stanford will not be affected.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information in a timely manner that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

Personal data related to your participation in the study will be replaced with a unique code referred to as a Subject Identification number (SID). All data and specimens obtained from this study will be identified using this SID number. Only your study doctor and study staff will be able to identify you from the code, and will be responsible for processing the information which will be stored under the code allocated to you and are responsible for ensuring your data remains confidential as required by applicable law.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain information on the safety and effectiveness of VK-2019; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health (NIH), which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
This research study is a Phase 1/2a open-label clinical trial to test the safety and efficacy of a study drug called VK-2019 for the treatment of Epstein-Barr-positive (EBV) nasopharyngeal cancer and other EBV- associated cancers, with pharmacokinetic and pharmacodynamic correlative studies.

Your health information will be utilized to check whether you meet eligibility criteria, to verify the study conduct, to analyze and process for study and scientific purposes including publications, study reports, correlative/special studies, to understand study treatment and disease, and to prepare regulatory documents for submission to FDA.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment.
Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health

information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:
A Dimitrios Colevas, MD
875 Blake Wilbur Dr., Stanford, CA 94305-5826

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, name, demographic information (date of birth/age, race, ethnicity, gender), medical records, medication history, and the results of all tests and procedures performed during this study (e.g., records from study visits, genetic, lab, imaging and diagnostic test results, diary), and survival information.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Dr. Colevas
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration

- National Institutes of Health (NIH)
- Stanford Cancer Institute Data and Safety Monitoring Committee (DSMC)
- Johns Hopkins University for PK analysis
- Wistar Institute

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2070 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment/Reimbursement

You will not be paid to participate in this research study. However, you may be eligible for a reimbursement for reasonable travel and housing expenses that you incur because of this study. Please talk with the study coordinator for more details.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor

This study is being paid for by a grant to Stanford from the National Cancer Institute (NCI), of the National Institutes of Health (NIH).

The NIH is also providing some financial support for the facility and staff where part or all of the study is taking place.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other

benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Colevas at 650-498-6000. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____

Print Name of Witness (e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*