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

PURPOSE OF RESEARCH

You are invited to participate in a research study of a medication called ibrutinib. We hope to learn whether this medication can help to cure leukemia after a blood stem cell transplant. You were selected as a possible participant in this study because you are going to have a blood stem cell transplant to treat acute leukemia.

Ibrutinib is a medication that blocks specific cell growth signals. It is a pill that is taken once a day. It is currently approved by the US Food & Drug Administration (FDA) to treat some kinds of leukemias and lymphomas, but is not currently approved by the FDA to prevent leukemia from coming back and to prevent GVHD after a blood stem cell transplant. Preliminary research suggests that ibrutinib might help to keep acute leukemia cells from growing, prevent graft-vs.-host disease (GVHD) after a transplant, and help the transplanted donor cells work better against leukemia. However, these possible benefits have not yet been confirmed in clinical trials. The purpose of this trial is to determine whether ibrutinib can help a) prevent leukemia from coming back, and b) prevent GVHD and other complications after a blood stem cell transplant.

The following information is provided in order to help you decide whether to participate in this clinical trial of ibrutinib. Please read the form carefully, and bring up any questions with your doctor and treatment team. Before you decide whether to participate, it is important to feel comfortable that you understand the possible risks and benefits of this clinical trial.

The choice to participate in this clinical trial is up to you. You may take home a copy of this form to think about or to discuss with your family or friends before deciding. If you do decide to participate, you will also be given a signed copy of this document to take home with you.

If you decide to terminate your participation in this study, you should notify Dr. Andrew Rezvani or the study staff at [redacted].

This research study is looking for 45 people who are having blood stem cell transplants to treat acute leukemia. Several other cancer centers are participating in this study. Stanford University expects to enroll 25 research study participants.

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 study will take a total of 2 years of participation. Participants will take ibrutinib for 18 months, starting at about 2 months after their blood stem cell transplant. Medical information will be collected for 2 years after the blood stem cell transplant as part of this study. After the study ends, their regular doctors will continue to follow them.

PROCEDURES

If you choose to participate, you will have screening procedures done before your transplant to make sure that you meet the requirements to be in this study. If you test positive for HIV, counseling will be provided. If you meet all study requirements, you will be enrolled in the study. Your actual blood stem cell transplant will be done according to standard practices. Your transplant itself, including the chemotherapy drugs, donor choice, and other medications, will not be affected by this trial and will not contain any experimental treatments.

You will be assessed again between 1 and 2 months after your blood stem cell transplant to make sure that you remain eligible to receive ibrutinib, which is the experimental drug in this study. If you are not eligible, then you will not receive ibrutinib, and the rest of your transplant care will be provided according to normal standards of care. If you remain eligible, then you will begin taking ibrutinib, which is the experimental drug in this study, between 2 and 3 months after your transplant.

While taking the study drug (ibrutinib), you will be monitored closely by your transplant doctor. The dose of ibrutinib may be adjusted by your transplant doctor to prevent interactions with other medications, and the study drug may be temporarily or permanently stopped if you experience side effects. This study will track side effects from ibrutinib, and the study will be stopped if there is evidence that ibrutinib is causing increased risks.

Other than taking ibrutinib (the study drug), the rest of your transplant care, testing, and follow-up will be provided according to normal standards of care.

The only other research procedures as part of this study will involve blood draws when you start chemotherapy before your transplant, when you start taking ibrutinib, and again at 6 months, 1 year, and 18 months after your blood stem cell transplant. For each draw, a sample (up to 3-5 tablespoons) will be collected. Whenever possible, we will try to combine these blood draws with other blood draws that you will be having as part of your regular medical care. These blood samples may be sent outside of Stanford for analysis. The results will not directly affect your medical care, but may be used to help understand the effects of ibrutinib and to help develop new studies in the future. Any of your samples 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 samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries. Any samples left over when the study is completed will not be saved for future research.

Reproductive effects

The effects of ibrutinib on a developing baby are unknown, so women who are pregnant or nursing are not allowed to be in this study. Nobody knows what these risks are right now. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects.

If you are able to have children, you must use a highly effective method of birth control while taking study treatment and also a barrier method, as well as for 1 month (women) or 3 months (men) after you stop taking study treatment, to prevent pregnancy in either you or your partner. A "highly effective method of birth control" is defined as a method that has a low failure rate (ie, less than 1% per year) when used consistently and correctly and includes implants, injectables, birth control pills with 2 hormones, some intrauterine devices (IUDs), sexual abstinence (which is defined as refraining from all aspects of sexual activity) or a sterilized partner. A barrier method of contraception (eg, condoms with spermicide, cervical rings, sponge, etc) must be used.
Note: Some birth control pills may not work when you are taking certain drugs. If you have any questions about this, please discuss this with the study doctor.

Be aware that you can still become pregnant even if you use a highly effective method of birth control.

Men: If your partner becomes pregnant while you are on study treatment, or within 3 months of your last dose of ibrutinib, you must notify the study staff.

The study staff will discuss this with you further. You should not donate sperm while you are taking the study drug and for 3 months after you stop taking the study drug. If your female partner becomes pregnant during your participation in the study you MUST notify your study doctor immediately. The Sponsor will ask your female partner for permission to collect information about the pregnancy and the birth of your baby even after study treatment is stopped for any reason.

Women: If you become pregnant while you are on study treatment or within 1 month of your last dose of ibrutinib you must notify the study staff. If you become pregnant on the study, you must immediately stop taking the study treatment. The Sponsor Investigator will continue to collect information about your pregnancy and the birth of your baby even after study treatment is stopped.

Breast-feeding

It is not known whether ibrutinib or its metabolites are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from ibrutinib, breast-feeding should be discontinued during ibrutinib treatment.

TISSUE SAMPLING FOR FUTURE RESEARCH

Research using tissues is an important way to try to understand human disease and how immune responses cure blood cancers and cause problems such as graft versus host disease. You have been given this information because the investigators want to include your tissue in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

You will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

You will be told the results of test that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

☐ I allow a sample of my tissues to be taken for research use

☐ I DO NOT allow a sample of my tissues to be taken research use

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.
- 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. Andrew Rezvani at [redacted]

If you withdraw from the study, or the study medication is stopped for any reason, we will no longer collect your information for the study, and you will be asked to return all study-related medication (ibrutinib).

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
- You need treatment not allowed in the study.
- Your leukemia comes back despite taking ibrutinib.

- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

You may develop side effects while participating in this study. You should tell the study doctor about any side effects that you develop.

The side effects listed below have been reported by patients who have received ibrutinib in clinical trials.

If you experience serious problems, you may be asked to return to the study center for more tests. If you experience the following symptoms of an allergic reaction, contact the Study Doctor or the Study Team **immediately**. If you are in distress, **CALL 911 immediately**.

- Allergic reaction, including rash, hives and/or itching of the skin, or blisters; increased heart rate (a fast pulse or tachycardia); and/or abnormal or increased sweating
- Swelling of the face, mouth, lips, gums, tongue and/or neck
- Wheezing; shortness of breath; or difficulty breathing
- Dizziness; confusion; feeling light-headed; pounding or racing heart; and/or fainting
- Fever; chills; weakness; confusion; body aches; cold or flu symptoms; and/or feeling tired
- Easy bruising and/or bleeding
- Sudden severe headaches; weakness in the arms or legs; difficulty speaking or understanding speech; and/or loss of balance
- Yellowing of the eyes and skin (jaundice), dark-colored urine; and/or gray- or clay-colored bowel movement (stools);
- Upset stomach (nausea), loss of appetite; tiredness (fatigue); and/or diarrhea
- Severe skin reactions and/or rash with blisters and peeling skin or spreads quickly, which may include open ulcers or sores in the mouth and other areas of the body

Most Common Side Effects of the Study Drug Ibrutinib [these side effects occurred in more than 1 in 5 people taking ibrutinib (more than 20%)]

- Occurrence or increase in frequency of loose or watery stools (Diarrhea)
- Muscle and joint pain (musculoskeletal pain)
- Nausea
- Low white blood cell count (WBC, blood cells that help fight infection) (neutropenia)
- Low Platelet count (cells that help blood to clot) (Thrombocytopenia)
- Bleeding (Haemorrhage)
- Rash
- Fever (pyrexia)
- Common cold (Upper Respiratory Tract Infection)

Less-likely Side Effects (these side effects occurred in more than more than 1 in 10 people taking ibrutinib (10% to 20%)

- Lung infection (pneumonia)
- Sores in the mouth (stomatitis)
- Skin infection
- High blood pressure (hypertension)
- Headache
- Joint aches (arthralgia)
- Vomiting
- Constipation
- Weakness, tingling, numbness, and pain from nerve damage, usually in the hands and feet (peripheral neuropathy)
- Dizziness
- Swelling of the hands or feet (peripheral edema)
- Urinary tract infection (UTI)
- Muscle spasms

Unlikely Side Effects (these side effects occurred in more than 1% to 10% of people taking ibrutinib)

- Sinus infection (sinusitis)
- Non-melanoma skin cancer
- Severe infection throughout the body (sepsis)
- Inflammation within the lungs that may lead to permanent damage (Interstitial lung disease)

- Abnormal heart rhythm (atrial fibrillation)
- Increased level of uric acid in the blood (hyperuricemia)
- Low white blood cell count (WBC, blood cells that help fight infection) with fever (febrile neutropenia)
- Increase in specific white blood cell count (Leukocytosis,Lymphocytosis)
- Blurry vision
- Skin redness (erythema)
- Fingernails or toenails breaking (onychoclasis)
- Increased level of "creatinine" in the blood (blood creatinine increased)
- Heart failure, which makes you short of breath and may lead to swollen legs

Unlikely Side Effects (these side effects occurred in less than 1% of people taking ibrutinib)

- High levels of cancer cell breakdown products, which may lead to changes in kidney function, abnormal heartbeat, or seizures (Tumor lysis syndrome)
- Liver failure (hepatic failure)
- Inflammation of the fatty tissue underneath the skin (Panniculitis)
- High WBC count with abnormal clumping that can lead to bleeding (leukostasis syndrome)
- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- Abnormal rapid and/or irregular heart rhythm that starts from the lower chambers (ventricles) of the heart (Ventricular tachyarrhythmias)
- Swollen face, lip, mouth, tongue or throat (angioedema)
- Itchy rash (urticaria)
- Temporary or permanent decrease of brain or nerve function due to reduced blood flow to the brain (mini-stroke or stroke)

Serious Side Effects of Ibrutinib – Contact your study doctor IMMEDIATELY.

Some reactions to ibrutinib can be serious or even fatal. If any of the events below happen, contact your Study Doctor **immediately** to help prevent the event from getting worse. If the event gets worse or you are in distress, **CALL 911**.

Effects on the heart

Abnormal rapid and/or irregular heart rhythm (atrial fibrillation, atrial flutter, and/or ventricular tachyarrhythmia with some fatal events) have been reported in patients treated with ibrutinib especially when they also have had heart conditions; increased blood pressure; infections; or an abnormal heartbeat in the past. Atrial fibrillation/flutter is a common type of abnormal heartbeat. The heartbeat may be fast or irregular causing symptoms such as a pounding or racing heart; dizziness; weakness; feeling light-headed; shortness of breath, chest discomfort or fainting. You should seek medical attention and notify your Study Doctor **immediately** if you develop any of these symptoms while receiving the study drug.

Interstitial lung disease (ILD)

Interstitial lung disease is a group of lung disorders in which the tissues become inflamed and may become damaged. Interstitial lung disease is not associated with infections (eg, bacteria, viruses, fungi) and has been reported in patients treated with ibrutinib. You should report to your physician if you have cough; or any signs of new or worsening respiratory symptoms, such as shortness of breath or difficulty breathing.

Infections

You may experience viral, bacterial, or fungal infections during treatment with ibrutinib. Some of these infections have been associated with hospitalization and death. Contact your study doctor **immediately** if you have fever; chills; weakness; confusion; body aches; cold or flu symptoms; vomiting; jaundice; feel tired; or feel short of breath. These could be signs of a serious infection. Your study doctor may start or continue medication to help prevent or treat an infection.

A rare and usually fatal viral disease in the brain, progressive multifocal leukoencephalopathy (PML), has been reported in patients treated with ibrutinib in combination with rituximab and in patients who were previously treated with rituximab. If you experience symptoms such as weakness, paralysis, vision loss and/or impaired speech, you should seek medical attention immediately and also tell your Study Doctor.

Bleeding effects

You may experience bruising or bleeding during treatment with ibrutinib. Rarely, serious or fatal internal bleeding may occur, such as bleeding in your stomach, in your intestine, or in or around your brain, sometimes resulting in death. If you take other medicines or supplements that increase your risk of bleeding (such as aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) or medicines used to

prevent or treat blood clots or stroke) ibrutinib may increase this risk. Blood thinners such as warfarin or other vitamin K antagonists should not be taken together with ibrutinib. Supplements such as fish oil and vitamin E preparations should be avoided while taking ibrutinib.

Seek medical attention **immediately** and also call your Study Doctor if you have signs or symptoms of severe bleeding in or around the brain such as sudden severe headaches; weakness in the arms or legs; difficulty speaking or understanding speech; or loss of balance. You should also seek medical attention **immediately** and notify your Study Doctor if you have signs or symptoms of serious bleeding, such as blood in your stools or urine or bleeding that lasts for a long time or that you cannot control.

Decreased blood counts

Severe decreases in white blood cells, red blood cells, and platelets (neutropenia, anemia, and thrombocytopenia) were reported in subjects treated with ibrutinib. If you experience symptoms such as fever; weakness; or easy bruising and/or bleeding; you should tell your Study Doctor **immediately** and seek medical attention.

Liver Failure

Rare cases of liver failure have been reported in patients treated with ibrutinib. Symptoms of liver failure include yellowing of the eyes and skin (jaundice), itching of the skin, dark-colored urine; gray-or clay-colored bowel movement (stools); confusion; Upset stomach (nausea), loss of appetite; tiredness (fatigue); or diarrhea. You should tell your study doctor **immediately** if you have any of these symptoms which may suggest liver disease. Your Study Doctor may be able to diagnose and provide you required medical care.

Allergic reactions

Sometimes people have allergic reactions to drugs. Serious allergic reactions can be life-threatening. If you have an allergic reaction to ibrutinib or the other study medications (idarubicin or cytarabine), you might develop a rash; difficulty breathing; wheezing when you breathe; sudden low blood pressure with light-headedness; swelling around the mouth, throat or eyes; a racing heartbeat; and/or abnormal or increased sweating. Before starting the study drug, you must tell your Study Doctor about any drug allergies. You should tell the Study Doctor **immediately** if you have any allergy symptoms listed above.

Rash

A maculopapular rash (flat, red areas on the skin with small bumps) has been commonly reported in patients treated with ibrutinib alone or in combination with

other drugs. Most rashes are mild to moderate in severity and begin 2 to 3 weeks or longer after starting ibrutinib.

There have been rare reports of severe skin reactions (known as severe cutaneous adverse reaction or "SCAR," involving more than 50% of the body), or rash with blisters and peeling skin, which may include open ulcers or sores in the mouth and other areas of the body (Stevens-Johnson Syndrome). These skin rashes could be life-threatening. You should notify your Study Doctor **immediately** if you develop a rash that spreads quickly, or if you notice peeling of your skin, with or without ulcers or sores in your mouth.

Interference with other drugs

Some juices or foods like grapefruit and Seville oranges, as well as some medications, may interfere with the way your body processes ibrutinib. This interference could cause the amount of ibrutinib in your body to be higher or lower than expected. It is also possible that taking the study drug with your regular medications or supplements, including fish oil, Vitamin E, or other vitamins, may change how your regular medications, or your regular supplements, work. It is very important that you avoid grapefruit juice and Seville oranges and tell the Study Doctor about all medications, supplements, or herbal medicine like St John's wort that you are taking during the study. You should notify your Study Doctor **immediately** about any side effects to avoid possible harm.

Other Serious Side Effects of Ibrutinib

Lymphocytosis and leukostasis (increases in WBC)

You may experience an increase in the number of lymphocytes, which is a specific type of white blood cell, in your blood (lymphocytosis). This may occur in the first few weeks of treatment and you should not assume that this increase in white blood cells means that your disease is worsening. This increase may last for several weeks to months. In rare cases, increased number of white blood cells in your bloodstream may change the blood flow resulting in bleeding or clotting (leukostasis). Isolated cases of these events have been reported in patients treated with ibrutinib. Your Study Doctor will monitor your blood counts and may administer additional therapy as needed. Talk to your Study Doctor about what your test results mean.

Tumor Lysis Syndrome (TLS)

Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells have happened during treatment of cancer and sometimes even without

treatment. This may lead to changes in kidney function, abnormal heartbeat, or seizures. Your Study Doctor may do blood tests to check for TLS.

High blood pressure (hypertension)

High blood pressure, also called hypertension, has been commonly-reported in subjects treated with ibrutinib. Sometimes people with high blood pressure may have headaches; dizziness; nervousness; sweating; difficulty in sleeping; facial flushing or nosebleeds; but in some cases, there may be no symptoms and it may go undetected. After starting ibrutinib, your doctor may measure your blood pressure regularly. You should let your study doctor know if you have any of the symptoms of high blood pressure, which may mean that you have developed hypertension or that your hypertension is getting worse. Your study doctor may adjust existing anti-hypertensive medications and/or start anti-hypertensive therapy as appropriate.

Stroke

Cases of stroke, with and without changes in heartbeat rhythm and/or hypertension have been reported with the use of ibrutinib. Some of these cases have led to death. Seek immediate medical attention if you notice or someone notices in you: sudden numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination, sudden severe headache with no known cause. These may be signs and symptoms of stroke.

Other Cancers

Other cancers have been observed in patients who have been treated with ibrutinib and with chemotherapy (such as idarubicin). These include, skin cancer, solid tumors, and blood cancers. The causal relationship with ibrutinib is unknown. You should tell your Study Doctor if you develop a new cancer while in the study.

Drug interruption for any surgical procedures

Ibrutinib may increase the risk of bleeding with any surgical procedure. Ibrutinib should be held at least 3 to 7 days before and after surgery depending upon the type of surgery and the risk of bleeding. For emergency surgical procedures, ibrutinib should be discontinued (stopped) after the procedure until the surgical site is reasonably healed (not oozing fluid).

Please contact your Study Doctor if you have any surgical procedures and your Study Doctor will tell you when to stop ibrutinib and when to restart it following a surgical procedure.

Please contact your study doctor as soon as possible and your study doctor will tell you when to stop ibrutinib and when to restart it following a surgical procedure.

In addition to the risks listed above, there could be unknown or unexpected side effects associated with the use of ibrutinib. You will be told in a timely manner, verbally and in writing, of any new information, findings, or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

You may have all, some, or none of the listed side effects of ibrutinib. Your study doctors and nurses will check you closely for side effects. You may receive medicines or other treatments to prevent or reduce some of these effects. Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think they are related to the study drug.

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

Any study drug can also have side effects that are unexpected or unforeseen. You will be monitored for any possible side effects during this study.

POTENTIAL BENEFITS

There are several potential benefits of taking ibrutinib after a blood stem cell transplant. These possible benefits are based on studies that have been done in the laboratory or in people being treated for other diseases. The possible benefits of taking ibrutinib after your transplant include:

- The possibility that ibrutinib will help cure your leukemia and keep it from coming back.
- The possibility that ibrutinib will help the transplanted donor cells work better to get rid of your leukemia.
- The possibility that ibrutinib will help prevent graft-vs.-host disease (GVHD), one of the most serious possible complications of a blood stem cell transplant.

This clinical trial is designed to determine whether ibrutinib has these benefits. Because these possible benefits are based on preliminary research, we cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this trial is to receive your transplant according to the normal standard of care, without taking ibrutinib.

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 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

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 data or information on the safety and effectiveness of ibrutinib; the results will be provided to the study supporter, Pharmacyclics LLC, its affiliates and its collaborators (Janssen Biotech, Inc.), the Food and Drug Administration and other federal and regulatory agencies as required.

Pharmacyclics LLC, its affiliates, and its collaborators (Janssen Biotech, Inc.) may study your data and tissue, blood, or other specimens collected from you. Your tissue, blood or other specimens may be used for any purpose including research, which may lead to the development of medical products such as devices, or new drugs or patentable processes and procedures. You will not be compensated for any patents or discoveries that may result from your participation in this research. Your signature on this form indicates that you understand and accept this.

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 biospecimens 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 biospecimens 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.

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 clinical trial is being done to determine whether the medication ibrutinib can help cure leukemia after a blood stem cell transplant. Your health information may be used to help answer this question as part of the study, and may be used in publications or presentations in the medical literature. The information gained in this study may also be reviewed by Stanford University study sponsor, Pharmacyclics study supporter,and to the US Food & Drug Administration (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: Andrew R. Rezvani, M.D., 300 Pasteur Drive, MC 5623, Stanford, CA 94305.

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, your medical condition, any complications of the study drug or of your transplant, blood test results, imaging studies or reports, pathology reports, and physical examination results.

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 (Andrew R. Rezvani, M.D.)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
- The Data Safety Monitoring Committee at the Stanford Cancer Institute

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 study supporter Pharmacyclics LLC, its affiliates, and its collaborators (e.g. Janssen Biotech, Inc)
- The Food and Drug Administration
- The NIH
- Researchers participating in this study at other institutions

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, 2025, 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
You will not be paid to participate in this research study.

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.

Support
Pharmacyclics is providing financial support and/or material for this study. The study drugs will be provided to you at no cost to you by Pharmacyclics.

The National Institutes of Health are providing some financial support for the facility and staff where part or all of the study is taking place.

Consultative or Financial Relationships
Dr. Wen-Kai Weng and Miklos are paid advisors to Kite Pharma and Janssen Pharma, the company whose products are being used in this study. Dr. Miklos is a paid advisor to Pharmacyclics, LLC the company funding this study.

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, Andrew R. Rezvani, M.D. You may contact him now or later at ([redacted].

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Andrew R. Rezvani, M.D., at ([redacted]

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 ([redacted] or toll free at 1-[redacted]. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Dr. David Miklos at ([redacted]

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.*