**INFORMED CONSENT DOCUMENT**

**AGREEMENT TO BE IN A RESEARCH STUDY**

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| **NAME OF SPONSOR COMPANY:** | **Curis, Inc.** |
| **STUDY NUMBER AND TITLE:** | CUDC-907-201: "Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of CUDC-907 in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma, Including Patients with MYC Alterations" |
| **PRINCIPAL INVESTIGATOR:** | «Name_of_investigator» |
| **ADDRESS OF STUDY SITE(S):** | «Study_site_1»<br>«Study_site_1_address»<br>«Study_site_1_city», «Study_site_1_state»<br>«Study_site_1_zip» |
| **TELEPHONE NUMBER(S), DAYTIME:**<br>**AFTER HOURS:** | «Site_phone_number»<br>«After_hours_number» |

## INFORMED CONSENT FOR CUDC-907-201 STUDY

### A. INTRODUCTION

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to participate in this study because you have diffuse large B-Cell lymphoma that has not responded to or has persisted after receiving up to two but not more than four prior therapies. Researchers want to find out if an investigational drug called CUDC-907 can help people with your condition. CUDC-907 is intended to block the function of the *MYC* gene, a gene that appears to be important in the growth of cancer cells in your type of lymphoma. We do not yet know whether blocking the function of this gene will prove to be an effective treatment for lymphoma.

## B. WHY IS THIS STUDY BEING DONE?

CUDC-907 is an investigational drug that has not been approved by the United States Food and Drug Administration (FDA). This is a phase II clinical trial, which means that it is designed to test the safety and preliminary effectiveness of an experimental treatment.

## C. HOW LONG WILL THE STUDY LAST AND HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 200 patients are expected to be in this study and it will last about 2 years.

If you qualify for the study and wish to participate, you may stay on this study and continue to receive study treatment until (1) your disease has progressed (worsened), (2) your study doctor thinks it is best that you stop treatment, (3) you no longer wish to receive treatment, (4) you are not able to keep your study appointments, (5) the study ends (6) you become pregnant, (7) you start other treatment for your cancer, (8) if you develop CMV infection at any point during the study.

## D. HOW DO I KNOW IF I CAN BE IN THE STUDY?

Before you can start the study, you will be asked to sign this consent form.

After you sign the informed consent, you will need to have tests performed and provide information about you and your disease to find out if you can take part in the study.

Some of these tests may be part of your regular medical care for your disease, even if you do not join the study. Your study doctor can tell you which of these tests would be part of your regular care, even if you do not join the study.

If you have had some of the tests done recently, you may not need to have them done again; your study doctor can tell you which of these tests do not need to be repeated.

The following tests and information will be needed to determine if you can take part in this study:

1. Your medical history, medicines that you are taking or have taken, and information about your gender, age, and race/ethnicity will be recorded.
2. A physical exam will be done which will include height, weight and vital signs (temperature, blood pressure, heart rate and breathing rate).

3. You will be asked how well you are able to do your normal activities like bathing, driving, shopping and working.
4. An electrocardiogram (ECG), which records the electrical activity of your heart, will be performed.
5. Blood samples (about 2,5 tablespoons) will be taken for routine tests to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body), and how well your organs are functioning. You will also be tested for cytomegalovirus (CMV). Cytomegalovirus (CMV) is a common virus that occurs widely throughout the population but rarely causes symptoms. However, in those with weakened immune systems CMV could cause serious illness and death. People with active CMV infection will not be able to participate in this study
6. If you are a woman who is able to become pregnant, ½ teaspoon of blood or a urine sample will be taken for pregnancy testing. The study doctor or study staff will tell you if the pregnancy results are positive. The results of the pregnancy test must be negative in order for you to be in this study.
7. Testing to determine the current status of your lymphoma. This testing may consist of a CT or MRI scan. You may also be asked to have a test called an FDG-PET/CT scan which provides different information than the other tests, and can be important for judging how well the treatment is working. It is likely that you will be familiar with some or all of these tests from your previous treatment.
8. A sample of your tumor must be available for testing to help predict how your cancer might respond to CUDC-907.
    - **A.** A tumor sample that was already obtained from you previously (most recent available) may be used for this testing.
    - **B.** Your study doctor can talk with you about what samples of your tumor are available for testing and if there is a need to obtain a new sample.
        - If there is a need to obtain a new sample, your study doctor will talk with you about the procedure.
    - **C.** Your tumor sample may also be tested for "tumor biomarkers" (parts of your tumor that may be used to study and/or measure your disease).
9. A sample of your blood will be tested to better understand your disease, and these tests will include the following:
    - Approximately 1 tablespoon of blood will be used to better understand how genes play a role in how your cancer responds to CUDC-907.

- Approximately 2 tablespoons of blood will be used to test for "plasma biomarkers", parts of your blood that may be used to study and/or measure your disease.

10. Urinalysis
11. You have the option to provide a separate sample of your tumor to analyze markers related to disease and/or pathways targeted by CUDC-907 (may be taken anytime up to first dose).

It is possible that after the test results are reviewed, you will not be able to take part in the study. If this is the case, your study doctor and study staff can talk to you about the reason why you cannot take part in the study.

If you are able to take part in the study and you agree to receive the study drug, you will need to come to the study site at various times to have procedures done as described in the next section.

## E. WHAT WILL HAPPEN DURING THE STUDY?

After you sign the consent form, agreeing to be part of the study; and, the results of your tests show that you can be part of the study you will be enrolled into the study.

After you are enrolled, you will be scheduled to receive *study dosing*.

Treatment on the study will be stopped if you are taken off the study, become pregnant, start any other anticancer treatment, if you develop CMV infection at any point during the study ,if you are unable to keep scheduled study visits or tests, or if the study is stopped.

### 1. <u>Study Dosing</u>

#### a. Study Dosing of CUDC-907

You will be scheduled to take CUDC-907, an *investigational agent.* CUDC-907 is not approved by the FDA or any other drug approving agency to treat your disease. **Section F** will tell you more about the possible risks in taking CUDC-907.

You will take CUDC-907 by mouth once daily for 5 days in a row with meals ± 30 minutes, then for the next 2 days you will not take CUDC-907; this will complete 1 week of study dosing. You will repeat this weekly dosing schedule (5 days of dosing with CUDC-907 followed by 2 days of no dosing) in a 21-day cycle until your disease has progressed (worsened), your study doctor thinks it is best that you stop treatment, or you no longer wish to receive this treatment. CUDC-907 dosing may be lowered, delayed or suspended if you develop signs of health problems that may be caused by CUDC-907. CUDC-907 will be stopped if you are taken off the study, become pregnant, start any other anticancer treatment, if you are unable to keep scheduled study visits or tests, or if the study is stopped.

You will write each dose of CUDC-907 you take in a dosing diary. You will take your dosing diary with you to each of your study clinic visits. The study staff will review your dosing diary with you on each visit.

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**2. Study Visits**

You will be scheduled for regular study visits to complete important study tests and procedures. You need to make every effort to attend each scheduled study visit, and complete all scheduled tests and procedures for each of these visits, as it will help your study doctor learn how you are doing on the study.

Your study visits will be grouped by Study Cycles; each Study Cycle will be 3 weeks (21 days). On Day 1 of the first 6 Study Cycles you will receive a 3 week supply of CUDC-907 with instructions on how to take it.

After the first 6 Study Cycles, you may keep taking CUDC-907. If you continue taking CUDC-907, you will need to return for additional study visits. More information about these study visits is below, under "Study Cycles 7 and Beyond".

The following tells about what to expect during each Study Cycle, and each study visit.

**a. <u>Study Visits Cycle 1:</u>**

You will have up to 4 study visits during the first 3 weeks you are on the study; each visit will be about a week apart. These first 3 weeks are named Cycle 1, since this is your first 3 weeks of CUDC-907 dosing.

During your first study visit (Cycle 1, Day 1) the following will be done:

1. A physical exam will be done which will include weight and vital signs (temperature, blood pressure, heart rate and breathing rate). You will also be asked about:
    - Your current health and how you are feeling.
    - Any changes in how you are feeling since you last visited the study doctor.
    - Any medicines you are taking, and how long you have been taking them.
2. You will be asked how well you are able to do your normal activities like bathing, driving, shopping and working.
3. Blood samples (about 2 tablespoons) will be taken for routine tests to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body), how well your organs are functioning.
4. Blood sample (about 1 teaspoon) will be taken to measure levels of CUDC-907 and its metabolites in your blood 2 hours after the first dose (pharmacokinetics).
5. If you are a woman who is able to become pregnant, ½ teaspoon of blood or a urine sample will be taken for pregnancy testing. The study doctor or study staff will tell you if

the pregnancy results are positive. The results of the pregnancy test must be negative in order for you to be in this study.

6. You will be given a bottle containing capsules of the investigational drug, CUDC-907.
    - You will take CUDC-907 the same time within 30 minutes of eating (at approximately the same time each day) on the 5 dosing days. Every time you take your capsules you will need to write it down in your dosing diary.
    - You will take the pill container and the dosing diary with you each time you go to a study visit.
    - On days you come into the clinic for study visits, you will take your CUCD-907 dose while at the clinic rather than at home.

During your second and third study visits (Cycle 1, Days 5 and 12) the following will be done:

1. A physical exam will be done which will include weight and vital signs (temperature, blood pressure, heart rate and breathing rate). You will also be asked about the following:
    - Your current health and how you are feeling.
    - Any changes in how you are feeling since you last visited the study doctor.
    - Any medicines you are taking, and how long you have been taking them.
2. Blood samples (about 2 tablespoons) will be taken for routine tests to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body), and how well your organs are functioning.
3. Your bottle of CUDC-907 and your dosing diary will be reviewed with you.

During your fourth study visit (Cycle 1, Day 15) the following will be done:

1. You will be asked about the following:
    - Your current health and how you are feeling.
    - How you have been feeling since your last study visit.
    - The medicines you are taking, and how long you have been taking them.
2. A count of capsules in your CUDC-907 bottle and your dosing diary
    - You will be asked about any problems or questions you may have about taking CUDC-907.
3. **Note:** If you are within the first 50 subjects to start the study under amendment 4 (your Study Doctor will let you know), 2 extra blood samples (each about 1 teaspoon) will be required, 2 hours after receiving CUDC-907 on Days 8 and 15 of Cycle 1. These samples will be used to measure how much CUDC-907 and its metabolites are in your blood (pharmacokinetics).

You may have a sample of your tumor taken to analyze markers related to disease and/or pathways targeted by CUDC-907 (may be obtained 8 hours post-dose on any dosing day from Cycle 1 Day 15 through Cycle 2, Day 1).

A. Your study doctor will talk with you about how the tissue sample will be taken.

**b. <u>Study Visits Cycles 2, 3, 4, 5, and 6:</u>**

After Cycle 1, you will have a study visit every 3 weeks. During these study visits the following will be done:

1. A physical exam will be done which will include weight and vital signs (temperature, blood pressure, heart rate and breathing rate). You will also be asked about the following:
    - Your current health and how you are feeling.
    - Any changes in how you are feeling since you last visited the study doctor.
    - Any medicines you are taking, and how long you have been taking them.
2. You will be asked how well you are able to do your normal activities like bathing, driving, shopping and working.
3. A CT or MRI scan will be done to measure your disease every 6 weeks. If your doctor considers it necessary, a FDG-PET/CT scan may also be performed.
4. Blood samples (about 2,5 tablespoons) will be taken for routine tests to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body), pregnancy test, and how well your organs are functioning. You will be tested for CMV infection on Day 1 of every other Cycle starting with Cycle 2.
5. A sample of your blood (will be tested to better understand your disease, tests will include the following:
    - Approximately 2 tablespoon of blood will be used to test for "plasma biomarkers", parts of your blood that may be used to study and/or measure your disease.
6. If you are a woman who is able to become pregnant, ½ teaspoon of blood or a urine sample will be taken for pregnancy testing. The study doctor or study staff will tell you if the pregnancy results are positive. The results of the pregnancy test must be negative in order for you to continue in this study.
7. A count of capsules in your CUDC-907 bottle and your dosing diary will be checked.
    - You will be asked about any problems or questions you may have about taking CUDC-907.
8. You will be given a new bottle of the investigational drug, CUDC-907.

- You will take CUDC-907 the same time once each day within 30 minutes of eating a meal for 5 days in a row; then, you will not take CUDC-907 for 2 days in a row. This will be repeated (5 days taking CUDC-907, then 2 days not taking CUDC-907) on a continuous basis as your study doctor tells you.
- Every time you take CUDC-907 you will need to write it down in your dosing diary.
- You will take the pill container and the dosing diary with you each time you go to a study visit.

9. On Day 1 of Cycles 4 and 6, a blood sample (about 1 teaspoon) will be taken to measure levels of CUDC-907 and metabolites 2 hours after receiving the dose on that day.

**a. <u>Study Visits Cycles 7 and Beyond:</u>**

You may keep taking CUDC-907 until the end of study.

While you are taking CUDC-907 in Cycles 7-13, you will have a study visit every 3 weeks. If you continue past Cycle 13 you will only be required to have a Day1 visit at the beginning of every other cycle (14, 16, 18, etc). The following will be done at these visits:

1. A physical exam will be done that includes weight and vital signs (temperature, blood pressure, heart rate and breathing rate). You will also be asked about the following:
   - Your current health and how you are feeling.
   - Any changes in how you are feeling since you last visited the study doctor.
   - Any medicines you are taking, and how long you have been taking them
2. You will be asked how well you are able to do your normal activities like bathing, driving, shopping and working
3. Blood samples (about 2,5 tablespoons) will be taken for routine tests to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body), pregnancy test and how well your organs are functioning. You will continue to be tested for CMV infection on Day 1 of every other Cycle starting with Cycle 2
4. Blood samples (about 1 teaspoon each) will be taken on Day 1 every other cycles (i.e., Day 1 of Cycles 8, 10, etc.) starting on Day 1 of Cycle 8, 2 hours after receiving CUDC-907 on that day. These samples will be used to measure levels of CUDC-907 and its metabolites (pharmacokinetics).
5. If you are a woman who is able to become pregnant, ½ teaspoon of blood or a urine sample will be taken for pregnancy testing. The study doctor or study staff will tell you if the pregnancy results are positive. The results of the pregnancy test must be negative in order for you to be in this study.
6. A sample of your blood (will be tested to better understand your disease, tests will include the following:

- Approximately 2 tablespoon of blood will be used to test for "plasma biomarkers", parts of your blood that may be used to study and/or measure your disease.

7. A count of capsules in your CUDC-907 bottle and your dosing diary will be checked.
   - You will be asked about any problems or questions you may have about taking CUDC-907
8. You will be given a new bottle of the investigational drug, CUDC-907.
   - You will take CUDC-907 the same time every day 30 minutes before or after eating food at for 5 days in a row; then, you will not take CUDC-907 for 2 days in a row. This will be repeated (5 days taking CUDC-907, then 2 days not taking CUDC-907) on a continuous basis as your study doctor tells you.
   - Every time you take CUDC-907 you will need to write it down in your dosing diary.
   - You will take the pill container and the dosing dairy with you each time you go to a study visit.
9. A CT scan or MRI scan will be done to measure your disease every 4th visit (about every 12 weeks, or Cycles 10, 14 and 18), until you have complete 12 months of CUDC-907 dosing. You will then have this same test done every 24 weeks (Cycles 26, 34, etc.) until you no longer take CUDC-907. If your doctor considers it necessary, an FDG-PET/CT scan may also be performed.

**b. <u>Study Visit After Completing CUDC-907 Dosing (End of Dosing Visit)</u>**

After you complete all study dosing, or discontinue from further treatment, you will be scheduled for an end of dosing study visit. The following will be done at this visit:

1. A physical exam will be done that includes weight and vital signs (temperature, blood pressure, heart rate and breathing rate). You will also be asked about the following:
   - Your current health and how you are feeling.
   - Any changes in how you are feeling since you last visited the study doctor.
   - Any medicines you are taking, and how long you have been taking them.
2. You will be asked how well you are able to do your normal activities like bathing, driving, shopping and working.
3. An electrocardiogram (ECG), which records the electrical activity of your heart, will be performed.
4. If you are a woman who is able to become pregnant, ½ teaspoon of blood or urine sample will be taken for pregnancy testing. The study doctor or study staff will tell you if the pregnancy results are positive. The results of the pregnancy test must be negative in order for you to be in this study.

5. A CT scan or MRI scan will be done to measure your disease, if this has not been done in the last 4 weeks. If your doctor considers it necessary, a FDG-PET/CT scan may also be performed to measure your disease.
6. Blood samples (about 2 tablespoons) will be taken for routine tests to check your blood counts (numbers of different types of cells in your blood), chemistries (elements and minerals in your body), and how well your organs are functioning.
7. A count of capsules in your CUDC-907 bottle and your dosing diary will be checked.
    - You will be asked about any problems or questions you may have about taking CUDC-907.

**c. <u>Follow-Up Visits After All Study Dosing</u>**

After you complete your End of Dosing Visit, you will continue to have about 3 study visits in the next 12 months.

- For the first 6 months after your End of Dosing Visit, you will have a study visit every 12 weeks (about 2 visits during this 6 month time).
- For the next 6 months, you will have a study visit every 24 weeks (about 1 visit during this 6 month time).

The following will be done at these visits:

1. A physical exam will be done. You will also be asked about the following:
    - Your current health and how you are feeling.
    - Any changes in how you are feeling since you last visited the study doctor.
    - Any medicines you are taking, and how long you have been taking them.
2. A CT scan or MRI scan will be done to measure your disease. If your doctor considers it necessary, a FDG-PET/CT scan may also be performed to measure your disease.

## F. WHAT ARE THE POTENTIAL STUDY RISKS AND DISCOMFORTS?

While on the study, you are at risk for side effects. You should discuss any side effects that you have with the study doctor. The study doctor may suggest treatment to help make side effects less serious and uncomfortable. Ask the study doctor what treatments you may receive for side effects (and any risks these medications may have).

Many side effects are mild or moderate and go away shortly after the study drug is stopped, but in some cases, side effects can be serious, long-lasting or permanent, and in rare cases, fatal (causing death).

### a. What are the Possible Side Effects and Risks of Taking CUDC-907

CUDC-907 works by inhibiting two enzymes, called HDAC (histone deacetylase) and PI3K (phosphoinositide 3-kinase). Each of these enzymes can cause different types of side effects through different mechanisms.

Studies conducted in animals have shown that CUDC-907 may make you less hungry, lose weight, reduce blood cell levels (especially white blood cells); and/or affect your kidneys, thymus gland, and the gastrointestinal (GI) tract, which may cause vomiting and diarrhea.

Over 90 patients have been treated with CUDC-907. The following potential side effects were reported as serious and/or have occurred in 2 or more patients, or resulted in a patient stopping CUDC-907 dosing:

Common (Greater than 20% chance that this will happen)

- Diarrhea (loose stools)
- Fatigue (feeling tired)
- Nausea (feeling sick to your stomach)
- Decreased appetite (feeling less hungry)

Occasional (Between a 4 to 20% chance that this will happen)

- Low platelet counts, which may increase your risk for bleeding (one patient had a serious nose bleed)
- Cough
- Throat pain
- Muscle spasms
- Low white blood cell counts, which may increase your risk for infection
- Constipation
- High blood sugar levels, which could be from interference in glucose metabolism
- Itchy skin
- Raised body temperature/fever
- Rash
- Sinus Congestion
- Sinus and/or throat infection
- Back pain
- Heartburn

- Difficulty speaking
- Bloody nose
- Numbness
- Decreased levels of potassium in the blood, which can cause irregular heart beat
- Low magnesium, which may result in muscle cramps, weakness, tremors or irregular heartbeat
- Low blood pressure
- Inflammation of the lungs, which can cause shortness of breath and difficulty breathing
- Lung infection
- Dehydration

Your doctor will provide you with medication to take for diarrhea, and will carefully monitor your blood test results to see if a treatment break is needed.

Other commonly reported or serious side effects from drugs that are similar to CUDC-907 are:

- Stomach and intestinal problems, including diarrhea, nausea, vomiting, weight loss, and loss of appetite
- Fatigue (feeling tired)
- Chills
- Anemia (a low red blood cell count that could make you feel tired)
- Taste changes
- Increase in blood creatinine, which could indicate kidney damage
- Increased liver blood tests, which could indicate liver injury
- Rash
- Pneumonia (an infection of the lung)
- Inflammation of the lungs, which could cause difficulty breathing and a cough
- Neutropenic fever (low white blood counts with fever)
- Changes in ECG readings, which could indicate damage to the heart

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If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you. Because CUDC-907 is investigational, all of its side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening. You must tell the study doctor or study staff about all side effects that you have. 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.

## c. What are the Other Potential Risks and Discomforts in Being in the Study?

There are potential risks and discomforts with some of the study tests you will need to take; these are listed in the following section. Your study doctor and talk to you about these risks and answer any questions you may have.

### 1. Blood Samples

Your study doctor or study staff will take your blood by sticking a needle in your arm. You will give about 1½ to 5½ tablespoons of blood during each study visit. There may be side effects of having blood drawn such as:

- Fainting (temporary loss of conscious)
- Dizziness
- Pain
- Bruising
- Bleeding
- Infection

### 2. Electrocardiogram (ECG):

The ECG test is harmless. The sticky pads used may sometimes cause some discomfort such as redness or itching. If the skin under the patches needs to be shaved, irritation from shaving also could occur.

### 3. Magnetic Resonance Imaging (MRI):

An MRI is a way of producing images of body structures and organs. You will lie down on a large magnet. A magnetic signal will be sent through your body and then received back. This process is safe for most people. Subjects with metal near important organs may not receive an MRI. The metal may be drawn away from the body and towards the large magnet, which could cause injury.

### 4. Computerized Tomography (CT) Scan:

A CT scan is a computerized picture which is used to find and measure the size of your tumor. You may feel some discomfort or anxiety when lying inside of the CT scanner. The dye that is injected into your body may cause you to have a metallic taste in your mouth, to feel warm, and

rarely cause nausea and vomiting. You will be exposed to a limited and medically acceptable dose of radiation during the scan. There is always a slight risk of damage from being exposed to any radiation.

5. **FDG-PET/CT Scan:**

You will be asked to fast (no food) for about 4 to 6 hours before the scan. A small amount of radioactive sugar will be injected into your blood about 1 hour before the scan. You may experience discomfort related to lying still in an enclosed space for a long period. You will be exposed to a limited and medically acceptable dose of radiation during the scan. There is always a slight risk of damage from being exposed to any radiation.

6. **Tumor Biopsy:**

Possible side effects from the collection of the tumor biopsy include:

- Pain
- Inflammation (redness)
- Bleeding
- Swelling
- Infection
- There is a rare possibility of tumor cells spreading from the tumor into the nearby area

7. **Allergic Reaction:**

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction are:

- Rash
- Having a hard time breathing
- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

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.

## G. BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

**Female subjects of Childbearing Age**

You cannot be in this study if you are:

- Pregnant
- Planning to become pregnant during the study
- Nursing a child

If you are pregnant or nursing a child while participating in this study, there may be risks to your unborn baby or nursing child. 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 a woman who can have children, the study doctor will talk to you about birth control methods you must use during the study and for 30 days after your last dose of CUDC-907. Some methods of birth control will not work when you are taking certain drugs.

If you are a woman of child bearing potential the study doctor will require women who join the study to have a pregnancy test during screening. A pregnancy test does not keep you from becoming pregnant. You should not breastfeed your baby while on this study or for 30 days after last dose of study drug.

If you think you are pregnant during the study or within 30 days from receiving your last dose of CUDC-907, you must tell the study doctor immediately. If you become pregnant, you will have to leave the study. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with the sponsor and the Institutional Review Board (IRB).

**Male Subjects Able to Father Children**

If you are a man, there may be risks to an unborn baby you father during or after the study. The study doctor will talk to you about the birth control options you and/or your partner must use during the study and for 30 days after your last dose of study drug. If your partner becomes pregnant during the study or within 30 days from receiving your last dose of CUDC-907, you must tell the study doctor immediately. The study doctor will contact your partner/spouse to get her permission to collect information about the pregnancy and birth of the baby. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

## H. POSSIBLE BENEFITS OF THE STUDY

You may receive no benefit by being in this study, but the information learned may help others in future studies. There is no promise that your disease will get better. It might stay the same or it might get worse.

## I. WHAT IF NEW INFORMATION BECOMES AVAILABLE?

During the research study, you will be notified of newly discovered significant findings that may affect your willingness to participate in this study. In this case, you may be asked to sign a new

consent form that shows that you have been informed of new information relating to this research study.

## J. WHAT HAPPENS IF I EXPERIENCE A STUDY RELATED INJURY?

In the case of injury or illness resulting from this study, emergency medical treatment will be provided. This study center has no program for financial compensation or other forms of compensation for injuries, which you may incur as a result of participation in this study.

The sponsor may pay for injuries or hospitalizations that are directly related to the study drug, as long as those costs are not covered by your health care payer.

The study doctor and sponsor will decide on a case by case basis whether your injury or illness was directly related to the study drug. You may have to pay the costs of diagnosing and treating a condition or injury that you or others think is a direct result of your being in the study. This could happen if:

- The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study.
- You have not followed the directions the study doctor or study staff gave you about the study.

Compensation for other expenses is not routinely available. You do not give up any of your legal rights by signing this form.

## K. DO YOU HAVE TO BE IN THIS STUDY?

Your decision to be in this study is voluntary. You do not have to be in the study if you do not want to, and you can change your mind at any time. There will be no penalty to you, and you will not lose any benefits.

The study doctor or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You are experiencing unacceptable side effects.
- You develop an active CMV infection
- You do not follow directions about the study.
- The sponsor stops the study for any reason.
- Your disease gets worse.

If you want to stop being in the study, tell the study doctor or study staff and return all unused study drug. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study and may continue to follow-up with how you are doing. To help you leave the study safely, the study doctor will ask you to complete the End of Treatment visit.

**RELEASE OF YOUR MEDICAL RECORDS AND CONFIDENTIALITY**

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- Study Doctor
- Sponsor company or representative
- The United States Food and Drug Administration (FDA)
- Other state or federal regulatory agencies
- Independent Review Board (IRB)

The groups listed above may inspect and copy your records, which may have your name on them. Therefore, your total privacy cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

The description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. The website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## L. WHAT OTHER OPTIONS ARE THERE?

You do not have to be in this study to get help for your condition. The study doctor will talk to you about other things you can do for your condition, including the important risks and benefits. Some other things you may be able to do are:

- Receive a different drug approved by the FDA for your condition.
- Receiving no treatment at this time
- Receive care that will not help your disease but may help you feel more comfortable.
- Participate in another research study with other investigational drugs.

## M. WILL YOU GET PAID?

You will not get paid for being in this study.

## N. WHO IS PAYING FOR THIS STUDY?

A company called Curis, Inc., the sponsor of the study, is paying for this study. Curis, Inc. is also paying this study center to compensate for institutional research related costs.

- **WILL IT COST ANYTHING TO BE IN THIS STUDY?**

All clinic fees, professional fees, diagnostic and laboratory fees that are part of this study and are done for research purposes only, including some physical examinations, ECGs, some blood tests, and pregnancy tests will be provided at no cost to you. The study drug CUDC-907 will be given to you free of charge while participating in the study.

Additional costs from procedures not needed by this study will not be paid for by the sponsor. You, your insurance company or other third party payers will be responsible for the costs of your routine care. You or your insurance company will have to pay for any medication you take for side effects. You should check with your insurance company before you enroll in this research study.

- **WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

You can ask questions about the study at any time. You can call the study doctor at any time if you have any concerns or complaints. You should call the study doctor if you have questions about the study procedures, study costs (if any), or if you get hurt or sick during the study. Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: [***Insert PI and site staff contact info here***]. Questions about the rights of research subjects may be addressed to the [***Add IRB contact info here***].

## TESTING FOR BIOMARKERS

### A. What are biomarkers and how will my samples be used to test them?

Biomarkers are naturally-occurring substances in the body. Examples of biomarkers include but are not limited to: proteins, peptides, or nucleic acid (DNA and RNA) in therapy-related biological pathways. Testing to see if biomarkers are present and/or the amount of biomarkers present can help to predict patient response (this is what we are mainly interested in), diagnose a certain disease, and/or determine the severity of the disease. Biomarker identification for lymphoma is a very active research field. New discoveries can improve the diagnosis and help predict patient response to treatment, which is why specific markers will not be listed. However, only therapy and indication-related biomarkers will be included in this study.

Curis would like to use your biological samples in biomarker testing. Your biological samples may also be stored for future testing when new biomarkers in lymphoma are identified. Curis, not the study doctor, will be conducting the biomarker research.

Throughout the study, the study doctor will collect samples for biomarkers - genes or proteins that may predict or show how your body may respond to CUDC-907.

### B. Optional Tissue Sampling

Optional tumor biopsies may be taken to test for biomarkers in the tissue before you receive your first dose of CUDC-907, and within eight hours after taking one of your CUDC-907 doses on Cycle 1 Day 15 through Cycle 2 Day 1.

These tissue samples are optional and you may choose to have one, none, or multiple tissue samples to be taken without any effect on being able to take part in the study.

1. Would you like to consent to have optional tumor biopsies taken (please indicate yes, or no below)?

   Yes: _____ No: _____

   **SIGNATURE BY THE SUBJECT**

| _____ | _____ | _____ |
|---|---|---|
| Printed Name of Subject | Signature of Subject | Date of Signature |

### C. How will Curis protect your identity?

Your samples will not have your name on them. Your samples will be labeled with a code. The code will link your samples to information about the test results.

### D. Where will my biomarker samples go?

People who work for Curis, Inc. will store your samples in a secure laboratory. Tests will be performed on these samples, as stated above. They will store your samples at least 24 months after the study is completed or CUDC-907 is no longer being tested in clinical trials.

**E. Will I get the results of my biomarker tests?**

Your test results are for research only. You will not get your test results. The test results will not be put in your medical records. Curis will not give your test results to any insurance company, your employer, your family, the study doctor, any other doctor, or anyone else, except as specified above for research purposes for this study. The test results are not for personal use, like making decisions about your medical care and whether or not to have children.

**F. Will I get payment if Curis makes new tests and medications?**

The samples you give for this biomarker study might help Curis come up with new tests or medications in the future. If Curis makes new tests or medications, you will not get any money for these tests or medications. Curis will own the results of this study and any new tests or medications the sponsor makes because of this study.

## HIPAA AUTHORIZATION

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

As part of the study, the study doctor and his [her] staff at will keep records of your study participation. These study records will include the results of tests you have during the study or had before the study, information about your response to treatments you have in the study, and other medical information about your participation in the study. Under federal law, your study records cannot be used or disclosed by [Institution] for research purposes unless you sign this authorization.

You may not participate in the study unless you sign this authorization form. If you sign it, you will be agreeing to the disclosures below:

Some or all of the test results and other information will be reported to the sponsor and any consultants that are helping the sponsor conduct the study. The sponsor and its consultants will look at these results and may report the results to the US FDA or agencies in other countries. Your study records will be given a code number by the study doctor, and you will not be identified by name in the study records that are sent to the sponsor. However, the sponsor will have the right to see your complete study records, as well as your medical records, and may choose to do so.

The sponsor or study doctor may publish reports or articles on the study, and the sponsor may also give your study records to other researchers involved with the study to write reports or articles on the study for publication, or for other study-related purposes. However, you will not

be identified by name in any reports or articles written by the sponsor or any of the researchers of the study.

Also, the Sponsor or its representatives will visit the study site to check on the conduct of the study, and they will review your study records and your medical records during these visits.

Health care providers that treat you while you are in this study [or that treated you before you came into the study for the condition or disease that is the subject of this study] may give your medical records to the study doctor and his [her] staff to look at during the study.

The study doctor and the Institutional Review Board will review and use your study records only to monitor the conduct of the study. They will keep your identity confidential and, except for the disclosures described above, will not disclose your study records to other people or agencies unless required by law. After the study doctor discloses information in your study records or medical records to the sponsor, that information may no longer be protected under federal privacy protection laws. However, the sponsor will use your information only for the study and will not disclose your study records to agencies other than the FDA and and/or other government agencies, unless required by law. Your study records will be kept by the study doctor for at least 2 years from the date of FDA approval of the study drug or, for at least 2 years from the date the study drug development is stopped by Sponsor, whichever is longer. You may have access to your medical records.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

You have the right to take back your authorization at any time. You can do this by giving written notice to the study doctor, telling him [her] that you are revoking your authorization for the sponsor and researchers to use and disclose your medical and study records. The study doctor's contact information is listed on page 1 of this form below.

If you take back your authorization to let the sponsor and/or researchers use and disclose your medical and study records, you cannot continue your participation in the study.

If you take back your authorization for any reason, the information that has already been collected in your study record may continue to be used and disclosed, but only as needed to protect the science of the study.

If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study personnel. You do not waive any of your legal rights by signing this consent document. You will be given a copy of the signed and dated consent document for your records.

**SIGNATURE BY THE SUBJECT**

| _____ | _____ | _____ |
|---|---|---|
| Printed Name of Subject | Signature of Subject | Date of Signature |

**SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL AUTHORIZED TO OBTAIN CONSENT:**

I attest that all the elements of informed consent described in this document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

_____

Printed Name of Individual Obtaining Consent

_____

Signature of Individual Obtaining Consent

_____

Date of Signature