The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A Phase I Clinical Trial Testing the Safety of IL-21-Expanded, Off-the-shelf, Third-party Natural Killer Cells (KDS-1001) for the Induction of Relapsed/Refractory Acute Myeloid Leukemia**
Principal Investigator:	**Sumithira Vasu, MBBS**
Sponsor:	**The Ohio State University**
KDS-1001 Provided by:	**Kiadis Pharma Netherlands B.V. , a Sanofi company (Kiadis Pharma)**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being invited to take part in a clinical research study because you have Acute Myeloid Leukemia (AML) that has failed to respond to treatment or returned after previous

treatment. Both failure to respond (refractory) and returned (relapsed) AML cannot be cured using standard therapies.

This study uses a short course of chemotherapy followed by infusions of natural killer (NK) cells (KDS-1001) that have been made from cells collected from the blood of a donor. NK cells are a type of white blood cell that are known to spontaneously attack cancer cells. It was recently discovered that infection with human cytomegalovirus (CMV) leads to the development of a unique NK cell population. These "adaptive" NK cells have a more potent anti-tumor killing action. This study uses a donor whose blood tests positive for prior CMV exposure. CMV is a common virus and more than half of adults by the age 40 test positive for it.

Taking part in any clinical research involves risks and benefits. You need to understand these risks and benefits to make an informed decision about whether or not to be in the study. You should ask your study doctor at any time if you have questions or concerns about this research.

1. Why is this study being done?

The primary purpose of this study is to identify a safe dose of KDS-1001. Other objectives are to estimate any reactions to therapy and how many people have a response of their leukemia after infusion. Those with a response may be offered a stem cell transplant as follow-up treatment after this study. However, the stem cell transplant would be part of your standard care and not related to this research.

2. How many people will take part in this study?

Up to 22 patients may participate in this study at The Ohio State University.

3. What will happen if I take part in this study?

Eligibility Screening

The following routine tests and evaluations will be performed to determine if you can safely participate:

- Medical history and physical examination, including vital signs, height, and weight
- Routine blood tests to evaluate bone marrow, kidney, and liver function, as well as general health status.
- Blood tests to check for exposure to hepatitis and HIV. If the test results are positive, you will be notified by your study doctor. If you test positive for some types of hepatitis or HIV you will not be eligible to take part in this study.
- A pregnancy test (blood) for women of childbearing potential.
- Tests to evaluate heart function including an electrocardiogram (ECG) and echocardiogram (echo).
- Tests to evaluate lung function including a noninvasive pulmonary function test (PFT) or pulse oximetry.
- Tests and procedures to evaluate your current disease status including a bone marrow biopsy. The bone marrow biopsy and aspirate at screening are considered

standard of care (what is normally done) for your condition.
- Any additional tests or evaluations, felt necessary by the medical staff, to evaluate your current health.

During the study:
All treatment will be given in the hospital. Before treatment is started, a central line will be placed if you do not already have one. A central line allows for easier administration of intravenous (IV) therapies and is used for drawing blood.

The study consists of 5 parts:
1) **Preparative Chemotherapy** using standard anti-cancer drugs
2) **KDS-1001 infusion** given in 6 doses starting after the last dose of chemotherapy
3) **Blood Count Recovery** which may take between 4 and 6 weeks
4) **Follow-up** in the out-patient clinic for up to 56 days from the first NK cell infusion.
5) **Maintenance period with KDS-1001 treatment** if you are in complete or partial remission, and if you don't qualify for or don't want to have a future bone marrow stem cell transplant (done independent of this study), you may be eligible to receive additional (maintenance) doses of KDS-1001.

1) Preparative Therapy (day -6 to -2)
Six days (Day -6) before the planned NK cell infusion, you will begin to receive a chemotherapy drug combination that will prepare your body for the KDS-1001 treatment, according to the following schedule:

DAY	*TREATMENT*
-6, -5, -4, -3, -2	Fludarabine as a 30 minute IV infusion Cytarabine as a 15-180 minute IV infusion
-1	Rest day – no treatment

2) Infusion of the KDS-1001 Cells (day 0)
The cell product infusion has already been produced by culturing NK and other immune cells from a donor using a cell growth factor. This process is key for making a sufficient amount of KDS-1001 enriched for adaptive NK cells.

The KDS-1001 is given as an intravenous (IV) infusion on Day 0, 2, 4, 7, 9, and 11. Each infusion may take up to 1 hour. This process will be similar to a blood transfusion.

This research design is considered a dose escalation study. Two (2) dose levels of KDS-1001 will be evaluated starting with the lowest dose, and dose increase will only occur after safety has been evaluated at the lower dose level. You will be assigned to the current "open" dose level that is available for enrollment. Once the best dose is determined, the remainder of participants will be enrolled at the level found to be the safest.

3) Blood Count Recovery

While receiving treatment and until your blood counts recover, you will have frequent blood tests and health assessments. NK cells may be administered in the hospital or clinic based on your condition. You may need hospitalization if you have a fever or there is suspected infection or bleeding. Your treating team will decide when it is safe for you to be discharged. You will return to clinic for frequent blood count checks for a few weeks. This includes up to two bone marrow biopsies and aspirate as shown on Table 1 below. These two bone marrow biopsies and aspirate are considered standard of care. This means that they are allowed as part of your normal care (done outside of this research study) for your condition.

4) Follow up

Your study doctor will closely monitor your condition though your Day 56 visit. After your Day 56 visit, if you don't participate in the Maintenance Phase, your electronic medical record may be reviewed by the study team after this follow up period. This is done in order to see how you're doing or if you've gone on to receive other therapy such as a stem cell transplant.

5) Maintenance Phase

After your Day 35 visit, if you achieve an adequate remission of your leukemia and if you don't qualify for or don't want to have a future bone marrow stem cell transplant, (done independent of this study), you may be eligible to receive additional (maintenance) doses of KDS-1001. You will be treated with KDS-1001 every 28 days for up to an additional 12 months. You will continue to receive the same dose of KDS-1001.

Table 1: Schedule of Activities up to 56 Days – Recipient

Schedule of Study Assessments	Screening	Days (-6 to -2)	Day +0	Day +2	Day +4	Day +7	Day +9	Day +11	Day +14	Day +21	Day +28	Day +35	Day +56
Informed Consent	X												
Medical History-anti-cancer therapies	X												
Chemotherapy		X											
NK cell infusion			X	X	X	X	X	X					
Concurrent medications	X		X	X	X	X	X	X		X	X	X	X
Physical exam	X		X	X	X	X	X	X		X	X	X	X
Vital Signs (1 hr pre-NK cell infusion, 15 mins and 60 mins post NK cell infusion)	X	X	X	X	X	X	X	X		X	X	X	X
Pulse Oximetry			X	X	X	X	X	X					
Performance status assessment	X	X	X	X	X	X	X	X		X	X	X	X
Side effect assessment	X	X	X	X	X	X	X	X		X	X	X	X
Acute GvHD assessment	X		X	X	X	X	X	X		X	X	X	X
Blood tests and/or samples	X	X	X	X	X	X	X	X	X	X	X	X	X
HIV evaluation	X												
Pregnancy test	X												
Pulmonary Function Test	X												
Echocardiogram	X												
Bone marrow biopsy & aspirate (response assessment and correlative studies)	X										X		X

Table 2: Schedule of Activities – Maintenance Phase

Schedule of Study Assessments	Month 1 Baseline	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13 Off Study
NK cell infusion	X	X	X	X	X	X	X	X	X	X	X	X	
Concurrent medications	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical exam	X	X	X	X	X	X	X	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X	X	X	X	X	X	X	X
Pulse Oximetry	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy Test	X												
Performance status assessment	X	X	X	X	X	X	X	X	X	X	X	X	X
Side effects assessment	X	X	X	X	X	X	X	X	X	X	X	X	X
Acute GvHD assessment	X		X	X	X	X	X	X	X	X	X	X	X
Blood tests and/or samples	X	X	X	X	X	X	X	X	X	X	X	X	X
Bone marrow biopsy & aspirate (response assessment and correlative studies)						X							X

4. How long will I be in the study?

You will be in the study from the time you sign this consent form up to about 14 months after the first dose of study drug.

If you achieve an adequate remission of your leukemia after 35 days after the first dose of KDS-1001, you may be considered either for a bone marrow transplant (done independent of this study) or you may be eligible to receive additional (maintenance) doses of KDS-1001 for an additional 12 months.

After you complete the study, you have no additional follow-up associated with the study; however your medical record may be continued to be reviewed or you may be contacted as required follow-up to the Food and Drug Administration (FDA).

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The preparative chemotherapy and study cells used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The investigator will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study cells.

Here are important points about side effects:

- The investigators do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.
- You may have some side effects we do not expect because we are still learning about the study cells and AML.
- *There may be unanticipated risk to an embryo or fetus if you or your partner becomes pregnant.*
- You may not have symptoms for some of these side effects, but you will be monitored by the investigator to check for any changes throughout the study.

Here are important points about how you and the investigator can make side effects less of a problem:

- Tell the investigator if you notice or feel anything different so they can see if you are having a side effect.

- The investigator may be able to treat some side effects.
- The investigator may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the investigator will discuss these with you.

There have been research studies with cells similar to the study cells for several years; however this is an early study of the cells in humans, so its side effects are not well documented.

Risks of the study cells

There is a rare risk of an allergic (anaphylactic) type reaction during or just after the KDS-1001 infusion. Symptoms of a reaction include change in blood pressure, difficulty breathing, feeling extremely hot or cold, and skin reddening (flushing). Before and after the KDS-1001 infusion, medications are given to lessen the risk of an infusion reaction. Most commonly, patients may experience transient (short-lived) infusional reactions, which include low or high blood pressure, shortness of breath, mild low blood oxygen (hypoxia), wheezing, rigors or chills, fevers and headaches. These are expected and managed with supportive care (such as Tylenol, Demerol, supplemental oxygen, nebulizers, anti-hypertensives and/or extra IV fluids). If a reaction occurs, the rate of the KDS-1001 infusion may be slowed or stopped and the symptoms treated as indicated.

Possible risks of the study cells

Likely (May happen in more than 20% of participants)	**Less Likely** (May happen in 20% or fewer participants, but more than 3%)	**Rare, but Serious** (May happen in 3% or fewer participants)

• Changes in blood pressure • Changes in heart rate • Unusual taste or smell • Chills • Cough • Feeling tired • Flu-like symptoms, including fever • Headache • Joint aches • Muscle aches • Shortness of breath • Flushing	• Blood in urine • Changes in kidney function • Nausea (feeling sick to your stomach) and vomiting (throwing up). At times, these may be serious. • Rash • Swelling in throat	• An infection, called cytomegalovirus, or CMV may develop or reactivate (in participants who have had a CMV infection in the past). CMV infection may cause no symptoms, but could cause fever and feeling tired. • A strong immune reaction, similar to a severe allergy or serious infection, when many small proteins, called cytokines, are released very quickly. • Very fast breakdown of AML or MDS cells. This can lead to damage to your kidneys, heart and liver. • Occurrence or Worsening of graft-versus-host disease (GVHD)

Cytokine release syndrome occurs when chemicals or cytokines are released from the NK cells. These can result in fevers, low blood pressure or shortness of breath. We have institutional protocols to recognize and treat this condition.

Tumor Lysis Syndrome is a risk of with any leukemia treatment. It is the result of rapid tumor cell death and the body's inability to handle the results. Rapid tumor cell death may cause changes in certain chemicals in the blood and may result in damage to organs, including the kidneys, liver and heart. Organ damage usually goes away after treatment, but in some cases may be permanent or could lead to death. There are preventative measures that your study doctor may take to protect the kidneys beginning before the first dose of chemotherapy and continuing until the day before the KDS-1001 infusion.

Neurologic symptoms such as changes in speech have been reported with other immune cell therapies. Although, these have not been observed in NK cell therapies, they could occur.

Possible Side Effects of Cytarabine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, more than 20 and up to 100 may have:
• Blood clot • Swelling in the rectum which may cause rectal pain • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth and GI tract which may cause difficulty swallowing or pain • Rash • Fever

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, from 4 to 20 may have:
• Heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness • Chest pain • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Damage to the lungs which may cause shortness of breath • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Severe blood infection • Liver damage which may cause yellowing of skin or eyes • Kidney damage which may cause swelling, may require dialysis • Numbness and tingling of the arms and legs • Muscle pain • Dizziness • Headache • Flu-like syndrome with fever, bone pain, rash, redness of eyes, or chest pain • Swelling and redness of the eye • Hair loss

RARE, AND SERIOUS In 100 people receiving Cytarabine, 3 or fewer may have:
• Brain damage, Posterior Reversible Encephalopathy syndrome, which may cause headache, seizure, blindness • Difficulty speaking, trouble standing or walking

Possible Side Effects of Fludarabine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Fludarabine, more than 20 and up to 100 may have:
• Cough • Shortness of breath • Infection, especially when white blood cell count is low

COMMON, SOME MAY BE SERIOUS In 100 people receiving Fludarabine, more than 20 and up to 100 may have:
• Anemia, which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Increased risk of unusual infections lasting more than 6 months • Vomiting, nausea, loss of appetite • Tiredness, fever • Pain

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Fludarabine, from 4 to 20 may have:
• Damage to organs (brain, lungs, others) which may cause tiredness, changes in thinking or shortness of breath • Chest pain • Swelling of the body • Kidney problems which may require dialysis • Internal bleeding which may cause belly pain, black tarry stool, blood in vomit, coughing up blood, blood in urine, nose bleeds • Diarrhea • Sores in mouth which may cause difficulty swallowing • Changes in vision • Chills • Muscle weakness, numbness, tingling or pain of the arms and legs • Feeling of "pins and needles" in arms and legs • Confusion • Hearing loss • Increased sweating • Rash, which may be severe with blisters and peeling which can involve mouth and other body parts

RARE, AND SERIOUS In 100 people receiving Fludarabine, 3 or fewer may have:
• Coma, seizures (with high doses) • Stroke, which may cause paralysis, weakness, headache • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Heart attack which may cause chest pain, shortness of breath • Blood clot which may cause swelling, pain, shortness of breath • Liver damage which may cause yellowing of eyes and skin, swelling • Blindness

Let the investigator know of any questions you have about possible side effects. You can ask the investigator questions about side effects at any time.

Reproductive risks:
The treatments (fludarabine and cytarabine) used in this trial have clear evidence of harm to an unborn baby. For this reason, women who can get pregnant and men with partners who can become pregnant will be asked to practice a highly effective method of birth control while participating in this study and considered medically acceptable by the study doctor. The research staff will give recommendations for highly effective contraception methods. If you or your partner become pregnant during the study, you must inform the study doctor immediately. The study doctor will advise regarding medical care and monitor the pregnancy.

If you are a woman who is able to become pregnant, you must agree to take pregnancy tests according to the study protocol (see Table 1 and Table 2).

Other Types of Risks
If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual.
- You may be asked sensitive or private questions which you normally do not discuss.
- The study cells may not be better, and could possibly be worse, than the usual approach for your cancer.
- The study cells or the dose you receive may not be effective in helping to treat your disease. This means you may spend time in the study and experience side effects taking a drug that may not provide you with any health-related benefits.

Confidentiality Risks: Because this study includes information about your health, there are potential risks to your privacy. All standard measures will be employed to protect your privacy and confidentiality. To help protect your privacy and confidentiality, you will be assigned a unique identification number. Any samples or data will only be linked to you through this code

7. What benefits can I expect from being in the study?

If you agree to take part in this study, there may or may not be any direct medical benefit to you. It is hoped the information learned from this study will benefit other patients with leukemia or other cancers that may be treated with NK cells in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

Other treatments that could be considered for your condition may include:

- Treatment with other drugs or combination of drugs
- Other investigational treatments at this institution or at other research centers
- No treatment at this time with comfort care only

Your study doctor can provide you with additional information regarding your options.

9. What are the costs of taking part in this study?

The study agent, KDS-1001, will be supplied by the sponsor and *will not* be billed to you or your insurance company. You and/or your insurance company *will not* be billed for the cost of any tests or procedures that are required as part of this research study and are outside the standard of care for your condition.

You and/or your insurance company *will* need to pay for the costs of your standard medical care, just as you would if you were not in the study. Some of these items may be considered part of the research study but are also standard for your condition. These include:

- Bone Marrow biopsies, the chemotherapy agents: Fludarabine and Cytarabine.
- The costs of giving you the study agent, KDS-1001 and the Fludarabine and Cytarabine.
- Tests, exams, procedures, and drugs that you get to monitor your safety and prevent and treat side effects.
- Your insurance co-payments, coinsurance, and/or deductibles.

Being in this research study may lead to additional costs to you. In some cases, it is possible that your insurance company will not pay for these costs because you are taking part in a research study. You will be billed for any costs denied by your insurance.

Talk to your insurance company and make sure that you understand what your insurance does and does not pay. Also, find out if you need approval from your insurance company before you can take part in a research study.

Ask your doctor, nurse, or study coordinator for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance company.

10. Will I be paid for taking part in this study?

You will not receive payment for taking part in this study.

For patients traveling a distance greater than 60 miles one-way, lodging and meals will be reimbursed up to the current federal per diem rate and mileage will be reimbursed at the current standard IRS rate for medical or moving purposes. Total reimbursement per subject not to exceed $375 per day and not to exceed $1,000 in total.

If you agree to participate, your samples will be considered a gift to The Ohio State University. The university may sell or share your samples and personal information with others, such as private companies, government agencies, or other universities. The university will be paid if your samples and personal information are sold.

- Your samples and personal information may be used to make new products or technologies. You will not be paid if these new products or technologies are sold or make money.
- You cannot choose how your samples and personal information will be used. If you do not want to let others decide how your samples and personal information will be used, then you should not donate your samples.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Also, Ohio State could benefit financially from the sale of the study drug (KDS 1001) being tested. A conflict of interest committee at Ohio State has reviewed this information and determined that the financial interest presents no additional significant risk to the study's participants. Co-investigator Dr. Dean Lee has licensed the technology used to manufacture the product and has received a payment, through Nationwide Children's Hospital, from Kiadis for his share of the distribution. Any questions about this information can be answered by Dr. Sumithira Vasu, 614-293-3196.

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, they may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Kiadis Pharma (a Sanofi company), the company providing support and the investigational product for this study;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

To meet regulatory requirements, your study data, including your personal health information, is required to be stored until 2 years after the last approval of a marketing

application for KDS-1001 in the US, Japan and the European Union (and there are no pending or contemplated marketing applications in these regions), or until 2 years after the formal discontinuation of clinical development of KDS-1001.

If we find any new information that significantly impacts your health or may affect your willingness to participate in the research study, we will share it with you. This information may be relayed to you by phone, email, mail, or routine clinic visit. You may be asked to sign a new consent form that includes the new information.

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

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  HIV / AIDS
  Hepatitis infection
  Sexually transmitted diseases
  Other reportable infectious diseases
  Physical exams
  Laboratory, x-ray, and other test results
  The diagnosis and treatment of a mental health condition; and
- Records about any study drug you received

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The company Kiadis Pharma Netherlands B.V. (a Sanofi company) and its affiliates.
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Use of study data and samples by Kiadis Pharma (a Sanofi company)

Kiadis Pharma, including its affiliates (or its agents), will receive coded study data including personal health information (PHI) and may receive blood samples, all as described in this ICF, for the purposes of the research, safety and reliability requirements, verification and monitoring, market approval and research. Your coded study data and blood specimens will not be stored for future unspecified research purposes and will only be used for analyses related to this research study.

Coded study data
Kiadis Pharma will receive coded data that may include your medical chart history, data about your health condition, life habits as well as tests, examination and procedure results that will be gathered about you during this study. The chart could also include other information such as your year of birth, race/ethnicity and gender.

To protect your identity and the confidentiality of the information, you will be identified only by a unique identification number as set out above, this is also being referred to as coded data. The coded data do not include your name or address.

The coded data, by itself or combined with coded data from other studies, may be shared with regulatory agencies in participating countries or with business partners of Kiadis Pharma. The coded data could also be used to obtain approval to market the study drug from authorized regulatory agencies. It could also be used for other data analyses related to the study or for the development of future research projects or studies on immunophenotyping or persistence of NK cells. The coded data may be published in specialized journals or be the subject of scientific discussions, but it will not be possible to identify you.

For purposes of monitoring and verification, your non-coded research record and medical records may be reviewed by representatives from Kiadis Pharma and independent safety

reviewers. All these people and organizations are obliged to adhere to a confidentiality policy. These representatives can only consult your data in the presence and under the responsibility of the investigator or the study staff. The personal data may not be used for any other purpose than verification and monitoring of the study. Kiadis Pharma or its delegates will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission.

Kiadis Pharma will store the coded data in a secure limited access file, but not longer than for a period of 2 years following the last approval of a marketing application for KDS-1001 in the US, Japan and the European Union (and there are no pending or contemplated marketing applications in these regions), or until at least 2 years have elapsed since the formal discontinuation of clinical development of KDS-1001.

Blood samples

Kiadis Pharma may receive coded blood samples (isolated peripheral blood mononuclear cells (PBMCs) and serum) that are provided by you during this study. Kiadis Pharma will only receive such samples upon its request, and provided that such samples are not used by the Sponsor or the third party researchers for the research referenced in question 13 above.

To protect your identity and the confidentiality of the samples, you will be identified only by a unique identification number as set out above, this is also being referred to coded samples. The coded samples do not include your name or address.
The coded samples, by itself or combined with coded samples from other studies, may be used by Kiadis Pharma for future research related to immunophenotyping, persistence of NK cells, and genomic/DNA/RNA sequencing. Should Kiadis Pharma not be able to perform the assays related to the research, a third party qualified laboratory will be contracted to do so on Kiadis Pharma's behalf. The results obtained through the research may be shared with regulatory agencies or with business partners of Kiadis Pharma and could also be published in specialized journals or be the subject of scientific discussions. In all events, it will not be possible to identify you.

The coded samples will be stored at the Sponsor or a third party appointed by the Sponsor. Only if Kiadis Pharma requests to receive samples and such samples are available, as set out above, will samples be sent to Kiadis Pharma. The transportation of the samples will be done via a vendor which Kiadis Pharma uses to securely transport biologic materials. Samples may be requested by Kiadis Pharma for up to 2 years following the last approval of a marketing application for KDS-1001 in the US, Japan and the European Union (and there are no pending or contemplated marketing applications in these regions), or for up to 2 years after the formal discontinuation of clinical development of KDS-1001. Any samples received by Kiadis Pharma will be stored in a secure limited access location until used by Kiadis Pharma.

Kiadis Pharma permission

The permission for Kiadis Pharma to use your study data and study samples as described in this ICF will continue unless you withdraw your authorization in writing. More information on this and on your rights regarding the personal data processed by Kiadis Pharma pursuant to this study:

a) can be found through the Sanofi Corporate Privacy Policy for Patients and Consumers through https://www.sanofi.com/en/our-responsibility/sanofi-global-privacy-policy/patients-and-consumers; and
b) can be requested with the Data Protection Officer, that can be reached at the following address: Global Privacy Operations, 46 av. De la Grande-Armée, 75017 PARIS, France or through the form available on this link https://www.sanofi.com/en/our-responsibility/sanofi-global-privacy-policy/contact.

If you withdraw your authorization, you will be removed from the study and the data and samples collected about/from you up to that point can be used and included by Kiadis Pharma in data analysis and future research. The withdrawal of consent does not have any consequences for the data and samples that were processed before withdrawal. Certain materials, samples and data will be kept after the withdrawal, e.g. for purposes of scientific integrity or legal requirements.

17. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Sumithira Vasu at (614) 293-3196**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **HIPAA Privacy Manager, The Ohio State University Medical Center, Suite E2140, 600 Ackerman Road, Columbus, OH 43202 or at 614-293-4477.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Sumithira Vasu at 614-293-3196 or 614-293-8000 (24 hours)**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)** **AM/PM**
Relationship to the participant	**Date and time**

CONSENT FOR RESEARCH BY KIADIS PHARMA

I understand the information in this consent form regarding the use of my data and samples for research by Kiadis Pharma (a Sanofi company) and consent to such use of my data and blood samples.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time