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INFORMED CONSENT FORM
AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION
FOR ADULT PARTICIPANTS, AND PARTICIPANTS REACHING AGE OF MAJORITY

Sponsor / Study Title:	Joseph Maakaron, MD - University of Minnesota / MT2020-033: Study of FT538 in Combination with Daratumumab in Acute Myeloid Leukemia
Protocol Number:	2020LS114 (MT2020-33)
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Supported By: The research related expenses for this study are covered by National Institutes of Health (NIH) grants. Fate Therapeutics, is supplying the FT538 investigational cell product without cost for the purposes of this study. DARZALEX FASPRO™ (Daratumumab and hyaluronidase-fihj for subcutaneous injection) is provided without cost to you for the purpose of this study.

Financial Interest Disclosure: This research is supported in part by Fate Therapeutics. The University of Minnesota has licensed certain aspects of FT538, the investigational cell product being tested in this study to Fate Therapeutics. The University of Minnesota may benefit financially if the investigational cell product is marketed in the future. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies. If you would like further information about this interest, please contact Jon Guden, Associate Director, Conflict of Interest Program, at jguden@umn.edu.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Study doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

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- The goal of research is to learn new things in order to help groups of people in the future. Study doctors learn things by following the same plan with a number of participants. You, as an individual, may or may not be helped by participating in a research study; however, your participation helps answer the research questions.
- The goal of routine (standard) treatment is to treat your medical condition. Standard treatments are available from any doctor.

Research and clinical care are often combined. One purpose of this consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?
You are invited to take part in a research study because you have acute myeloid leukemia (AML) that has not responded to treatment (refractory) or returned after treatment (relapsed). To be eligible for this study your AML cells must show CD38, a protein “marker” present in some types of cancer. The FT538 and daratumumab given in this study target CD38 cells. If your CD38 status is not already known, it may be determined by reviewing bone marrow cells.

The purpose of this consent form is to help you decide if you want to participate in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this research study, your doctor will continue to treat you.
- You may change your mind and take back (withdraw) your consent at any time during your participation in the study without penalty or loss of any benefits to which you are otherwise entitled.
- Parts of this study involve standard medical care.
- Other parts of this study may involve experimental (investigational) therapy or procedures that are being tested for a certain condition or illness. An investigational therapy is one that has not been approved by the U.S. Food and Drug Administration (FDA) to treat the condition or illness for which it is being studied.
- After reading this consent form and speaking with the study staff, you should understand which parts of the study are investigational and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by Fate Therapeutics, Inc., which is supplying the investigational product FT538, the Advarra Institutional

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Review Board (IRB) reviewing this research study, as well as government agencies responsible for overseeing the conduct of the study, such as the FDA and health authorities from other countries.

- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed, then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

If you take part in this research study, you will be asked to sign and date this consent form confirming that all of your questions about what the study is and what you will have to do during the study have been answered. By signing and dating, you are freely consenting to join this research study. You will be given a copy of your signed and dated consent form. If you decide not to take part in this research study, there may be other choices available to help treat your cancer. Ask the study doctor to discuss these choices with you.

Study Treatment Overview

Your participation in this study will include:

1. Screening tests and procedures to see if you are eligible to participate in the study
2. A period in which you will receive the study drugs
3. Follow-up tests and procedures to check on you after you receive the study drugs

This study is testing up to 4 dose levels of FT538 (with one additional dose level in reserve if unacceptable side effects are seen in the lowest dose level). You are assigned to the currently enrolling FT538 dose level depending on when you enter the study. You will be told the dose level. All other study drugs are given at fixed doses (either a flat dose for everyone or adjusted based on your weight depending on how the study drug is usually given).

Enrollment in the study is as follows:

The study starts with 1 participant enrolled in a dose level starting at Dose Level 1, until any one of the following possible situations occurs which determines the design flow for the rest of the study enrollment (each bullet is its own path). The person providing you with the consent can let you know. Regardless of the path, enrollment in the study ends once 10 participants are treated at the same FT538 dose level.

- Dose Level 4 (the highest dose level) is reached without an unacceptable side effect. Ten participants total are treated at this dose level and the study is done.
- One of the participants experiences a pre-defined side effect, in this situation 2 additional participants are treated at the same dose level to see if the side effect was a fluke or it occurs in other participants. From this point forward, a minimum of 3 participants are enrolled in all future dose levels. Higher dose levels (up to

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Dose Level 4) may be tested based on the side effects experienced by each group of 3. If an unacceptable side effect occurs (a long pre-defined list), the study again switches the dose level assignment design, and 10 participants are treated at the dose level considered the maximum tolerated dose and the study is done.

- One of the participants experiences an unacceptable side effect, the study moves to enrollment to 3 participants per dose level and, based on the side effects experienced, future dose level assignment is based on the side effects of all participants enrolled to date. Each group of participants may be treated at the same dose level, a higher dose level or a lower dose level. Once 10 participants in a row are treated at the same dose level the study is done

Regardless of the FT538 dose level assignment, the study activities are the same and all other study treatment is the same as reflected in the study calendar attached at the end of this document. However, this is just a plan and changes may be made on an individual participant basis as medically indicated as determined by the treating study doctor.

Why is this research being done?
The purpose of this study is to test the safety of FT538 at different doses in combination with daratumumab DARA and to gain some very preliminary disease response information. Up to 4 dose levels of FT538 will be tested in this study with 1 more dose level (Dose Level -1) in the unlikely event there is unacceptable side effects at Dose Level 1.

FT538 is investigational, meaning that the United States Food and Drug Administration (US FDA) have not approved FT538 for the treatment of cancer or any other disease. It is only available through a research study such as this clinical trial. DARA when given as a subcutaneous injection (there also is an IV (into a vein) formulation available) only is approved for the treatment of Multiple Myeloma, another cancer of the blood. Its use in this study is investigational.

FT538 is a type of cell product made up of “natural killer” or NK cells. NK cells are a type of immune blood cell that are known to attack cancer cells. The University of Minnesota has used NK cells obtained from a close relative (the donor) of the patient for close to 30 years. FT538 is produced by growing cells that come from a healthy human donor, not an embryo or fetus. The donor cells are treated with a process that turns them into a type of cell called an induced pluripotent stem cell, which means that these cells can be turned into any type of human cell. In this case, the cells are turned into NK cells which, once ready as FT538, are frozen, stored, and shipped to the study site.

FT538 is different from the NK cells in your body because the donor cells were changed through a process known as cell engineering. This type of cell engineering changes the

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coded blueprint of cells, known as DNA, to change how the cells work in the body. Specifically three changes were made:

- A special protein called “hnCD16” has been added to FT538 so it can attach to a type of anti-cancer drug called monoclonal antibodies to help NK cells target and kill cancer cells.
- Another protein called an “IL-15/IL-15 receptor complex” has also been added to FT538 to help the NK cells stay alive
- A protein called “CD38” was removed. CD38 is naturally present on NK cells. Removing CD38 allows certain monoclonal antibodies that target CD38, such as the 2nd study drug DARA, to kill the cancer cells, but not to kill FT538.

The removal of CD38 may also increase the activity of NK cells.

FT538 is considered a xenotransplantation product because it comes in contact with cells of animal origin during the manufacturing process. There are risks of taking a xenotransplantation product. Refer to the sections “What are the risks of being in this study? Is there any way being in this study could be bad for me (Detailed Risks) ?” for more information.

DARA belongs to a class of drugs called monoclonal antibodies. Antibodies are large, Y-shaped proteins used by your body’s immune system to identify and remove anything that can be harmful to your body such as bacteria, viruses, and cancer cells. Monoclonal antibodies are antibodies that have been designed and engineered to attack a specific target, such as cancer cells. In this study, DARA plays two roles. The dose given before the CY/FLU may improve the effect of tamping down the immune system and may improve the NK cell survival.

How long will I be in this study?

After learning about this study and reading through this consent form, if you are interested in taking part, you will be asked to sign this consent form. This allows a review of your medical history and routine tests to make sure you are healthy enough to be in this study. This is called a screening period and may take up to 4 weeks.

A single course of study treatment is given over approximately 5 weeks. Refer to the calendar attached as the last page of this document. Weekly visits and blood work are required for at least 2 weeks after your last dose of FT538. Additional visits may be required depending on your disease status and blood count recovery.

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Follow-up for this study matches standard of care visits at 3 month, 6 month, 9 months and 12 month (1 year) from the 1st infusion of FT538. Routine information obtained from these visits (physical exam results, lab work, disease response) will be recorded in the study record. If at any time your disease worsens or your study doctor feels other treatment is needed, participation in this study will not affect those decisions; however, information will still be collected from your medical record as described above.

Your direct participation in this research study is about 1 year; however, as part of this study you must agree to take part in a long-term follow-up (LTFU) study. FT538 is a genetically modified product and the US FDA requires additional follow-up in these products. After your participation ends in this research study, follow-up will continue at least once a year either in person, by mail, email, telephone or other method for an update on your overall health and if you have any new diagnoses of immune related conditions (for example, rheumatoid arthritis), neurological changes or new cancers. You will receive a separate consent form for the LTFU study.

What will I need to do to participate?
After you hear about the study, read through the consent and have your questions answered, you will be asked to sign and date this consent form if you are interested in the study. By signing and dating this consent, you are giving permission for the study staff to review your medical record to determine if you qualify for the study.

More detailed information about the study procedures can be found under **"What happens if I say yes, I want to be in this research?"**

Is there any way that being in this study could be bad for me?
Injection Related Reaction to the DARA: The change to a formulation that is given as an under the skin injection greatly reduced this risk as compared to the IV (into a vein) infusion. Approximately 10% of patients (1 in 10) has a mild to moderate injection reaction. Medications are given before and after the injection to reduce this risk.

You will receive the common chemotherapy drugs, cyclophosphamide and fludarabine to lower your immune system and blood counts before starting FT538. This may increase your **risk of infection and/or make you feel tired**.

Risks associated with FT538 are based on experience with other NK cell products and may include:

Infusion Related Reaction is a potential risk FT538 during the infusion or shortly after. This reaction could be mild (skin irritation/rash) to life-threatening (difficulty breathing, swelling of the face and throat). Medications are given before and after each infusion to lessen the risk of an allergic reaction. If a reaction occurs, the symptoms are treated with the appropriate medications.

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Cytokine release syndrome (CRS) is a serious and potentially life threatening systemic (whole body) inflammation response. CRS is seen with other types of cell therapies, but is not typically seen with NK cell therapies. Signs of CRS include fever, nausea, headache, rash, rapid heartbeat, low blood pressure, and trouble breathing. Most participants who develop CRS have a mild reaction, but sometimes, the reaction may be severe or life threatening. CRS is treated with supportive care and steroids.

More detailed information about the risks of this study can be found under **"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section.**

Will being in this study help me in any way?
If you agree to take part in this study, there may or may not be direct medical benefit to you. The information learned from this study may benefit other patients with AML or other cancers of the blood.

What happens if I do not want to be in this research?
You do not have to participate in this research. Your doctors will let you know of other treatment options. Your decision will not affect your future cancer care or your relationship with your doctor.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be enrolled in this study?
This study is only available at the University of Minnesota. Most likely 17 participants will be treated, but it could be as many as 25 participants if there are more side effects than expected.

What happens if I say "*Yes, I want to be in this research*"?
After signing the consent form, a screening period is done make sure you are healthy enough for the study and meet the enrollment criteria. This may take up to 28 days, but often is much shorter.

Screening Period to confirm study eligibility
The following procedures are part of the screening period:

- Review of your medical history
- Recording of your demographic information (such as age and ethnicity)
- Assessment of your performance status (daily functioning)
- Review of your current medications
- Review of how you are feeling

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- Complete physical examination, including height and weight
- Vital signs (such as your blood pressure, heart rate, respiratory rate)
- Electrocardiogram (ECG) to measure the electrical activity of your heart
- Echocardiogram (ECHO), multiple-gated acquisition (MUGA) scan, or cardiac magnetic resonance imaging (MRI) to check your heart's function
- Blood samples (about 5 tablespoons) will be taken for the following reasons:
  - Check your state of health through standard laboratory tests
  - To see if you are pregnant if you are a woman who is able to have children. If you are pregnant or breastfeeding, you will not be able to participate in this study.
  - For infectious disease evaluation and viral monitoring, including HIV and hepatitis testing. Minnesota requires reporting of a positive test for HIV and some types of hepatitis, to the state health department.
- Bone marrow biopsy with aspirate samples will be collected before you receive any study drugs. An aspirate is usually done together with a bone marrow biopsy and involves using a syringe to obtain a liquid bone marrow sample.
  - The biopsy/aspirate may be done at any time during screening - If you have had a bone marrow biopsy in the previous 28 days, this biopsy may be used for the pre-study treatment assessment. Your study doctor can let you know.
  - The sample will be used to assess the status of your cancer, provide information about your cancer cells, and may be used for additional research purposes.
- Other tests and procedures may be done based on your individual medical situation.

Study Treatment Overview:
If you are eligible and still want to participate in this study you will receive the study drugs as described below.

Please refer to the study calendar attached to this document for an overview of the study treatment plan.

Note about Day numbering: this study mimics the day counting long established by hematologic treatments. FT538 is considered the primary study drug so the 1st dose is given on Day 1. Any treatment or activities before Day 1, are assigned a negative (Day-) number counting backwards from Day 1. For example, fludarabine is given on day -6, -5, -4, -3, and -2, and cyclophosphamide is given on Day -4 and Day -3. The dose of DARA is given on Day -5, or 5 days before the 1st FT538. The study calendar attached to this document reflects this day counting method using Monday as the Day 1.

There are windows built into the study plan in case of a holiday, bad weather or other reason the study treatment cannot be given or a follow-up visit needs to be changed.

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Daratumumab (trade name DARZALEX FASPRO) or DARA for short is given as an under the skin (subcutaneous) injection near the belly button before the 1st dose of FT538.

Fludarabine (FLU) chemotherapy is given over a five-day period in the outpatient clinic to improve the survival of the FT538 cells, as an intravenous (IV – into a vein) infusion.

Cyclophosphamide (CY) chemotherapy is given to over a 2 day period in the outpatient clinic to improve the survival of the FT538 cells. Like fludarabine, cyclophosphamide is given as an intravenous (IV –into a vein) infusion.

FT538 is given once a week for 3 weeks in a row as an intravenous (IV –into a vein) infusion. FT538 cells come in pre-dosed bags and depending on the dose you are assigned you will receive one or more bags. Each bag takes about 15 minutes to be infused.

Study Related Sample Collection (Research Related):
Because this is a research study, you will have research blood samples taken at the time you sign and date this consent, before the dose of DARA, before and after each dose of FT538, and at each follow-up visit through the 12 month visit. Approximately 5 tablespoons of blood will be collected at each time point. The 1st and the one at 4 weeks after the 1st dose of FT538 will be approximately 6 tablespoons as additional testing is done. During follow-up at Months 3, 6, 9, and 12 the amount of blood will be reduced to approximately 3 tablespoons of blood. The blood samples will be collected at the time you are having blood work for your medical care except for a small sample (about 2 teaspoons) collected about 30 minutes after each FT538 infusion.

Blood from the research samples will be tested and analyzed to look at your immune system and the effects of FT538. The testing may include testing using genetic markers to see how much and how long FT538 is present in your blood. This research will provide a better understanding of how FT538 works. If there are tests that cannot be done at the study site, blood may be sent to outside labs, including Fate Therapeutic labs. Any samples leaving the study site will not contain information that could directly identify you.

Each time you have a bone marrow biopsy for your medical care through the 12 month study period, additional cells (aspirate) may be collected for research related testing; an aspirate will also be collected on your day +3 after receiving your first dose of FT538. In addition, if, at the time of going on study you had a recent bone marrow biopsy (within 28 days), part of those stored (archived) samples will be made available for research purposes.

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If any blood or bone marrow cells left over from the collections described above, the extra samples may be stored for additional future research related testing. This may include further tests about how FT538 works against cancer, or it may include research tests about other cancer treatment or prevention methods. This testing may include future genetic testing.

Information obtained from the research samples will be used only for purposes of research and development. None of the research-related testing results will affect your care or your participation in this study. The research results will not be placed in your medical record and will not be given to your insurance company or employer unless required by law. Neither you nor your health insurance provider will be charged for the cost of research sample processing, storage or testing. If the results from this study are published in a medical journal or presented at a scientific meeting, you will not be identified.

Genome Testing and Handling of Genetic Information

Biomarkers are substances in your body that may indicate something abnormal is happening in your body. Biomarkers may be tested as part of this study, including possible analysis of your genome (DNA).

Your blood and/or your bone marrow samples may be tested to find about possible mutations (permanent alterations) and other possible changes to your genome. Testing will not be done to determine whether any mutations are inherited.

Studying the blood and bone marrow samples from a large number of people may help researchers learn more about new treatments, cancer biology, and how mutations affect a person's response to treatment. The genetic test results are not intended to be used to guide you or your doctors in making any health care decisions. Research performed on these samples may benefit other patients with cancer similar to yours. There are no plans to return the results of this research to you.

The Genetic Information Nondiscrimination Act of 2008 generally makes it illegal in the United States for health insurance companies, group health plans, and most employers to discriminate against you on the basis of your genetic information. The law generally will protect you in the following ways:

- Health insurance companies and group health plans cannot request your genetic information from this research;
- Health insurance companies and group health plans cannot use your genetic information when making decisions regarding your eligibility or premiums; and
- Employers with 15 or more employees cannot use your genetic information from this research when setting the terms of your employment.

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This United States federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

New findings
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Alternative Treatments
You do not have to be in this study to receive treatment for your AML. Your options may include:

- Receiving treatment that is available without being a research study.
- Participating in another study.
- Getting no treatment. If you decide that you don't want any more active treatment, one of your options is called "comfort care", also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible. If you think you might prefer comfort care, please discuss this with your family, friends and your regular doctor.

What happens if I say "Yes", but I change my mind later?
If you take part in this research study, and want to leave, you should let a member of the study staff or your study doctor know. Your choice not to be in this study will not negatively affect your right to any present or future medical care. If you decide to leave the study before the End of Study Treatment visit 4 weeks (28 days) after the 1st FT538 dose, you are asked to maintain contact with your study doctor in case of side effects.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

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What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)
You may experience all, some, or none of the side effects described below. If you do experience any of them, they may vary in severity. The severity may be mild, moderate, or severe, up to and including death. You may experience side effects that are not expected and side effects may happen long after you receive treatment on this study.

Possible Risks of FT538
This is one of the first time that FT538 has been given to people. The risks are not known at this time. The potential risks of receiving FT538 include those related to how FT538 may work in the body and how the body may react to FT538. The potential side effects listed below are based on laboratory studies and knowledge of similar cell therapy drugs.

FT538 is stored in a solution containing dimethyl sulfoxide (or DMSO) and human albumin. Both of these ingredients are commonly used in cell therapies and may have risks in addition to those of the cell therapy itself.

DMSO may cause side effects like:
- Coughing
- Chest tightness
- Wheezing
- Flushing (redness),
- Rash
- Nausea
- Vomiting
- High or low blood pressure

You will receive intravenous (IV - into a vein) fluids before and after the FT538 to lessen the risk of a reaction.

Human albumin and other ingredients of animal origin are used to make FT538 cells and may contain viruses that cause infection or disease. FT538 is tested to reduce the risk of certain viral infections. Allergic reactions may occur with human albumin. Symptoms could include:
- Fever
- Chill
- Rash
- Nausea
- Vomiting
- Fast heart rate
- Low blood pressure

Other potential risks for FT538 related to how FT538 may work in the body are described below.

Infusion-related or allergic reaction
There is a potential risk for an allergic reaction which, may occur during the infusion (while the study drug is being given through your vein). This reaction could be mild (skin irritation/rash) to life-threatening (difficulty breathing/swelling of the face and throat). The study doctor will give you medications such as acetaminophen (Tylenol®) and diphenhydramine (Benadryl®) before receiving FT538 to lessen the risk of an infusion-related or allergic reaction.

You will be closely monitored during and after the infusion. If any sign of a reaction occurs, additional medications are given and the infusion stopped (and, if applicable, any remaining bags of cells not given). Additional FT538 doses may be given with adjustments to the pre-medications, or if a severe reaction, the FT538 will be permanently discontinued.

Cytokine release syndrome
Cytokine release syndrome (also called CRS) is a generalized inflammation response, which may be produced in the body with therapies that turn on the immune system, including immune cell therapies like FT538. CRS symptoms are usually mild to moderate and include fever, nausea, chills, decreased blood pressure, increased heart rate, weakness, headache, rash, scratchy throat, and difficulty breathing. However, in rare instances, patients can develop severe, even potentially life-threatening symptoms of CRS.

Please seek treatment immediately and tell the study doctor or the study staff if you have any of these symptoms, or any other side effects, during the study.

Tumor lysis syndrome
Tumor lysis syndrome (also called TLS) can happen when cancer cells have broken down and byproducts of that breakdown have entered the bloodstream. Symptoms may include:

- Weakness
- Low blood pressure
- Muscle cramps
- Decreased urination

TLS can lead to kidney damage and/or other organ damage. In addition to cancer treatment, many factors, including the type and extent of the cancer, as well as treatments given to an individual, can contribute to TLS. Let the study doctor know immediately if you develop these symptoms.

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Effects on the nervous system
Receipt of cell therapies may result in side effects involving the brain and other parts of the nervous system. Effects on the nervous system observed with other cell therapies include confusion, delirium (loss of contact with reality), and sometimes seizures and cerebral edema (swelling) that could lead to death. This has not been a common risk associated with NK-cell therapies. As a part of this study, frequent neurologic assessments will be done.

Increased risk of infection
Because FT538 is a cell therapy of human origin, there is a risk that you could receive infectious agents such as viruses, and/or other non-infectious agents, which may also cause side effects. FT538 has been extensively tested to reduce the risk of disease infection. However, these tests do not completely eliminate this risk. For some infectious agents, there are no routine tests to predict or prevent their presence.

Graft-versus-host disease
Because FT538 is created from the cells of a donor who is not related to the participant receiving FT538, there is a risk of a condition called graft-versus-host disease (also called GvHD). This is a condition where the donor's immune cells (the graft) view the participant's healthy cells (the host) as foreign, and attack and damage the healthy cells. GvHD may cause damage to several organs including the skin, liver, and the gastrointestinal tract. GvHD can be mild, moderate, or severe. In some cases, it can be life-threatening. Depending on the severity of GvHD, you may need medication designed to control the immune system to treat GvHD. The medication that may be needed to control the immune system to treat GvHD also could affect the effectiveness of FT538.

Risks Related to Xenotransplantation Products
FT538 is considered a xenotransplantation product because it comes in contact with cells of animal origin (mouse cell) during the manufacturing process. Risks of receiving a xenotransplantation product may include, but are not limited to, developing infections from agents that may be associated with cells of animal origin, transmitting these infectious agents to others, and the growth of tumors. The animal cells, which come into contact with the FT538 cells during the manufacturing process, originate from a master cell bank that has been extensively tested to reduce these risks. However, these tests do not completely eliminate this risk. The likelihood and timing for developing a condition or illness from xenotransplantation products is unknown. If you have any questions about the risks involved in receiving a xenotransplantation product, ask the study doctor or a member of the study staff.

Because FT538 is a xenotransplantation product, you are also expected to have certain responsibilities in the future. These future responsibilities may include, but are not limited to, having regular check-ups and telling your regular doctor or other healthcare providers about receiving a xenotransplantation product in the event of unexplained illnesses. You and your family members and intimate contacts should not donate blood, sperm, or other body fluids or tissues. If needed, ask the study doctor or a member of the study staff to help you discuss this with your family members and intimate contacts, or if you have any questions.

Possible Risks of Daratumumab (DARA)

In this study DARA is given as a subcutaneous (under the skin) injection that was developed to avoid the infusion related reactions experienced with DARA when given into a vein. The change to a formulation that is given as an under the skin injection greatly reduced this risk as compared to the IV (into a vein) infusion. Approximately 10% of people (1 in 10) has a mild to moderate injection reaction. Medications are given before and after the injection to reduce this risk.

Possible risks of DARA during and/or after an injection (occurs in about 1 in 10 people, less than 1 in 10 people had a severe reaction). Signs and symptoms included:

- Shortness of breath or trouble breathing
- Dizziness
- Lightheadedness
- Hypotension(low blood pressure)
- Cough
- Wheezing
- Throat tightness
- Runny or stuffy nose
- Headache
- Itching
- Nausea
- Vomiting
- Chills or fever
- Chest pain

The most common side effects of DARA given as an under the skin injection include:

- Cold-like symptoms (upper respiratory infection)
- Changes in blood cell counts which may result in an increased risk of infection, bleeding/bruising and/or fatigue.

Some people experience pain during the injection. If this occurs, the injection can be slowed or stopped. In addition, some people may have skin reactions at or near the injection site (local), site redness the most frequent reaction occurred in about 8 out of 100 people.

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Daratumumab can affect the results of blood tests to match your blood type. These changes can last up to 6 months after your final dose of daratumumab. Your blood type will be confirmed prior to receiving DARA. **Tell all of your doctors that you are taking or received daratumumab before receiving blood transfusions.**

Daratumumab may cause rare and unexpected side effects other than those described here. Tell your study doctor if you have any unusual problems while receiving this study drug.

Possible Risks of Cyclophosphamide and Fludarabine
Both of these study drugs are commonly used as a cancer treatment or in preparation for a cell infusion (as in this study).

The side effects are well known, although an unknown or serious side effect may occur in an individual patient. Very rarely a side effect is severe enough to prevent a patient from continuing with the planned research treatment or even be fatal.

Cyclophosphamide (CY)	
Common Side Effects (occurring in more than 30 out of 100 participants)	
• Low blood counts: Your white and red blood cells and platelets may temporarily decrease. This can put you at increased risk for infection, anemia, and/or bleeding. • Poor appetite	• Nausea and vomiting (more common with larger doses) • Temporary hair loss • Discoloration of the skin or nails
Less Common Side Effects (occurring in about 10-29 out of 100 participants)	
• Loss of fertility • Diarrhea • Mouth sores	• Bladder problems and bleeding (hemorrhagic cystitis)

Serious, but uncommon, side effects of CY include:

- Increased risk of developing other cancers, such as bladder cancer, acute leukemia (a type of blood cancer), lymphoma (a type of lymph node cancer), thyroid cancer, and/or sarcoma (a type of cancer that can start in the soft tissue, bone, or other tissue).
- Liver problems, which can be fatal
- Heart failure, which can be fatal
- Inflammation of the lung

CY may cause rare and unexpected side effects other than those described here. Tell the study doctor if you have any unusual problems while receiving this study drug.

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Fludarabine (FLU)	
Common Side Effects (occurring in more than 30 out of 100 participants)	
• Fever • Infection • Weakness • Cough • Nausea and vomiting	• Poor appetite • Low blood counts. Your white and red blood cells and platelets may temporarily decrease. This can put you at increased risk for infection, anemia, and/or bleeding.
Less Common Side Effects (occurring in about 10-29 out of 100 participants)	
• Chills • Fatigue • Pain • Sweating • Numbness and tingling of hands and feet	• Shortness of breath (lung problems) • Diarrhea • Rash (skin reactions) • Swelling • Taste changes, metallic taste

Serious, but uncommon, side effects of FLU include:

- An increased risk of infection (such as herpes, fungal infection, and *Pneumocystis carinii*) due to suppression of the immune system
- Severe side effects involving the brain and other parts of the nervous system, which were seen at doses higher than the dose you will receive in this study
- Hemolytic anemia (destruction of red blood cells)
- A rare condition called transfusion-associated graft-versus-host disease (also called GvHD), which occurs when immune cells in a blood transfusion attack cells in the body causing fever, rash, liver problems, and abdominal pain and diarrhea. If you require a blood transfusion while on this study, you will receive only blood transfusions that have received radiation treatment to reduce the risk of transfusion-associated GvHD.
- Tumor lysis syndrome (also called TLS) can happen when cancer cells have broken down and byproducts of that breakdown have entered the bloodstream. Symptoms may include weakness, low blood pressure, muscle cramps, and/or decreased urination. TLS can lead to kidney damage and/or other organ damage.
  You may receive allopurinol, an oral medication, beginning before the start of study treatment to reduce this risk.

Other study risks may include:

- Blood Draws: you may feel pain and have minor bruising or bleeding at the needle site. There is a small chance of infection, and sometimes people feel faint or lightheaded when their blood is drawn.

- Bone Marrow Biopsy/Aspiration: Common side effects of a bone marrow biopsy/aspirate include pain, swelling, bleeding, and drainage from the biopsy site. Although less common, there is a risk of infection and abnormal wound healing following any biopsy. The study doctor will explain the details and risks of the biopsy procedure, which may vary depending on how the biopsy will be obtained.
- Risks of Genetic Research - The risks to you and your family from genetic research on the blood samples are very low, as the testing is on the abnormal cells, not your family genetics. The unique participant code assigned at study enrollment is used instead of your name or other identifying information making it difficult for anyone looking at the sample to know it belongs to you. Testing is done in batches (more than 1 participant at a time) and no research results will be placed in your medical record.
- Because this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. There are procedures in place to lessen the possibility of this happening (see "*What happens to the information collected for the research, including my health information?*" section below).

What do I need to know about reproductive health and/or sexual activity if I am in this study?
The effect of FT538 on an unborn baby or on sperm are not known. The risks of the other study drugs are known and some cause harm to an unborn baby.

Women who are pregnant are not eligible to take part in this study.

Females: Women of childbearing potential (WOCBP) must use a highly effective form of contraception from the screening visit until at least 12 months after the final dose of cyclophosphamide (CY), at least 4 months after the final dose of FT538, and at least 4 months after the final dose of daratumumab, whichever is latest.

Males: Men who are in this research study should not get a sexual partner pregnant. Males with a female partner of childbearing potential or a pregnant female partner must be sterile (biologically or surgically) or use a highly effective method of contraception from the screening visit until at least 14 months after the final dose of CY and at least 6 months after the final dose of FT538, and at least 5 months after the final dose of daratumumab, whichever is latest.

Acceptable methods of birth control for use in this study are:
- Double barrier contraception
- Inserted, injectable, transdermal, or combination oral contraceptive
- A surgically sterile sexual partner
- Abstinence.

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If you or a female partner of a male participant become pregnant within 4 months after the last dose of FT538, it is important that you notify the study doctor or another study staff member.

Will it cost me anything to participate in this research study?
FT538 is provided at no cost by Fate Therapeutics for the purpose of this study. DARA is being provided at no cost by the study. The cost of processing and testing any samples collected for research is paid for by study funds.

You and/or your insurance company will be billed for any standard medical care given during this research study. This means your insurance company will be billed for the CY/FLU, administration of all study drugs, medications given to prevent or treat side effects, clinic visits, hospitalization, routine medical care, all lab tests done for standard safety assessment, and assessments that are done for your medical care. You will continue to be responsible for any copays or deductibles associated with your insurance.

Compensation For Participation
You will not receive any monetary compensation for your participation in this study.

What happens to the information collected for the research, including my health information?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and has a potential for breach of confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Overview
If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research. If you sign and date this Consent Form, you are giving permission to use and share your health information for these purposes and you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?
Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, electroencephalography (EEG), electrocardiogram (ECG), and echocardiogram ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?
Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

- ☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)
- ☒ My HIV/AIDS testing records _____ (initial)
- ☒ My genetic testing records _____ (initial)
- ☐ My mental health diagnosis/treatment records ____ (initial)
- ☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?
If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)), individuals involved in processing any compensation you may receive for your participation, and others);

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- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
- Advarra IRB, the independent external Institutional Review Board that is responsible for the review of this study.
- Fate Therapeutics will receive copies of serious adverse events without direct identifiers and cumulative study patient data without direct patient identifiers. Some of the research samples will be batch analyzed by Fate, the results will be incorporated in to the overall study data to be correlated with clinical data.

How will my information be used in publications and presentations?
Your health data will be used to conduct and oversee the research. We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, social security number (SSN) and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Optional Consent for Future Use of Identifiable Data or Specimens
At the completion of this research study, we would like to store and be able to use and share your identifiable research related samples and/or health information with researchers at the study site or affiliated hospitals for other research related to the immune system and/or cancer. Any research that involves identifiable information will be reviewed by an Institutional Review Board (IRB), which is the committee that provides ethical and regulatory oversight of research, prior to use. Because these specimens and/or health information are identifiable, we are asking your permission to store, use and share these for other research.

We may not ask for your consent before using or sharing your identifiable specimens or data. You will not receive any results or financial benefit from the future research done on your specimens or data. We may share your identifiable specimens or data with outside researchers who will use them for future research. Samples are labelled with your unique study code assigned at study enrollment and information such as the date of collection/study day that can be linked back to your health information through a master study list.

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If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been shared.

Please indicate whether you will allow the identifiable research related samples and/or health information to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable research related samples and/or health information may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable research related samples and/or health information may be used for other future research studies

Do I have to sign and date this authorization and give my permission to make my information, including my health information, available for use and sharing?
No, you do not have to sign and date this authorization. But if you do not sign and date it, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing and dating this authorization.

Does my permission for making my health information available for use and sharing ever expire?
No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?
Yes. You may cancel your permission at any time by writing to the study doctor at the address on the first page of this form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this authorization.

What happens to my health information after it is shared with others?
When we share your information with others as described in this authorization, privacy laws may no longer protect your information and there may be further sharing of your information.

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Will I be able to look at my records?
It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

STATEMENT OF AUTHORIZATION
I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ
The study participant has indicated that he/she is unable to read. This Authorization document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

FOR CHILDREN WHO BECOME ADULTS
I have been told that my parents/legal guardian agreed to the use and disclosure of my Protected Health Information as outlined in this document. I have read and understand the information in this authorization. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I continue to authorize the use and disclosure of my Protected Health Information. I will receive a copy of this signed and dated authorization.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

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What will be done with my data and specimens when this study is over?
We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of the study site. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data. No results from research related testing will be placed in your medical record.

Research samples may be sent to an outside laboratory for testing (including to Fate Therapeutics) that cannot be routinely performed at the study site. No information to directly identify you will be provided on these samples.

Will I receive research test results?
No, individual tests results will not be shared with participants. Research related testing is not done in real-time like lab work for medical care. Instead the samples are stored frozen and tested in batches at a future date. If the research with your identifiable information or samples gives results that do have meaning for your health, the study doctor will contact you to let you know what they have found.

Whom to contact about this study
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail: Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the number when contacting the Study Subject Adviser: Pro00055619.

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To share feedback privately with the University of Minnesota HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

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.

Will I have a chance to provide feedback after the study is over?
You may be asked to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team at the contact information located on page 1 of this form.

What happens if I am injured while participating in this research?
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury, let the study staff know right away. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

Optional Storing of Leftover Research Samples for Future Research:
Once the research associated with this study is completed, there may be some leftover blood and cells from the samples collected for research purposes. With your permission we would like to store them after the study ends for future analysis as new things are learned about the immune system and cancer. Leftover samples may be sent to labs

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outside of the study site if specialized testing cannot be performed locally. There is no cost to you or your insurance company for long-term storage. If you agree to storage now and later change your mind, you may contact a member of the study team and request that any remaining identifiable samples be destroyed.

Use of Identifiable Research Related Samples and/or Health Information

Please indicate whether you will allow the identifiable research related samples and/or health information to be used for future research by putting your initials next to one of the following choices as you indicated in this consent:

_____ (initials) NO, my identifiable research related samples and/or health information may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable research related samples and/or health information may be used for other future research studies

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Signature Block for Capable Adult:
Your signature documents your permission to take part in this research study. You will be provided with a copy of this signed and dated document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ
The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

FOR CHILDREN WHO BECOME ADULTS
I have been told that my parent/legal guardian agreed for me to participate in this research study as a minor. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

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RESEARCH STUDY CALENDAR EXAMPLE

Note about Day numbering: this study mimics the day counting long established by hematologic treatments. FT538 is considered the primary study drug so the 1st dose is given on Day 1. Any study treatment or activities before Day 1, are assigned a negative (Day-) number counting backwards from Day 1. For example, cyclophosphamide and fludarabine are given on Day -4 and Day -3 (the Thursday and Friday before the 1st FT538 on Monday). The dose of DARA is given on Day -5, or 5 days before the 1st FT538. The attached calendar reflects this day counting method.

Follow-up continues with a clinic visit and bloodwork at approximately 3, 6, 9 and 12 months after the 1st FT538 infusion.

The 12 month visit is the end of study visit. Follow-up transfers to the long-term follow-up study as described in that consent form.

Study Treatment Plan with FT538 given on Mondays						
Sun	**Mon**	**Tue**	**Wed**	**Thu**	**Fri**	**Sat**
Day -8	Day -7	Day -6 **FLU**	Day -5 **DARA/FLU**	Day -4 **CY/FLU**	Day -3 **CY/FLU**	Day -2 **FLU**
Day -1	Day 1 **FT538 #1**	Day 2 blood work	Day 3 bm aspirate	Day 4	Day 5	Day 6
Day 7	Day 8 **FT538 #2**	Day 9	Day 10	Day 11	Day 12	Day 13
Day 14	Day 15 **FT538 #3**	Day 16	Day 17	Day 18	Day 19	Day 20
Day 21	Day 22 Follow-up visit	Day 23	Day 24	Day 25 bm bx	Day 26	Day 27
Day 28	Day 29 Follow-up visit	Day 30	Day 31	Day 32	Day 33	Day 34
Day 35	Day 36 Clinic visit if needed	Day 37	Day 38	Day 39	Day 40	Day 41
Day 42	Day 43 Follow-up visit or check-in					