Official Title: A Phase Ib, Open-Label, Randomized, Dose-Finding, Multicenter Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of GDC-8264 in Combination with Standard of Care in the Treatment of Acute Graft-Versus-Host Disease in Patients who have Undergone Allogeneic Hematopoietic Stem Cell Transplantation

NCT Number: NCT05673876

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MASTER INFORMED CONSENT FORM

TITLE:	**A PHASE Ib, OPEN-LABEL, RANDOMIZED, DOSE-FINDING, MULTICENTER STUDY TO EVALUATE THE SAFETY, PHARMACOKINETICS, AND EFFICACY OF GDC-8264 IN COMBINATION WITH STANDARD OF CARE IN THE TREATMENT OF ACUTE GRAFT-VERSUS-HOST DISEASE IN PATIENTS WHO HAVE UNDERGONE ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION**
PROTOCOL NUMBER:	GA43861
SPONSOR:	Genentech, Inc.
STUDY DOCTOR:	{Name} {Phone number}
NAME OF INSTITUTION:	{Name}
INSTITUTION ADDRESS:	{Address}
NAME OF IRB/EC:	{Name}
IRB/EC APPROVAL DATE:	_____

SECTION 1: STUDY OVERVIEW

{Table of contents may be deleted to reduce length of consent form}

1.1 INTRODUCTION

- You are being asked to take part in this research study (also known as a clinical trial) because you have undergone an allogeneic hematopoietic stem cell transplantation (HSCT) and have been diagnosed with acute graft-versus-host disease (acute GVHD). "Graft" represents the cells that you received from the donor. "Host" represents the person (in this case, you) receiving the cells. Acute GVHD is when the donor graft attacks and damages some of your tissues. Acute GVHD can cause skin rash and stomach or intestinal problems such as nausea, vomiting, or diarrhea. It may also damage your liver and cause hepatitis or jaundice (yellowing of the skin). Acute GVHD may also increase your risk of developing an infection.
- Some people who have acute GVHD are at increased risk of non-relapse mortality, that is, dying from acute GVHD or other causes not related to their primary cancer. Based on your symptoms, you may be at higher risk of a poor outcome.
- This study is testing *an experimental* drug called GDC-8264, which is being developed to treat acute GVHD. GDC-8264 will be given to you in addition to *prednisone or methylprednisolone, which are* standard medications *used* to treat acute GVHD after HSCT. *This is the first study of GDC-8264 in patients with acute GVHD after HSCT.*
- All individuals will be considered for this clinical trial, regardless of race, ethnicity, sex, sexual orientation, gender identity, veteran status, or disability status.
- Genentech, Inc. (a member of the Roche Group) is the sponsor of this study and is paying {Name of Study Site} to cover the costs of this study.
- This consent form tells you what will happen if you take part. It also tells you about the possible benefits and risks of being in the study.
- Taking part in this study is your choice. Please read the information carefully and feel free to ask questions. It may be helpful for you to discuss this information with your family and friends.
- Instead of participating in this study, you may choose to
  - Get treatment with standard medications prescribed by your doctor to treat acute GVHD without being in this study
  - Join a different study
- Talk to your doctor about all of your choices, and the risks and benefits of each choice. If you choose not to take part, you will not lose the regular care you receive from your doctors.
- If you decide to take part, you will be asked to sign this consent form. You will be given a copy of your signed consent form.

1.2 WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to *compare* the effects, good or bad, of GDC-8264 plus *prednisone or methylprednisolone* on patients who have been diagnosed with acute GVHD and have increased risk of poor clinical response to standard treatment.

GDC-8264 has been designed to block the activity of a certain kind of protein (the receptor-interacting protein 1, also known as RIP1 kinase), which plays a role in inflammation (your body's normal response to injury or infection) and cell death in several tissues in the body.

Laboratory studies have shown that blocking RIP1 kinase activity may protect the cells in the intestine and other tissues from GVHD without suppressing the immune system, which suggest that GDC-8264 works differently from current standard medications used to treat acute GVHD.

About 40 people in the United States *and Canada* will take part in this study.

GDC-8264 is an experimental drug, which means health authorities have not approved GDC-8264 in combination with standard medications for the treatment of acute GVHD.

1.3 WHAT WILL HAPPEN IF I PARTICIPATE?

This study has three parts:

1. Screening (to see if you are eligible for the study), which may last up to 3 days
2. Treatment with GDC-8264 for 28 days

   If you respond to treatment, GDC-8264 may be continued for another 28 days.
3. Follow-up (to check on you after treatment is finished) for approximately [redacted]

You will receive standard medications to treat acute GVHD and GDC-8264 as follows:

- Standard medication of either prednisone, given as pills every day, or methylprednisolone, given as intravenous (IV) (in your vein) infusions every day

  Standard medication will be started up to 3 days before you begin receiving GDC-8264. The dose of your standard medication may be increased before starting GDC-8264 and may be tapered (reduced) over time, as directed by your study doctor.
- GDC-8264, given as pills every day for approximately 28 days

  If you respond to treatment, GDC-8264 may be continued for another 28 days.

  If you are an outpatient, you will be provided a paper diary in which you must record when you take each dose of GDC-8264.

During this study, you will have visits approximately [redacted] while you are receiving treatment with GDC-8264 [redacted] visits, depending on how long you receive GDC-8264). Thereafter, your study doctor will follow-up with you a total of [redacted] times ([redacted] at the clinic and [redacted] either at the clinic or by telephone) to understand any long-term effects. Visits may last 2–3 hours.

Your total time in the study will be about [redacted] from the time of your diagnosis of acute GVHD.

The study procedures are described in detail in Section 2.2. Some procedures will be the same as your regular care for acute GVHD and some procedures will be just for this study.

1.4 ARE THERE ANY BENEFITS?

Your health may or may not improve in this study, but the information that is learned may help other people who have a similar medical condition in the future.

1.5 ARE THERE ANY RISKS?

You may have side effects from the drug or procedures used in this study, as described in Sections 2.1 and 2.2. Side effects can be mild to severe and even life threatening, and they can vary from person to person. Talk to your study doctor right away if you have any of the following during the study:

- Symptoms that are new or have worsened
- Changes in your prescribed or over-the-counter medications (including herbal therapies)
- Visits to the doctor or hospital, including urgent care or emergency room visits

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to study drug, as described in Section 1.6. If you are pregnant, become pregnant, or are currently breastfeeding, you cannot take part in this study.

1.6 ARE THERE ANY SPECIAL REQUIREMENTS?

While participating in this study, there are certain requirements, as listed below:

- If you are thinking about joining another research study, or if you are already involved in another research study, you should talk with your study doctor.
- For women: If you can become pregnant, you must use a reliable birth control method during the study and for [redacted] after your final dose of GDC-8264. Talk with your study doctor about what method may be best for you. Tell your study doctor right away if you get pregnant during this period. If you get pregnant, the study doctor will want to follow up with you on the outcome of the pregnancy and will ask for your permission to collect information on the baby.
- For men: If your partner is pregnant or able to become pregnant, you must use a condom during the study and for [redacted] after your final dose of GDC-8264. You must not donate sperm during this same period. Tell your study doctor right away if your partner gets pregnant during this period. The study doctor may ask you and your partner for permission to collect information about the pregnancy and the baby. No matter what you and your partner decide, you can continue to take part in this study.

- Certain medications should not be used during this study. Your study doctor will talk to you about these medications. You should talk to your study doctor before starting any medications, vitamins, or other supplements (including vaccines, topical medications, or herbal remedies), even if they don't need a prescription.

1.7 WILL I BE PAID TO PARTICIPATE?

{If participants will not be paid, include the following:}

You will not be paid for taking part in this study.

{If participants will be paid the same amount per visit, include the following:}

You will be paid {per visit amount} for each visit that you complete, {including} ***[or]*** {not including} the screening visit.

{If participants will be paid a varying amount per visit, include the following text and a payment schedule (see sample schedule):}

You will be paid for each visit you complete, according to the following schedule:

{Sample payment schedule:}

{Visits (e.g. Screening visit and Days XX, XX, and XX)}	${amount} per visit
{Visits (e.g. Days XX, XX, and XX)}	${amount} per visit

{If reimbursement for travel expenses is allowed, include the following:}

You will be reimbursed for your reasonable costs (for example, transportation, parking) to travel from your home to the study site.

Information from this study, including information from research on your samples, may lead to discoveries, inventions, or development of commercial products. You and your family will not receive any benefits or payment if this happens.

1.8 WILL IT COST ME ANYTHING?

While participating in this study, you will not have to pay for drugs or procedures that are required only for this study and are not part of your regular medical care. {Responsible party [e.g., "You or your health plan"]} will have to pay for medicines and clinic, hospital, and doctors' services that are part of your regular medical care.***{Delete the following for sites not requiring this language:}*** Some health plans will not pay for medications or procedures for people participating in research studies. Your study doctor can find out what your health plan will pay for.

1.9 WHAT HAPPENS IF I AM INJURED?

If you get injured because you took part in this study, contact your study doctor as soon as possible at {telephone number}. Your study doctor will explain your options and tell you where to get treatment.

Genentech will pay for reasonable costs of immediate care for any physical injury that results from the study drug but only if all of the following are true:

- Genentech and the study doctor agree that your injury resulted from the study drug and not from a preexisting medical condition
- The costs are not paid for by your medical insurance
- Your injury was not because you or the study team did not follow instructions

You will not receive any other kind of payment.

If you get injured in this study, you will not lose any of your legal rights to seek payment by signing this form.

1.10 CAN I STOP BEING IN THE STUDY?

You can leave this study at any time. Tell your study doctor if you are thinking about stopping, and your study doctor will tell you how to stop safely. If you leave this study, you will not lose access to any of your regular care.

If there are important new findings or changes in this study that may affect your health or willingness to continue, your study doctor will let you or your legally authorized representative know as soon as possible.

You may be required to stop participating in the study, even if you wish to continue. Below are some of the reasons why you may be asked to stop:

- Your safety would be at risk if you continued
- You were unable to or did not follow study instructions or procedures
- You need medical care that is not allowed by this study
- This study has been stopped by Genentech or a health authority

When your participation ends, no new information will be collected about you with *three exceptions: 1) if you experience a side effect after the study that is believed to be related to GDC-8264, the study doctor may report the side effect to Genentech, 2) information may be obtained from records available to the public to help track the course of your disease, and 3*) any laboratory samples collected prior to stopping may still be tested, unless you specifically ask for your samples to be destroyed. However, Genentech will still be able to use information that was collected prior to stopping, including information from samples that were tested prior to stopping.

SECTION 2: STUDY DETAILS

{Table of contents may be deleted to reduce length of consent form}

2.1 STUDY TREATMENT RISKS

Risks Associated with GDC-8264

GDC-8264 has had limited testing in humans. In the first study in healthy volunteers, 55 people received GDC-8264 and the most common side effects observed (reported by 5 people or more) were, headache, dizziness, rash or skin reactions, sleepiness, abdominal pain, diarrhea, nausea, and catheter-site bruising. Of these, the most common side effect was headache, which was reported by 20% of the healthy volunteers (11 out of 55 people) who received GDC-8264. All side effects were mild to moderate in severity. Potential side effects, based on human and animal studies or knowledge of similar drugs, are convulsion and increased risk of bacterial or viral infection. There may be side effects that are not known at this time. You will be closely monitored for potential side effects while participating in this study.

2.2 STUDY PROCEDURES AND POTENTIAL RISKS

Procedures with associated risks are listed below. The study doctor will provide more detailed information about the risks and their frequency.

Procedures with Associated Risks		
Procedure	Approximate Timing	Potential Risks
Blood sample (about 1–3 tablespoons at each visit)	• Screening • Multiple times on *two days* • Once a week while you are receiving GDC-8264 • Twice during follow-up	Drawing blood can cause pain, bruising, or infection where the needle is inserted. Some people experience dizziness, fainting, or upset stomach when their blood is drawn.
Mouth swab	• Day 1	A mouth swab could be painful if your mouth is inflamed due to your acute GVHD. Your study doctor may wait to take the mouth swab once your mouth has begun to heal.

Non-invasive procedures with minimal risks are listed below.

Non-Invasive Procedures with Minimal Risks	
Procedure	Approximate Timing
Review of medical history, including medications	• Screening
Recording of demographic information, such as age, sex, race/ethnicity	• Screening
Vital signs: temperature, pulse rate, blood pressure, breathing rate	• Screening • Every 2 weeks during the treatment period • [redacted] your final dose of GDC-8264
Complete or limited physical examination (may include height or weight)	• Screening • Four times during the treatment period • [redacted] your final dose of GDC-8264
Neurological examination	• Screening • Three to five times during the treatment period • [redacted] your final dose of GDC-8264
Electrocardiogram (ECG): measures electrical activity of your heart	• Screening • Two to three times during the treatment period
Assessment of disease status	• Screening • Every visit
Review changes in your health or medications	• Every visit
Urine sample (if you can become pregnant)	• Once during the treatment period • [redacted] your final dose of GDC-8264
Follow-up after you discontinue treatment: telephone call or clinic visit to check your health and find out if you are taking any anti-cancer drugs	• [redacted] after your final dose of GDC-8264 • [redacted]

2.3 ACCESS TO STUDY DRUG AFTER COMPLETING THE STUDY

Currently, Genentech does not have any plans to provide the Genentech study drug (GDC-8264) or any other study treatments to you *or other participants* after you complete the study.

2.4 USE AND HANDLING OF LABORATORY SAMPLES

Sample Use

Blood and tissue samples will be collected for reasons such as the following:

• Check your health through standard laboratory tests • Find out if you are pregnant • Check how quickly your blood clots • Find out how GDC-8264 is processed by your body	• Perform additional analyses related to processing of GDC-8264 • Find out how variations in biomarkers (such as proteins or genes) affect your disease or your response to GDC-8264

{Include the following if the site allows screening samples from individuals who do not enroll in the study to be used for additional research related to the disease and the development of disease-related tests or tools:} blood samples collected at screening may be used for research related to your disease and the development of tests or tools that help with detecting or understanding your disease, even if you are not eligible for or decide not to take part in this study, unless you specifically ask for your samples to be destroyed.

Tissue samples may be collected during routine clinical procedures, such as skin biopsy or intestine biopsy (done by endoscopy or colonoscopy), for diagnosis and management of your acute GVHD (in other words, not only for this study). If these tissue samples are collected, and only when they are no longer needed for your clinical care, they will be shared with Genentech. These leftover (unused) tissue samples may include any that were collected from up to 2 weeks before the study or obtained during the study. The tissue samples will be used to learn more about your disease or your response to GDC-8264.

Genome Testing

{If IRB/EC has <u>not</u> granted approval for collection of buccal scraping samples for whole genome sequencing (WGS) or whole exome sequencing (WES) (as described in Section 4.5.11} of the protocol), delete the entire "Genome Testing" section. If IRB/EC has granted approval for collection of buccal scraping samples for WGS or WES, include the following:}Biomarker testing may involve analysis of your genome (DNA), an "instruction book" for the cells in your body. Tissue samples from your mouth (taken with a mouth swab) may be tested for inherited genome variations associated with acute GVHD. Testing may include analysis of all of your DNA (whole genome sequencing) or analysis of all of your DNA that codes for proteins (whole exome sequencing). Analyses of samples from a large number of people may help researchers learn more about GDC-8264 and similar drugs, acute GVHD and other diseases, possible links among diseases, genome variations and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalized therapies.

Sample Storage

Samples will be securely stored for a defined period (as described below) and will then be destroyed, with one exception: Leftover tissue samples from a previous biopsy or biopsy during the study and subsequently shared with Genentech will be returned to your doctor upon request or no later than 5 years after the final study results have been reported.

{If IRB/EC has granted approval for collection of buccal scraping samples for WGS or WES, include the following:}

Samples will be stored for up to 5 years after the final study results have been reported, with the following exceptions:

- ***{If the site does not require a defined storage period for WGS or WES samples, include the following:}*** Samples for whole genome sequencing or whole exome sequencing will be stored until they are no longer needed or until they are used up.
- ***{If the site requires a defined storage period for WGS or WES samples, include the following:}*** Samples for whole genome sequencing or whole exome sequencing will be stored for up to 15 years after the final study results have been reported.
- Samples for biomarker testing will be stored for 10 years after the final study results have been reported.

{If IRB/EC has not granted approval for collection of buccal scraping samples for WGS or WES, include the following:}

Samples will be stored for up to 5 years after the final study results have been reported, with the following exception:

- Samples for biomarker testing will be stored for 10 years after the final study results have been reported.

2.5 PROTECTION, USE, AND SHARING OF INFORMATION

During this study, health and personal information ("information") about you will be collected. This section describes the protection, use, and sharing of your information, which consists of the following:

- Information in your medical record, which is held by {Study Site} ("study site")
- Information (including imaging data) that is collected or produced during this study ("study data"), which is held by the study site, Genentech, other Roche affiliates, Genentech's collaborators, and Genentech's representatives (people and companies who work for Genentech)

Your privacy is very important, and Genentech uses many safeguards to protect your privacy, in accordance with applicable data privacy laws and laws related to the conduct of clinical trials.

Your study data and samples will be labeled with a participant identification (ID) number that is unique to you and not related to or derived from information that identifies you (such as your name or any other personally identifying information). Genentech, other Roche affiliates, Genentech's collaborators, and Genentech's representatives will only have access to study data and samples labeled with a participant ID number, except when accessing your medical record under certain circumstances, as described below:

Your information (including your medical record, which contains personal information that can identify you) may need to be reviewed to make sure the study is being done properly or to check the quality of the information. This information will be kept private. The following people and groups of people may review ***{If copying of information is not allowed, delete "and/or copy":}***and/or copy this information:

- Authorized individuals (such as study monitors and auditors) representing Genentech and Genentech's collaborators and licensees (people and companies who partner with Genentech)
- The Institutional Review Board or Ethics Committee (people responsible for protecting the rights and safety of people who take part in research studies)
- Regulatory authorities (government agencies involved in keeping research safe for people)

Genentech, other Roche affiliates, and Genentech's collaborators and licensees may use study data labeled with your participant ID number. Your study data may also be shared with independent researchers or government agencies, but only after personal information that can identify you has been removed. Your study data may be combined with other people's data and/or linked to other data collected from you. Your study data may be used to help better understand why people get diseases and how to best prevent, diagnose, and treat diseases, and to develop and provide access to new medicines, medical devices, and health care solutions.

Your information will not be given to your insurance company or employer, unless required by law. If the results from this study are published in a medical journal or presented at a scientific meeting, you will not be identified.

Information from this study will be retained by the study site for 15 years after the end of the study or for the length of time required by applicable laws, whichever is longer. In addition, Genentech will retain the study data for 25 years after the final study results have been reported or for the length of time required by applicable laws, whichever is longer.

If a participant is eligible for Medicare, federal law requires Genentech to inform the Centers for Medicare & Medicaid Services (the agency responsible for the Medicare program) when Genentech is going to pay for a participant injury. Genentech may need

to share information, such as your name, date of birth, sex, and Medicare ID number (if you have one), with the Centers for Medicare & Medicaid Services.

{For U.S. sites providing a separate HIPAA authorization, ensure that the authorization includes the following:}

Your health information (including imaging data) may be used or shared for the purposes of this research study and for research related to acute GVHD, common pathways (links) among diseases, the use of experimental drugs in disease therapy, and/or the development of tests or tools that help with detecting or understanding acute GVHD. Your health information may be used by and/or shared with Genentech, other Roche affiliates, Genentech's collaborators and licensees, the Institutional Review Board or Ethics Committee, and regulatory authorities.

{For U.S. sites NOT providing a separate HIPAA authorization, include the following:}

If you sign this consent form, you give permission to the study site to use and/or share your "health information," which includes all information about you that has been and will be collected by the study site (including imaging data) and information in your study site medical record. Your health information may be used or shared for the purposes of this research study and for research related to acute GVHD, common pathways (links) among diseases, the use of experimental drugs in disease therapy, and/or the development of tests or tools that help with detecting or understanding acute GVHD. You do not have to sign this consent form, but if you do not, you cannot take part in this research study.

Your health information may be used by and/or shared with Genentech, other Roche affiliates, Genentech's collaborators and licensees, the Institutional Review Board or Ethics Committee, and regulatory authorities. Your health information and samples may be analyzed in any country worldwide. Those persons who receive your health information may not be required by federal privacy laws to protect it and may share your health information with others without your permission, if permitted by laws that apply to them.

You have the right to see and get a copy of your medical records kept by the study site that are related to the study. However, by signing this consent form, you agree that you generally will not be able to review or receive some of your records related to the study until after the entire study has been completed. This is to protect the scientific integrity of the study.

Your permission to use and share your health information does not have an expiration date.

You may change your mind and take back your consent at any time. If you take back your consent, no new health information will be collected about you. However, Genentech will still be able to use and share any health information about you that has already been collected during this study. To take back your consent, you must do so in writing by contacting your study doctor (see Section 2.8).

2.6 HANDLING OF GENETIC INFORMATION

{If IRB/EC has <u>not</u> granted approval for collection of buccal scraping samples for WGS or WES, delete Section 2.6. If IRB/EC has granted approval for collection of buccal scraping samples for WGS or WES, include the following:}

Testing of your samples may provide information related to your genome ("genetic information"), including information about inherited characteristics. Your samples and genetic information will not be labeled with your name, your picture, or any other personally identifying information. Genentech uses many safeguards to protect your privacy.

{For U.S. sites that have granted approval for collection of buccal scraping samples for WGS or WES, include the following:}

The Genetic Information Nondiscrimination Act generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you on the basis of your genetic information. This act 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
- Employers with 15 or more employees cannot use your genetic information from this research when setting the terms of your employment

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

2.7 STUDY RESULTS

{If IRB/EC has granted approval for collection of buccal scraping samples for WGS or WES, include the following:} You may request access to the genome sequencing data obtained from your blood sample (as described in Section 2.4), if permitted by local law. You must submit any request for access to such sequencing data to your study doctor. This information shared with you and your study doctor may be available in the form of a file of raw genomic sequencing data. This file will not contain any interpretation of your data, and no clinical report will be available. The data will not be included in your medical record. Your blood sample may be tested many years after the study has ended, or may never be tested. This means your genomic sequencing data may not be available at the time of your request, or may never be

available. Genentech will do its best to forward available data, but there is no guarantee that data will be forwarded in response to every request.

{If IRB/EC has granted approval for collection of buccal scraping samples for WGS or WES, include the following:}

Results from exploratory biomarker tests will not be shared with you or your doctor, unless required by law, and will not be part of your medical record, except as described above.

{If IRB/EC has <u>not</u> granted approval for collection of buccal scraping samples for WGS or WES, include the following:}

Results from exploratory biomarker tests will not be shared with you or your doctor, unless required by law, and will not be part of your medical record.

A clinical study report containing the results of this trial will be made available to anyone who requests a copy. Before this report is provided, additional steps will be taken to protect your information from being linked to you.

An easy-to-understand summary of the results of this study will be *made* available *to you. Your study doctor may inform you* about the *availability* of *the summary for this study.* The summary will not include any information that could *be used to* identify *you or any other* study *participants.* Once available, you can *obtain the summary from your study doctor or you may be able to* view the *summary* by entering the study number (GA43861) in the search bar at the following site:

https://forpatients.roche.com/

A description of this clinical trial will be available at 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 this website at any time.

2.8 CONTACT INFORMATION

If you have any questions, contact your study team, listed below:

	Study Doctor	Study Coordinator
Name:		
Address:		
Telephone number:		
Email address:		

If you have any questions about your rights while taking part in this study, call {Study Site}'s Institutional Review Board or Ethics Committee (a group of people who review the research to protect your rights) at {telephone number}:

2.9 OTHER RESEARCH STUDIES

Genentech may inform your study doctor about other Genentech or Roche research studies that might be of interest to you, taking into consideration your medical records and/or information collected as part of this study. If allowed by local laws, your study doctor may contact you in the future to see if you would like to learn more about taking part in a new research study. Taking part in a new research study would be entirely voluntary.

Signature

I confirm that I have read this consent form, or it has been read to me. I understand the information presented and have had my questions answered. I understand that I will be given a copy of all {total number of pages} pages of this form after it has been signed and dated. I agree to take part in this research study as described above and authorize {Study Site} to use and share my information as described in this form.

Participant name (print)	
If applicable – Name of participant's legally authorized representative (print)	Relationship to participant
Participant signature or signature of participant's legally authorized representative	Date

I, the undersigned, have fully explained this informed consent to the participant named above and/or the participant's legally authorized representative.

Name of person conducting informed consent discussion (print)	
Signature of person conducting informed consent discussion	Date
Witness name [a] (print)	
Witness signature [a]	Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).

SECTION 3: CONSENT FOR OPTIONAL COLLECTION AND/OR STORAGE OF SAMPLES FOR THE RESEARCH BIOSAMPLE REPOSITORY AND THE MOUNT SINAI ACUTE GVHD INTERNATIONAL CONSORTIUM BIOREPOSITORY

INTRODUCTION

The Research Biosample Repository (RBR) is a collection of samples that will be tested by researchers during Study GA43861 and for future research. Reasons for testing may include:

- Finding out why certain people are more likely to respond to treatments than others
- Finding out how and why diseases act differently in different people
- Developing new treatments for diseases or medical conditions
- Finding out why certain people are more likely to have side effects than others
- Finding out how treatments are processed in the body
- Finding out how treatments affect the body
- Developing better ways for preventing diseases or treating diseases earlier
- Developing or improving tests or tools that help with detecting or understanding diseases and identifying the right medicine for the right patient

The Mount Sinai Acute GVHD International Consortium (MAGIC) biorepository is a collection of samples that will be tested by researchers during Study GA43861 and for future research on graft-versus-host disease (GVHD).

You are being asked to donate leftover (unused) blood and tissue samples to the RBR and the MAGIC biorepository. MAGIC may share some leftover blood samples and related medical information with independent researchers outside of the consortium, but only for research that MAGIC has approved and after personal information that can identify you has been removed.

Donating your samples to the RBR and the MAGIC biorepository is your choice. No matter what you choose, it will not affect your participation in the main study or the regular care you receive from your doctors.

WHAT WILL HAPPEN IF I PARTICIPATE?

Listed below are the procedures for donating samples, along with any potential risks.

Procedure	Potential Risks
Leftover (unused) blood and tissue samples that were collected during the study (including any additional tissue samples your doctor decided to collect) will be donated to the RBR.	There are no additional risks associated with donating your leftover samples to the RBR.

Leftover (unused) blood samples collected to measure biomarkers for tests used in estimating risk of non-relapse mortality during the study will be donated to the MAGIC biorepository.	There are no additional risks associated with donating your leftover samples to the MAGIC biorepository.

{If the site does <u>not</u> require a defined storage period, include the following:}Samples will be securely stored in the RBR and the MAGIC biorepository until they are no longer needed or until they are used up, and will then be destroyed.

{If the site requires a defined storage period, include the following:}Samples will be securely stored in the RBR and the MAGIC biorepository for up to 15 years after the final study results have been reported, and will then be destroyed.

Testing of RBR samples may involve analysis of your genome (DNA), the "instruction book" for the cells in your body. Your samples may be tested for inherited or non-inherited genome variations, to allow for exploration of broad health research questions across disease areas. Testing may include analysis of all of your DNA (whole genome sequencing) or analysis of part of your DNA. Analyses of samples from a large number of people may help researchers learn more about GDC-8264 and similar drugs, acute GVHD and other diseases, possible links among diseases, mutations and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalized therapies.

ARE THERE ANY BENEFITS TO DONATING SAMPLES?

You will not receive any direct benefit from donating your samples. However, research performed on these samples may benefit patients with acute GVHD or a similar condition in the future.

WILL I BE PAID IF I DONATE SAMPLES?

You will not be paid for donating samples to the RBR and the MAGIC biorepository.

Information from research on your RBR and MAGIC biorepository samples may lead to discoveries, inventions, or development of commercial products. You and your family will not receive any benefits or payment if this happens.

HOW WILL MY PRIVACY BE PROTECTED?

Your samples and information will be labeled with your participant ID number; they will not be labeled with your name, your picture, or any other personally identifying information. Your samples and information will be kept under the same level of privacy used for the main study. Genentech uses many safeguards to protect your privacy.

Information from the analyses will not be given to your insurance company or employer, unless required by law. If the research results are published in a medical journal or

presented at a scientific meeting, you will not be identified. Information from the sample analyses will not be part of your medical record.

Genentech, other Roche affiliates, Genentech's collaborators and licensees, and MAGIC and MAGIC collaborators may study the RBR and MAGIC biorepository samples and information in any country worldwide.

Data from analysis of RBR and MAGIC biorepository samples may be shared with researchers or government agencies, but only after personal information that can identify you has been removed. These data may be combined with or linked to other data and used for research purposes, to advance science and public health, or for analysis, development, testing, and commercialization of products that treat or diagnose disease, or improve patient care. These data will not include information that identifies you.

WILL I HAVE ACCESS TO MY TEST RESULTS?

Information from the sample analyses will not be shared with you or your doctor, unless required by law, except as described below.

You may request access to the genome sequencing data obtained from your RBR blood sample, if permitted by local law. You must submit any request for access to such sequencing data to your study doctor. This information shared with you and your study doctor may be available in the form of a file of raw genomic sequencing data. This file will not contain any interpretation of your data, and no clinical report will be available. The data will not be included in your medical record. Your blood sample may be tested many years after the study has ended, or may never be tested. This means your genomic sequencing data may not be available at the time of your request, or may never be available. Genentech will do its best to forward available data, but there is no guarantee that data will be forwarded in response to every request.

CAN I CHANGE MY MIND ABOUT STORING MY SAMPLES IN THE RBR?

You can change your mind at any time. If you want to withdraw your consent for the RBR and the MAGIC biorepository, tell your study doctor that you no longer want your samples stored or used for research. After you withdraw consent, any samples that remain will be destroyed. If you change your mind and your samples have already been tested, Genentech and MAGIC will still be able to use the results from those tests. If you withdraw or discontinue from the main study, your RBR and MAGIC biorepository samples will continue to be stored and used for research unless you specifically ask that they be destroyed.

Signature

I willingly consent to allow my samples to be stored in the RBR and the MAGIC biorepository and used for the research described above.

Participant name (print)	
If applicable – Name of participant's legally authorized representative (print)	Relationship to participant
Participant signature or signature of participant's legally authorized representative	Date

I, the undersigned, have fully explained this informed consent to the participant named above and/or the participant's legally authorized representative.

Name of person conducting informed consent discussion (print)	
Signature of person conducting informed consent discussion	Date
Witness name [a] (print)	
Witness signature [a]	Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).