NCI Protocol #: 10434
Protocol Version Date: March 03, 2025

Protocol Title: Randomized Phase 2 Study of CPX-351 + Pomalidomide versus CPX-351 in Newly Diagnosed AML with MDS-Related Changes

Informed Consent Version Date: March 03, 2025

The summary of changes table below provides a detailed summary and rationale for all changes to the treatment consent form for protocol #10434, from amendment 11 (Version 07/11/2023) to amendment 12 (Version 03/03/2025). The amendment is being submitted to make additional modifications.

SUMMARY OF CHANGES -CONSENT FORM: SCREENING

I. Changes to the consent per Protocol Amendment 11

Summary of changes for Amendment #12 version 03/03/2025		
#	**Section**	**Comment**
1.	General	The protocol version date was updated to "03/03/2025".
2.	Medical Information	Updated organization information to include Baylor College of Medicine
3.	Eligible Participation	Updated biobank information to include UNC-Chapel Hill

Research Study Screening Informed Consent Document

Study Title for Participants: Comparing the Addition of an Anti-Cancer Drug, Pomalidomide, to the Usual Chemotherapy Treatment (daunorubicin and cytarabine liposome) in Newly Diagnosed Acute Myeloid Leukemia with Myelodysplastic Syndrome-Related Changes

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol 10434, Randomized Phase 2 Study of daunorubicin and cytarabine liposome + Pomalidomide versus daunorubicin and cytarabine liposome in Newly Diagnosed AML with MDS-Related Changes, (NCT#TBD)

Overview and Key Information

What am I being asked to do?

We are asking you to undergo screening in order to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have acute myeloid leukemia with myelodysplastic syndrome-related changes or acute myeloid leukemia after previous chemotherapy or radiation treatment. Myelodysplastic syndromes occur because the bone marrow cells do not develop into mature blood cells and stay within the bone marrow in an immature state.

Taking part in this study is your choice.

You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the screening. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this screening study being done?

The purpose of the associated clinical trial is to evaluate the addition of the study drug pomalidomide to the usual treatment, daunorubicin and cytarabine liposome to see if it will improve the treatment responses in acute myeloid leukemia (AML). In order to participate in this treatment trial, we will need to make sure your AML is the correct type to be eligible for the main study. Your doctor will inform you of the results, and if your AML has the genetic changes

required for the main study, he or she will discuss the clinical study in more detail and present you the study informed consent as a separate document.

There will be about 131 people taking part in the screening study with about 78 people taking part in the treatment trial.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this screening?

If you decide to take part in this screening, you will receive a bone marrow aspirate and biopsy to confirm whether or not you may be eligible for the study. If you are eligible for the study and choose to participate then you will sign a separate informed consent document for the clinical trial. The screening will allow us to collect the necessary information from your bone marrow aspirate and biopsy to determine if you may be eligible for the study.

What are the risks and benefits of taking part in this screening study?

There are both risks and benefits to taking part in this screening study. It is important to think carefully about these as you make your decision.

Risks

If you choose to take part in this study, there is a risk that you may be asked sensitive or private questions which you normally do not discuss

Bone Marrow Aspirate Risks

The risks associated with having extra bone marrow aspirate collected during the bone marrow biopsy is minimal. The amount of pain and discomfort will depend on your pain tolerance, which differs from person to person. Some patients describe a sharp pain in the bone or leg or lower back; others say it feels like a long hard punch or kick. This usually lasts only a few seconds during the actual procedure. Tenderness over the area may last for a few days. Bleeding from the site or infection may occur but is rare.

Genetic Testing Risks

The genetic test used in this study will test your tumor for genetic changes in your bone marrow. This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

Benefits

This screening study will help determine whether you could be eligible for the main drug study. Otherwise, there will be no benefit to you.

If I decide to take part in this study, can I stop later?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so testing on your sample can be stopped. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

What is the purpose of this study?

The purpose of this study is to compare the usual treatment alone to using pomalidomide plus the usual treatment. The addition of pomalidomide to the usual treatment could help treat your cancer. However, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better than the usual approach. To decide if it is better, the study doctors will be looking to see if the pomalidomide increases the response of patients to therapy compared to the usual approach.

This chemotherapy drug, pomalidomide, is already approved by the FDA for use in multiple myeloma. There will be about 78 people taking part in this study.

How long will I be in this screening study?

You will be part of the screening study for only the time required to perform the test to determine the type of your AML. Your sample will be sent to a local laboratory for testing. It may take up to 1-2 weeks to get the full results to determine whether you are eligible for the study. Your study doctor will discuss them with you at that time.

What are the study groups?

The screening study does not have any study groups.

More details will be provided to you in the main study consent if you have the type of AML required for this study.

What extra tests and procedures will I have if I take part in this screening study?

You will be asked to provide an extra bone marrow sample of the liquid part of the bone marrow (called an aspirate) during your standard of care bone marrow biopsy. Allowing researchers to collect an extra bone marrow sample for prescreening purposes as part of a routine bone marrow biopsy procedure will prevent you from having to have an additional bone marrow biopsy

procedure solely for the purpose of the main study. This is mandatory in order to participate in the main trial.

What are my rights in this screening study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

What are the costs of taking part in this screening study?

You and/or your health plan/insurance company will have to pay for the bone marrow biopsy and blood collections completed during the screening as per your routine care.

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

What happens if I am injured or hurt because I took part in this screening study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study treatment now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.

- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The University of North Carolina at Chapel Hill,Johns Hopkins University, and Baylor College of Medicine.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*)

What if I am not eligible to participate in the main study?

Once the results from your test come back and are discussed with you, you may not be eligible for the main study. If you are NOT eligible for the main study, you have the choice to allow your tissue and information that was collected for this study, to be used for future research or have your tissue and information destroyed.

If you chose to allow your tissue to be used for future research, this tissue would be stored until used. Storing samples for future studies is called "biobanking." The biobank is being run by Johns Hopkins University and The University of North Carolina at Chapel Hill and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your bone marrow samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Please indicate if you will allow your tissue and information to be used in future research.

____YES, if I am not eligible for the main study, my tissue and information can be used for future research

____NO, if I am not eligible for the main study, my tissue and information may not be used for future research.

Conflicts of Interest

Joshua Zeidner, the Principal Investigator on this study, receives money from Bristol Myers Squibb for work that is not part of this study. These activities may include consulting or serving on advisory boards. If you would like more information, please ask the researchers listed on the first page of this form.

My signature agreeing to take part in the screening study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature