EFFECTIVE

5/25/2021

MCW/FH IRB

Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

IIT-Michaelis: A multi-institutional, phase IV project to study the feasibility of safely managing patients receiving induction with liposomal daunorubicin and cytarabine (CPX-351) for acute myeloid leukemia (AML) in an outpatient environment

Caregiver Consent

Laura Michaelis, M.D.
Department of Medicine
Division of Hematology and Oncology
Medical College of Wisconsin & Froedtert Hospital
9200 W Wisconsin Ave
Milwaukee WI 53226
414-805-6700

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

CPX-351 – also called Vyxeos, an FDA approved induction therapy for AML

Induction Therapy – the first treatment given for a disease

Inpatient/Outpatient – describes the location where you stay after receiving your treatment, in the hospital (inpatient) or at home (outpatient)

Count Recovery – when the blood cell counts, including your infection-fighting cells and bleeding-prevention cells, return to safe levels

EFFECTIVE

5/25/2021

MCW/FH IRB

Purpose

This project is being done to study the drug CPX-351 when given in an outpatient setting and to assess the quality of life and management of health-related issues for you and the individual you provide care for.

Length

- You will be in this research project for about 3 months.

Procedures *or* Activities

List of visits:

- You will need to come with the patient to all of their visits. For a full list of visits for the individual you provide care for, please see the full list included later in this document.
- Questionnaire visits (these will take place during the patient visits listed above)
  - Total Number: 4 visits
  - Total Time: 15-30 minutes per visit

Procedures/Activities that will occur at various visits:

Non-invasive Procedures/Activities

- Questionnaires

Risks

This is a brief list of the most commonly seen side effects/risks. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Questionnaire risks:

- You may feel uncomfortable answering some questions.
- Your answers are confidential, but there is a risk that your answers could be read by people who should not read your personal information.

My Other Options

You do not have to join this project. You are free to say yes or no.

Benefits

This project will not help you, but we hope the information from this project will help us develop a better treatment strategy for individuals with AML and their caregivers.

If you have more questions about this project at any time, you can call Dr. Michaelis at 414-805-6700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are invited to participate in this research because you provide care for an individual who has been newly diagnosed with acute myeloid leukemia (AML) or AML with myelodysplastic-related changes and is eligible for treatment with CPX-351 therapy.

A total of about 120 participants and 120 or more of their caregivers are expected to participate in this research nationally including about 20 participants and 20 or more of their caregivers at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Laura Michaelis, MD in the Department of Medicine. A research team works with Dr. Michaelis. You can ask who these people are.

Jazz Pharmaceuticals, a drug company, is funding the research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

CPX-351, an induction treatment for AML is approved by the U.S. Food and Drug Administration. Traditionally, treatment is provided in an inpatient environment where patients stay in the hospital for between three to five weeks. This study is designed to assess CPX-351 given in an outpatient setting where treatment is given in the hospital, but the patient goes home every day after the treatment is completed. Patients continue in that setting as long as they respond well and are considered safe to be treated as an outpatient.

The purpose of this project is to study the feasibility of giving CPX-351 to adult patients with AML as an outpatient therapy. This study will also monitor the experiences of both you and the individual you provide care for on the management of side effects and their quality of life.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

Before any study tests or procedures are done, you will be asked to sign this consent form. The study doctor will discuss the study with you and answer your questions.

Screening procedures:
The screening procedures and assessments must be completed prior to starting the study treatment to confirm that you are eligible for this study.

Nurse Teacher Program
You and the individual you provide care for will be enrolled in an education program, Nurse Teacher training. This must be completed 7 days prior to treatment. The Nurse Teacher training will provide education on the outpatient management program including the completion of

subject diaries that will allow patients to keep track of their symptoms and temperature on a daily basis.
If the screening information, including the completion and understanding of the Nurse Teacher Program shows that you meet the requirements of the study, then you will be able to start the study. If the screening information shows that you cannot be in the research study, the study doctors will discuss other options with you.

Clinic Visits
You must come with the patient to all study visits.

- During treatment: days 1, 3, 5, and 6
- Then three times a week until count recovery or until day 60 (whichever is first)
- Then monthly at day 30, 60 and 90.

If the patient experiences any side effects, they may need to come to the clinic for additional visits.

You must reside with the patient for the length of this study, which is until the patient has their cell counts recover or 90 days after treatment, whichever comes first.

Study Questionnaires
You will be asked to complete questionnaires with a member of the study team asking about the symptoms and health of the patient you care for at the following time points:

- The first day of treatment for the individual you provide care for; this will be done with a member of the study team (Day 1)
- Once between Days 7-10
- Day 30
  Day 60

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for about 3 months.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

If you decide to leave the project, the research subject will need to select a new caregiver in order to continue in the project.

The research investigator may stop your participation in the project at any time for any reason without your consent. Your doctor will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. (If you become upset, please let us know and we can give you information about individuals who may be able to help you.)

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C2. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project will not help you, but we hope the information from this project will help us develop a better treatment for patients with AML and provide better health services for their caregivers.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. Michaelis.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will not be paid for participating in this project.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about CPX-351 that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

When research data is collected and analyzed , there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research data. The results of your research data will be placed in your medical record.

The results from the data we collect in this research study are the same quality as what you would receive as part of your health care. The data will be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

D5. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Michaelis, 414-805-6700.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate-Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this project is:

- Health information collected during this project, such as questionnaires

E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who don't work at MCW/Froedtert Hospital because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

- The U.S. Department of Health & Human Services (DHHS)
- Jazz Pharmaceuticals and its affiliates, representatives, contractors, collaborators and licensees
- The Office for Human Research Protections (OHRP)
- Other government agencies in this or other countries
- The designated Data Safety Monitoring board and Institutional Review Board which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner, and Privacy Boards and their related staff that have oversight responsibilities for this study.
- Personnel from the study site that provide study related treatment, procedures, or audits
- Those required by law

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to:

Laura Michaelis, MD
Froedtert Hospital & the Medical College of Wisconsin
Division of Hematology and Oncology,
9200 W Wisconsin Avenue
Milwaukee, WI 53226

The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document, including Appendix 1. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Witness *please print*	**Signature of Witness**	**Date**

Rationale for Use of Witness

☐ Subject has limited/no literacy
☐ Subject has limited English proficiency
☐ Subject has limited/no vision
☐ Sponsor requirement
☐ Other _____

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*

EFFECTIVE

5/25/2021

MCW/FH IRB

Appendix 1: Example of Visit Schedule

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
	LABS/Vitals Visit with MD or APP Day 1: TREATMENT	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Physical Assessment by MD or APP TREATMENT	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Physical Assessment by MD or APP TREATMENT	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic
LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP; Quality of Life Surveys	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic		LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic
PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	
LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Bone Marrow biopsy	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic		LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic
PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	