Study Title:	VICCHEM2163: Phase 2 study of decitabine and cedazuridine in combination with venetoclax for AML relapse after allogeneic hematopoietic cell transplantation
Version Date:	2022DEC21 NCT05799079
PI:	Sanjay Mohan, MD

Name of participant:_____ Age:_____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The purpose of this research study is to find out if a drug called DEC-C (also known as ASTX727), combination of decitabine [35 mg] and cedazuridine [100 mg], to be given with a drug called venetoclax, is effective at treating people who have Acute Myeloid Leukemia (AML) that came back after an allogeneic hematopoietic cell transplantation.

If you enroll on this study, you will take drugs orally and have up to two cycles of pre-remission therapy and several cycles of post-remission therapy, depending how well your body reacts to the treatment. You will have tests, exams and procedures, including bone marrow biopsies and blood draws, that are part of your standard care. You will also have bone marrow biopsies and genetic testing done for study purposes. Each clinic visit will last several hours.

There are risks to this study drug that are described in this document. The most frequent risks associated with this treatment regimen are: low white and red blood cell counts, low number of platelets, tiredness, nausea, constipation, diarrhea, decreased appetite, and fever with a dangerously low white blood cell count. Many people with acute myeloid leukemia already have these signs/symptoms.

If you are interested in learning more about this study, please continue reading below.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

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You are being asked to take part in this research study because you have Acute Myeloid Leukemia (AML) that came back after you had an allogeneic hematopoietic cell transplantation. The purpose of this study is to learn if the investigational drug DEC-C (also known as ASTX727 or decitabine [35 mg] + cedazuridine [100 mg]) and venetoclax can help your condition when used in combination.

Venetoclax has been approved by the FDA for use in AML and chronic lymphocytic leukemia (CLL). DEC-C has been approved by the FDA for use in MDS. Investigational means that both DEC-C and venetoclax, in combination, is still being tested in research studies and has not yet been approved by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA) for your disease.

There may or may not be a direct benefit to you as a result of your participation in this study. This research may contribute to the understanding of cancer and its treatment and may eventually lead to improvements in treatment.

This research study was developed at Vanderbilt University Medical Center (VUMC). Sanjay Mohan, MD at the Vanderbilt-Ingram Cancer Center (VICC) is the sponsor-investigator of this study. This study is supported by National Comprehensive Cancer Network (NCCN)through a grant from Taiho Pharmaceutical Co., Ltd (Taiho). Personal information being collected as part of this study may be shared with NCCN and Taiho. Neither NCCN or Taiho are sponsors of this study.

Choosing to participate in this study will mean you are choosing to receive the standard treatment for your disease (venetoclax) in combination with an investigational agent (DEC-C). There may be other treatment options that are available to you, including receiving only the standard therapy. You should speak to your doctor about all of your treatment options prior to deciding to participate in this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

If you decide you would like to take part in the study and you sign this informed consent form, you will have screening tests and procedures done to make sure you are eligible to participate.

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Screening

The following must be completed ≤ 14 days prior to your first dose of study treatment:

- You will be asked questions about your past and current health including any past treatments for your condition, and any ongoing medical conditions you may have
- You will be asked about any medications you are currently taking
- You will have a physical exam and a measure of your vital signs including height and weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- 12-Lead Electrocardiogram (ECG) to check the electrical activity of your heart, using 12 sticky pads attached to the surface of your skin.
- If you are female with the potential of becoming pregnant, you will have a pregnancy test. This may be a blood test or a urine test
- Urine will be collected to check your organ function
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements and minerals in your blood)
- Blood will be drawn (about 4 tablespoons) for research testing:
  - Pharmacodynamic (PD) blood draw. Pharmacodynamic testing is done to test the effects of drugs in your system.
- You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

Pre-treatment

- Prophylactic hydration treatment to prevent tumor lysis syndrome (TLS) at least 2-3 days prior to the start of therapy
- Laboratory monitoring for TLS will occur prior to the first dose on cycle 1 day 1. Blood will be drawn (about ½ tablespoon) to check TLS laboratory studies.

Treatment

Cycle 1 Study Treatment:

- Prophylactic hydration treatment to prevent tumor lysis syndrome (TLS) on days 1-3
- Treatment with DEC-C will begin on Cycle 1 Day 1 after receiving anti-TLS hydration/prophylaxis. DEC-C is taken with food at the same time each day.
- Venetoclax will begin on Cycle 1 Day 1 after receiving anti-TLS hydration/prophylaxis. Venetoclax dosing is ramped to 400mg/day over three days, followed by continuous once daily oral dosing. Venetoclax is taken with food at the same time each day.

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On some of your clinic visit days, you will be asked not to take study drug until after you have had your blood drawn. The study staff will go over this with you.

You will come to the clinic multiple times during each 28-day cycle for your study treatment and for procedures and tests. Some of the procedures are being done as part of your routine cancer care. Some are being done because you are participating in this study. You will continue on the study treatments until your disease gets worse, you have intolerable side effects, you decide to stop, or your doctor decides it would be in your best interest to stop.

You will be given a dosing diary in which to record your doses of DEC-C and venetoclax. You will be asked to record the time you take your pills each day and the reason for any missed doses. You will be asked to bring this diary with you along with all remaining pills to each appointment to review with the study staff.

<u>Cycle 1, Day 1-3:</u>

- On Cycle 1, Day 1 you will be given a pill diary for DEC-C and venetoclax. You will be asked to bring the study treatment containers and dosing diary with you at each visit and compliance with protocol-defined study treatment intake will be checked by pill count and review of the dosing diary
- On Cycle 1, Day 1 only if not performed within seven days prior:
    - Physical exam
    - Performance assessment (your ability to do daily activities)
    - Weight will be obtained
    - Confirmation of a negative pregnancy test is required in all women of childbearing potential prior to beginning protocol-directed therapies.
- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)
- If you are female with the potential of becoming pregnant, you will have a pregnancy test. This may be a blood test or a urine test (if not performed previously within 72 hours of Cycle 1 Day 1)
- During the first three days of therapy, tumor lysis syndrome (TLS) precautions will include scheduled outpatient visits.
- Therapy with a uric acid reducing agent (e.g., allopurinol initiated at least 2-3 days prior to the start of therapy) is required.

- Laboratory monitoring for TLS will continue for the first three days of cycle 1. Blood will be drawn (about ½ tablespoon) to check TLS laboratory studies.
- Unless contraindicated, allopurinol must be continued through the end of cycle 1.
- Intravenous fluids will be administered daily during the ramp-up period.

Cycle 1, Day 5

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)
- Treatment with DEC-C and venetoclax

Cycle 1, Day 8

- You will have a physical exam and a measure of your vital signs including weight
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Cycle 1, Day 15

- You will have a physical exam and a measure of your vital signs including weight
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Cycle 1, Day 22

- You will have a physical exam and a measure of your vital signs including weight
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

- Blood will be drawn (about 4 tablespoons) for research testing:
  - Pharmacodynamic (PD) blood samples to study biomarkers for research. (Biomarkers are biological indicators of how your body and illness may be reacting to the drugs that you are receiving.)
- You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

Pre-remission Therapy, Post-remission Therapy, and Post Treatment for patients with C1D22 Marrow involved

Study Treatment in this phase:

- Venetoclax daily per protocol
- DEC-C (RP2D) Post-remission Cycle 1 D1, 5 per protocol
- DEC-C (RP2D) Post-remission Cycle 2 D1 and beyond per protocol

Pre-remission Therapy – Cycle 2 Day 1

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Pre-remission Therapy – Cycle 2 Day 8

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Pre-remission Therapy – Cycle 2 Day 15

- You will have a physical exam and measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:

- Blood Cell Counts (numbers of each type of blood cell)
- Chemistries (proteins, elements and minerals in your blood)

Pre-remission Therapy – Cycle 2 Day 22

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)
- Blood will be drawn (about 4 tablespoons) for research testing:
  - Pharmacodynamic (PD) blood samples
- You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

Post-remission Therapy C1 Day 1

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C1 Day 5

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C1 Day 15

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing

- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C2 Day 1

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C2 Day 15

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing

Post-remission Therapy C3 and beyond

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

  Cycle 3 Day 1: You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

Post-Treatment End of Treatment less than or equal to 10 days after last study dose

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing

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- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements and minerals in your blood)
- 12-Lead Electrocardiogram (ECG) to check the electrical activity of your heart, using 12 sticky pads attached to the surface of your skin.
- If you are female with the potential of becoming pregnant, you will have a pregnancy test. This may be a blood test or a urine test
- Urine will be collected to check your organ function
- At end of treatment or Progressive disease: Blood will be drawn (about 4 tablespoons) for research testing:
  - Pharmacodynamic (PD) blood samples
- At end of treatment or Progressive disease: You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

<u>Post-Treatment Follow Up: 35 days after last study dose</u>

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Chemistries (proteins, elements and minerals in your blood)

<u>Survival follow up</u>

- You will be followed approximately every 3 months for survival status for up to two years after your last dose of study drug. Survival contact can be made via clinic visit, chart review, telephone, or publicly available information.

<u>Pre-remission Therapy, Post-remission Therapy, and Post Treatment for patients with C1D22 Marrow uninvolved</u>

<u>Study Treatment in this phase:</u>

- Venetoclax daily per protocol
- DEC-C (RP2D) Post-remission Cycle 1 D15 per protocol
- DEC-C (RP2D) Post-remission Cycle 2 D1 and beyond per protocol

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Post-remission Therapy C1 Day 1

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C1 Day 5

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C1 Day 15

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C2 Day 1

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

Post-remission Therapy C2 Day 5

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

<u>Post-remission Therapy C2 Day 15</u>

- You will have a measure of your vital signs
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

<u>Post-remission Therapy C3 and beyond</u>

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)
- Cycle 3 Day 1: You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

<u>Post-Treatment End of Treatment less than or equal to 10 days after last study dose</u>

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Coagulation (how your blood clots)
    - Chemistries (proteins, elements and minerals in your blood)

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- 12-Lead Electrocardiogram (ECG) to check the electrical activity of your heart, using 12 sticky pads attached to the surface of your skin.
- If you are female with the potential of becoming pregnant, you will have a pregnancy test. This may be a blood test or a urine test
- Urine will be collected to check your organ function
- At end of treatment or Progressive disease: Blood will be drawn (about 4 tablespoons) for research testing:
    - Pharmacodynamic (PD) blood samples
- At end of treatment or Progressive disease: You will have a bone marrow biopsy or aspirate for disease assessment and for determination of cancer-associated mutations.

Post-Treatment Follow Up: 35 days after last study dose

- You will have a physical exam and a measure of your vital signs including weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- You will be asked about any medications you are currently taking
- You will be asked how you feel and about any side effects you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
    - Blood Cell Counts (numbers of each type of blood cell)
    - Chemistries (proteins, elements and minerals in your blood)

Survival follow up

- You will be followed approximately every 3 months for survival status for up to two years after your last dose of study drug. Survival contact can be made via clinic visit, chart review, telephone, or publicly available information.

Side effects and risks that you can expect if you take part in this study:
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drug(s). In some cases, side effects can be serious, long lasting, or may never go away.

Risks and side effects related to **Venetoclax (also known as ABT-199 and Venclexta)** include those which are:

Side effects observed in patients receiving Venetoclax

Tumor Lysis Syndrome (TLS).
Treatment with venetoclax sometimes leads to tumor lysis syndrome (TLS). TLS can occur when cancer cells break down rapidly and your body can not get rid of the broken-up cancer cells quickly enough. Sometimes your body, especially the kidneys, can't remove these cell parts quickly enough, so the level of some salts and acids can rise. TLS has been more commonly seen in patients with blood cancers such as chronic lymphocytic leukemia or mantle cell lymphoma than in other cancer types and is most likely to occur in the beginning of venetoclax treatment. TLS can lead to serious problems, including effects on the kidneys, heart, or brain, and may result in needing kidney dialysis (a special machine to remove toxins from the blood) or lead to death. Depending on the type and size of your tumor and on your kidney function, you may need to drink plenty of fluids, take medications to help the body get rid of salt, chemicals or broken up cancer cell parts, and/or be hospitalized before starting venetoclax. Treatment with venetoclax may be started at a low dose to be gradually increased over days or weeks. If you develop TLS, your urine may look dark, thick, or cloudy. You may experience fever, chills, nausea (feeling sick to your stomach), vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, unusual tiredness, muscle pain, joint discomfort and/or seizure. If you notice any of these, notify your study doctor or nurse right away. Blood tests have shown TLS in some patients after receiving the initial dose of venetoclax, or after receiving a higher dose of venetoclax than previously received. In other studies, two deaths in patients with chronic lymphoid leukemia (CLL) who experienced TLS have been reported after receiving venetoclax, and 1 CLL patient with TLS has needed dialysis.

Before starting treatment with venetoclax, your study doctor may ask you to drink plenty of fluids. Your study doctor may give you medications to help the body get rid of the salts or chemical or broken up cell parts from your cancer. In order to help reduce the risk of TLS, you will begin treatment with venetoclax at a low dose. During your first week on the study, your study doctor will gradually increase your venetoclax dose, until you reach the full dose of venetoclax you will receive during the rest of the study. For your safety, your study doctor may decide to admit you to the hospital before or after you start venetoclax, in order to give fluids into your vein, do blood tests, and check for TLS. If you develop TLS, your urine may look dark, thick, or cloudy. You may experience fever, chills, nausea (feeling sick to your stomach), vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, unusual tiredness, muscle pain, joint discomfort and/or seizure. If you notice any of these, notify your study doctor or nurse right away. Your study doctor will closely monitor and treat you as needed to decrease the risk of any serious changes in your blood or other complications of TLS. If blood tests suggesting TLS are seen, extra blood tests or monitoring of your heart rhythm may be recommended by your study doctor.

Low Blood Counts
Anemia (low levels of red blood cells that carry oxygen throughout your body) may occur while taking venetoclax. When treatment with venetoclax is given with other cancer drugs, the risk of anemia may be higher. You may experience weakness or fatigue. If you notice this, notify your doctor. Your study doctor

will take regular blood tests to monitor for these changes. You may require blood transfusion. Decreases in platelets (type of cells which help prevent bleeding) can occur while taking venetoclax. When treatment with venetoclax is given with other cancer drugs, the risk of decrease in platelet may be higher. If you notice any bruising or bleeding, notify your doctor. Your study doctor will take regular blood tests to monitor for these changes. You may require platelet transfusion.

Serious Infections
Infections, including serious infections and some infections leading to death, have been reported in patients taking venetoclax. Your doctor may advise you to take medicines to help prevent some common infections for which you may be at risk. Your doctor may also advise you to take other measures to reduce your chance of developing an infection. If you notice fever or other symptoms of infection, notify your doctor or nurse right away. Other cancers Some patients who have received several previous chemotherapy treatments may develop another cancer. It is unknown if venetoclax has contributed since these types of cancers can happen in people who have not received venetoclax .

The following side effects may happen with when taking venetoclax:
Very common side effects of venetoclax (may affect greater than 10% of patients):

- Upper respiratory tract infection – signs include runny nose, sore throat, or cough
- Pneumonia
- Low number of white blood cells (neutrophils), sometimes with fever. A decreased number of white blood cells may increase your risk of infection including serious infections that may lead to death.
- Diarrhea
- Nausea or vomiting
- Constipation
- Feeling tired
- Low number of red blood cells (anemia). A decreased number of red blood cells may result in weakness and fatigue. In severe cases, a blood transfusion may be necessary.
- A decrease in platelets in your blood can increase bleeding and bruising (thrombocytopenia)
- Abdominal Pain
- Swelling, redness and pain of the mouth (Stomatitis)
- Blood bilirubin increase
- Weight decrease
- Decreased appetite
- Lower level of potassium (hypokalemia)
- Joint Pain (arthralgia)

- Dizziness
- Headache
- Shortness of breath (dyspnea)
- Nose bleeds (epistaxis)
- Low blood pressure (hypotension)

Common side effects of venetoclax (may affect from 1% up to 10% of patients):

- Urinary tract infection
- Very serious infection in your blood caused by a bacteria (sepsis)
- Low number of lymphocytes (another type of white blood cell) A decreased number of white blood cells may increase your risk of infection including serious infections that may lead to death.
- Tumor lysis syndrome (described above; may experience fever, chills, nausea (feeling sick to your stomach), vomiting, diarrhea, confusion, shortness of breath, irregular heart beat, unusual tiredness, muscle pain, joint discomfort and/or seizure.)
- Higher level of phosphorous (hyperphosphatemia)
- Higher level of uric acid/urate (hyperuricemia)
- Higher level of potassium (hyperkalemia)
- Lower level of calcium (hypocalcemia)
- Higher level of creatinine (blood creatinine increase)
- Bacteria in your blood (bacteraemia)
- False sense of spinning (vertigo)
- Feeling of weakness or lack of energy (asthenia)

Venetoclax may be given at the same time as other cancer drugs. If venetoclax and the other cancer drugs have the same side effects, the risk of those side effects may be higher than when venetoclax is given alone.

Unknown Side Effects

Problems and side effects may occur with the use of venetoclax that are not expected or are unknown at this time. You or your legal representative will be informed in writing in a timely manner of any new information or findings that become available that may affect your choice to continue to take part in this study. Side effects observed in pre-clinical studies Side effects that have been seen in pre-clinical studies, are reported below. Some of these side effects have been also observed in clinical trials, where patients with cancer have been treated with venetoclax. It is not clear, at this time, if venetoclax treatment is causing the side effects to happen or if they are caused by other medical conditions that the patients were having at the same time or had in the past.

- Decrease in sperm cells in male dogs. It is unknown how long this decrease may last. It could be permanent. This may affect the ability of a man taking venetoclax to father a child. If you are a man who is planning to have children in the future, you should consider sperm banking before receiving treatment on this study.
- Areas of hair color change (to white or gray) without changes in the skin or eye color.
- Proteins blocked by venetoclax may be involved in protecting the ear against hearing loss. As a precaution, you should wear ear plugs or other appropriate hearing protection when involved in a loud activity. The meaning of these findings in pre-clinical animal (word animal maybe deleted if requested by IRB or site) studies to humans is unclear. You will be watched closely for signs of these and other potential side effects.

Reproductive Risks

Pregnancy and Birth Control

When pregnant animals were dosed with venetoclax, decreased weight or premature loss of the developing baby was observed. It is unknown if any of the effects seen in animals will occur in humans. While participating in this research study, you should not become pregnant. You should not nurse a baby while taking venetoclax because it is unknown if this could affect the baby. Women who are able to have children must use a highly effective means of birth control approved by your study doctor. Some examples of highly effective birth control for heterosexual partners are included in the list below. This list is not exhaustive and patients should discuss with their study doctor which method should be used, based on institutional, hospital and or national guidelines.

- Some examples of highly effective birth control methods include the following:
- Surgical sterilization:
    - For females: bilateral tubal occlusion/ligation at least 1 month before study participation. For studies in Healthy volunteers for at least 3 months prior to study participation. Removal of fallopian tubes, ovaries removed, or uterus removed
- Intrauterine device (IUD) or Intrauterine hormone-releasing system (IUS)
- Hormonal contraceptives (examples include birth control pills, vaginal rings, or patches), associated with inhibition of ovulation for at least 1 month prior to taking study drug. For studies in healthy volunteers, for at least 3 months prior to taking study drug. Please ask your study doctor about specific hormonal contraceptive methods that you can use. Also use a barrier method during this study along with hormonal contraceptives from initial study drug administration to 30 days after the last dose of study drug as drug-drug interaction with venetoclax is unknown.
- Vasectomized partner (provided the partner has received medical confirmation of the surgical success of the vasectomy and is the sole sexual partner of the trial subject)
- Abstinence: refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the subject. Periodic abstinence (e.g., calendar, ovulation, symptothermal

[abstaining from heterosexual intercourse on days that a woman is fertile, or capable of becoming pregnant], post-ovulation methods) and withdrawal are not acceptable.

You must continue the use of birth control during the entire time of your study participation and for at least six months after the last dose of venetoclax. Your study doctor will discuss the need for birth control with you.

If you are a female who has stopped having menstrual periods for at least 1 year (menopause), please discuss the need for birth control with your study doctor. If you become pregnant, you must stop taking venetoclax at once and notify your doctor immediately. You will not be allowed to continue in the study. You may be asked questions about the outcome of your pregnancy and the baby.

Male patients:

You should not father a child while on this study or for 3 months after your last dose of study treatment because the treatments in this study can affect an unborn baby. Participation in this study may affect your ability to father a child. For future childbearing, you should consider banking sperm prior to beginning this study. Due to unknown risks and potential harm to an unborn child/infant, you should not get a partner pregnant while you are getting the study treatment. Male patients must meet 1 of the following conditions:

- Patient is surgically sterile (has had a vasectomy), or patient's sexual partner is post-menopausal or surgically sterile (i.e. patient has had a bilateral tubal ligation, a bilateral oophorectomy, or a complete hysterectomy), or
- Patient agrees to practice effective barrier contraception from the time of signing the informed consent through 3 months after patient's last dose of selinexor or venetoclax (whichever dose occurs last), or
- Patient agrees to practice true abstinence (defined as complete avoidance of heterosexual intercourse), when this is in line with the preferred and usual lifestyle of the patient.

If you are a male, you are responsible for informing your partner(s) that the effects of venetoclax on an unborn fetus or embryo in humans are unknown. If your partner becomes pregnant while you are on study, you must notify your doctor immediately. You and your partner may be asked questions about the outcome of the pregnancy and the baby. Written informed consent for release of medical information from your partner will be obtained prior to collecting any information about the pregnancy and baby.

All patients (male or female):

- You are responsible for informing your partner(s) that the effects of venetoclax on an unborn fetus or embryo in humans are unknown If your partner becomes pregnant during this study, you must tell the study doctor immediately. The study doctor will advise you of the possible risks to your unborn child and discuss options for managing the pregnancy with you. For female patients who become pregnant while on this study, the study treatment will be stopped immediately and the pregnancy will be followed until conclusion. For partners of male patients who become pregnant, the partners will be asked to consent for their pregnancy will be followed until conclusion.

Highly effective methods of contraception (birth control) include:

- Hormonal contraceptives (for example, combined oral contraceptives, patch, vaginal ring, injectables, and implants).
- Intrauterine device or intrauterine system.
- Vasectomy or tubal ligation.

Effective methods of contraception (birth control) include:

- Barrier methods of contraception (for example, male condom, female condom, cervical cap, diaphragm, contraceptive sponge).

Contraception Notes:

- No barrier method by itself achieves a highly effective standard of contraception.
- The proper use of diaphragm or cervical cap includes use of spermicide and is considered one barrier method.
- The cervical cap and contraceptive sponge are less effective in women who have given birth (parous women).
- The use of spermicide alone is not considered a suitable barrier method for contraception.
- When used consistently and correctly, “double barrier” methods of contraception (for example, male condom with diaphragm, male condom with cervical cap) can be used as an effective alternative to the highly effective contraception methods described above.
- Male and female condoms should not be used together as they can tear or become damaged.
- Total (true) abstinence (when this is in line with the preferred and usual lifestyle of the patient), is an acceptable method of contraception. However, periodic abstinence (for example, calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

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Risks and side effects related to DEC-C include those which are:

Very Common (greater than 10% - more than 10 out of 100 people):

- Condition in which the number of white bloods cells called neutrophils is abnormally low. This increases the risk of infection, which may be serious or life-threatening. Symptoms of infection may include fever, pain, redness, and/or difficulty breathing.
- Low number of red blood cells that can causes tiredness and shortness of breath. May require a blood transfusion
- Low number of platelets, which may cause bleeding and bruising. Bleeding may be serious or life threatening and may require a blood transfusion.
- Feeling tired, tiredness, weakness.
- Condition in which the number of white blood cells circulating in the blood is abnormally low. This increases the risk of infection, which may be serious or life threatening.
- Feeling sick to the stomach
- low blood cell counts (white blood cells). A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection).
- Decreased number of blood cells that help to clot blood. This is associated with an increased risk of bleeding.
- Constipation
- Diarrhea
- Fever with low white blood cell count
- Decreased Appetite

Common (greater than 1% but less than 10% - more than 1 but less than 10 out of 100 people)

- Mouth sores; inflammation of the mouth
- Dizziness
- Vomiting
- Alanine Aminotransferase Increased (increase in a type of liver enzymes)
- Aspartate Aminotransferase Increased (increase in a type of liver enzymes)
- Blood Alkaline Phosphatase Increased (increase in a type of liver enzymes)
- Headache
- Shortness of breath
- Lung infection. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and/or difficulty breathing.
- bruising
- Fever
- Weight loss

- Feeling weak and having no energy
- White Blood Cell Count Decreased
- Muscle pain
- Bloody nose
- Decreased number of a type of white blood cells. This is associated with an increased risk of infection.
- Swelling (arm/leg)
- Infection of the skin
- Taste changes which may affect the way foods normally taste
- Very small broken blood vessels in skin or lining of the mouth which may result in bleeding
- A serious condition that occurs in response to an infection that causes widespread inflammation, resulting in poor blood supply to vital organs (Sepsis). Symptoms may in clude a fast heart rate, fever, confusion and rapid breathing. Sepsis can rapidly lead to a life threatening clinical deterioration.
- Urinary Tract Infection
- low blood levels of magnesium (possible weakness, muscle cramps, and/or irregular heartbeat)
- Abdominal Pain
- Heartburn
- mouth blisters/sores
- Dry Mouth
- Night Sweats

Other potentially serious side effects include (not already listed above):

- Due to the decrease in cells that fight infection, you may experience an infection in the lungs (pneumonia) that could lead to shortness of breath. You could also experience an infection in the body that may result in a decrease in blood pressure, your kidneys not working adequately, or your heart suddenly stopping. This is a syndrome of events called sepsis/septic shock.
- Bleeding in the brain. In rare cases, these reactions to DEC-C have been reported:
- Hypersensitivity reaction related to the drug, which could include one or more of the following: rash; hives; swelling of the face, lips, tongue, or throat; and difficulty swallowing or breathing.
- Tumor lysis syndrome: may include nausea, vomiting, diarrhea, muscle cramps, fatigue, decreased urination, irregular heart rate, confusion and increased blood levels of uric acid, potassium, phosphate and low blood levels of calcium, caused by a large number of tumor cells being destroyed.
- Sweet's syndrome (acute neutrophilic dermatosis): a condition that involve s the lungs and may include cough, shortness of breath, fever, and a painful rash on the arms, legs, trunk, face, or neck.

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Previous human studies have been conducted with IV decitabine which is one of the two components of DEC-C, and the adverse events reported are listed below:

In more than 30% (more than 30 out of 100 people) of subjects:

- Decreased platelet blood cells that help your blood to clot which may lead to an increased risk of bleeding
- Decreased red blood cells (also called anemia) which may lead to you feeling tired
- Nausea
- Constipation
- Diarrhea
- Fever
- Increased blood sugar
- Cough
- Small red or purple spots on the skin
- Tiredness

In 20% to 30% (between 20 and 30 out of 100 people) of subjects:

- Vomiting
- Fever along with decreased blood cells that are important in fighting infections
- Decreased blood cells that are important in fighting infections
- Swelling of tissues
- Rigors (a feeling of cold with shivering, with a fever)
- Pneumonia
- Low levels of albumin (a protein) in blood which may be a sign of inflammation, shock or malnutrition
- Low levels of magnesium in blood
- Joint pain
- Headache
- Trouble sleeping
- Bruising of skin
- Pale skin color

The adverse effects of DEC-C are expected to be the same as with IV decitabine, because decitabine is one of the two components of DEC-C. In rare cases, a potentially life-threatening allergic reaction has been seen with IV decitabine.

You may also experience adverse effects that are related to your medical condition and not necessarily to the study drug. As described above, a decrease in certain blood cells may result in severe infection,

bleeding, and possibly death, even with medical care. If you experience fever or other signs and symptoms of infection or bleeding, you should contact your study doctor or study coordinator right away and seek medical attention. If you vomit your tablet or forget to take your tablet, contact your study doctor or study coordinator.

Allergic Reaction to Study Drug

An allergic reaction to the study drugs can occur, which could be life threatening. Signs of allergic reactions include rash, hives, having a hard time breathing, wheezing, sudden change in blood pressure (making you feel dizzy or lightheaded), swelling around the mouth, throat or eyes, fast pulse and sweating. If you think you are having symptoms of a very bad allergic reaction, please get immediate medical help, which may include calling 911. You should inform the study doctor or study staff as soon as possible if you experience any of these side effects.

Risks that are not known:

Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study:

- This research may contribute to a better understanding of cancer and its treatment and may eventually lead to improvements in treatment.

The benefits you might get from being in this study:

- There may or may not be a direct benefit to you as a result of your participation in this study.

You may experience side effects from some of the procedures in this study:

Electrocardiograms (ECGs): To measure your heart rate an electrocardiogram (ECG) will be done. This is a test that records the electrical activity of the heart. You will be asked to lie down and sticky patches will be fixed to your chest. You will be asked to lie still. The sticky pads used for the ECG may cause skin irritation.

Blood samples: When giving blood or when having a cannula inserted in your arm, you may feel faint, or experience mild pain, bruising, irritation or redness at the site. In rare cases, you may get an infection or damage to nerves at the site. A cannula is a small tube that stays in your arm so that you will not need a lot of needle sticks when blood is drawn. Study staff will remove the cannula before you leave the clinic.

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Biopsy Risks: When you have a bone marrow biopsy, your study doctor and the person performing the procedure will explain the procedure to you before it is performed. Bone marrow biopsies typically involve the removal of a small piece of bone and bone marrow by inserting a needle into your hip bone.

Biopsy risks can include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

You may receive an injection of lidocaine to numb the area of the biopsy site. Lidocaine, a numbing drug, may burn or cause a rash, redness, or soreness where you get the shot. There is a risk that this drug may cause problems with heart rhythm.

Privacy Risk:
One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only the principle investigator and their team will have access to your name.

Payments for your time spent taking part in this study or expenses:
You will not be paid for participating in this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for

paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

The study will provide DEC-C.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling may be available through your site's Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the sponsor-Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the sponsor-investigator to pay for any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Sanjay [redacted]. If you cannot reach the research staff, please page the study doctor at [redacted].

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

- The study doctor feels it is not in your best interest to continue in the study,
- You fail to follow the study doctor's instructions,
- You experience an adverse reaction that requires other medical treatment,
- You become pregnant, or
- The sponsor or the FDA or other regulatory authority stops the study for any reason.

If you are removed from the study, the reason will be explained to you.

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What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Clinical Trials Reporting Program.
Vanderbilt's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a unique code instead of your name to help protect your identity. Dr. Mohan, his staff at Vanderbilt University Medical Center and other authorized people will be the only people who know your personal information. Results of this study may be presented in meetings or in publications. Your identity will not be released in those presentations. Your study records will be secured in the clinical trials office. Your research data will be kept for an unknown period of time. Your tissue and blood samples will be kept in locked storage and may be used or stored indefinitely from the end of the study. Any samples that are not needed will be destroyed.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Mohan, and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we l earn of possible harm to yourself or others, or if you need medical help.

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Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:
Results of your treatment will be shared with you by your study doctor. Results of this study may be presented in meetings or in publications. A summary of results will be available on www.clinicaltrials.gov, as required by U.S. Law.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the study sponsor Vanderbilt Medical Center and its agents or contractors, study safety monitors and auditors, data managers and other agents and contractors used by the study team, researchers and study team members. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. Also, your records may be seen by people from regulatory authorities (like the US Food and Drug Administration [FDA]), auditors, and the IRB. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the funder of the study and its agents or

contractors, outside providers, government agencies and other sites in the study, as well as NCCN and Taiho Pharmaceutical Co. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY
I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

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Consent obtained by:

Date	Signature
	Printed Name and Title

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Consent for Genetic Research

The purpose of this part of the study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give biopsy tissue, bone marrow, bone marrow aspirate, and blood for genetic research. With the possible exception of any potential information directly related to managing your disease, what we learn about you from these samples will not be put in your health record. It is possible that information about your disease [i.e. Acute Myeloid Leukemia (AML)] might appear in your health record (if not already in your health record), because your study doctor will likely use this information to understand how your body and your disease react to the study treatment (for example, if you needed a biopsy prior to receiving study treatment, in order to confirm your diagnosis.) No one else (like a relative, boss, or insurance company) will be given your test results.

- A blood sample of 4 tablespoons will be drawn from a vein in your arm using a needle.
- About 2-3 mL of bone marrow tissue will be obtained by bone marrow biopsy.
- Blood will be drawn (about 4 tablespoons) for research testing at five times during the study:
  - Pharmacodynamic (PD) blood samples to study biomarkers for research. (Biomarkers are biological indicators of how your body and illness may be reacting to the drugs that you are receiving.)
- Bone marrow aspirate material (2-3 mL) will be obtained at five times during the study: within 14 days of beginning treatment on this study. Post-enrollment tissue to be collected on Cycle 1 Day 22, Cycle 2 Day 22 (only if C1 Day 22 marrow is involved), post-remission Cycle 3 Day 1 (acceptable windows up to 3 days before or after); and at End-of-Treatment (≤14 days after treatment was discontinued) or at time of suspected progressive disease.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

Bone marrow biopsy: When you have a biopsy, your study doctor and the biopsy doctor will explain the procedure to you before it is performed. Bone marrow biopsies typically involve the removal of a small piece of bone and bone marrow by inserting a needle into your hipbone.

Biopsy risks can include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.
- You may receive an injection of lidocaine to numb the area of the biopsy site. Lidocaine, a numbing drug, may burn or cause a rash, redness, or soreness where you get the shot. There is a risk that this drug may cause problems with heart rhythm.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Mohan will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Mohan at [redacted] to have your sample destroyed and no longer used for research. We will not be able to destroy

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research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer or heart disease).

☐ Yes ☐ No

Signature: _____ Date: _____