THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase II Study of Venetoclax in Combination with 10-day Decitabine in Newly Diagnosed Elderly or Relapsed/Refractory Acute Myeloid Leukemia, Relapsed High-Risk Myelodysplastic Syndrome and Blastic Plasmacytoid Dendritic Cell Neoplasm
2017-0912

Study Chair: Abhishek Maiti

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if venetoclax in combination with decitabine can help to control acute myeloid leukemia (AML), high-risk mylodysplastic syndrome (HR-MDS), high-risk chronic myelomonocytic leukemia (CMML) or blastic plasmacytoid dendritic cell neoplasm (BPDCN) in newly diagnosed elderly patients or younger newly diagnosed AML patients with FLT3 mutations (a genetic change), in newly diagnosed younger patients with poor-risk type of leukemia, or in patients with disease that has relapsed (come back after treatment). The safety of this drug combination will also be studied.

This is an investigational study. Venetoclax and decitabine are FDA approved and commercially available. Venetoclax is FDA approved and commercially available for the treatment of chronic lymphocytic leukemia. Decitabine is FDA approved and commercially available for the treatment of MDS. Venetoclax and 5-day Decitabine combination is FDA approved for elderly patients who are unable to tolerate intensive chemotherapy. It is considered investigational to use venetoclax in combination with decitabine to treat younger AML, CMML, HR-MDS or BPDCN patients and to use 10-day decitabine. The study doctor can explain how the study drugs are designed to work.

The study drugs may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may not want to take part in this study due to the potential for the costs of the study drugs, as well as the inconvenience of having to be hospitalized for at least 3 days and then stay in Houston during the first cycle.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may continue taking the study drugs for as long as the doctor thinks it is in your best interest.

You and/or your insurance provider will be responsible for the cost of venetoclax and decitabine, as well as the cost of hospitalization while you are receiving the study drug(s).

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard chemotherapy. You may choose to receive a hypomethylating agent (such as azacitidine or decitabine) without the addition of venetoclax. The study doctor will discuss the possible risks and benefits of these treatments. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

Within 28 days before your first dose, you will have a bone marrow biopsy and aspirate to check the status of the disease, for biomarker, and for cytogenetic testing. Cytogenetic testing looks at how genetic changes that may be related to the disease can predict how the disease will react to the study drug. To collect a bone marrow biopsy and aspirate, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow is withdrawn through a large needle. If you have BPDCN with skin involvement, you will also have a visual skin exam of the lesions, and full-body CT scan.

Within 14 days before your first dose:

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for routine tests. If you can become pregnant, part of the above routine blood draw or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Up to 440 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

If you are found to be eligible to take part in this study, you will receive decitabine by vein over about 1 hour on Days 1-10 of each 28-day study cycle. Note that the start of future cycles may be delayed if you have side effects to the study drug.

You will take venetoclax by mouth on Days 1-28 of the first cycle and Days 1-21 of all other cycles. Each dose should be taken within 30 minutes after eating a meal (preferably breakfast) with about a cup (8 ounces) of water. If the study doctor thinks it is needed based on any side effects you may be having (such as low blood cell counts and/or infections), your dose(s) of venetoclax may be delayed until it is thought to be safe for you to receive it.

If venetoclax is not available at the start of treatment for any reason (insurance, financial, transportation, and so on), you can begin receiving decitabine and venetoclax can be added when it is available.

During Cycle 1, you will be admitted into the hospital as an inpatient for at least the first 3 days of combination therapy. During this time, you will also be given drugs to prevent tumor lysis syndrome (TLS). TLS happens when breakdown products of the cancer cells entering the blood stream, causing possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage. You may be given fluids (either by mouth or by vein) and treatment with allopurinol or rasburicase. After Day 3, if there is no evidence of TLS, you may be discharged. You will then receive the rest of the study drug doses as an outpatient.

If the study doctor thinks it is in your best interest, you may be able to also receive standard of care therapies (such as sorafenib, midostaurin, imatinib, dasatinib, ponatinib, ivosidenib, enasidenib, ruxolitinib, and so on) while you are on study. The study doctor will discuss these treatments with you, as well as their risks and benefits.

If the study doctor thinks it is needed for your safety, you may also receive cytarabine to help prevent central nervous system side effects. Cytarabine will be given intrathecally (through a spinal tap) on either Day 21 of Cycle 1 or Day 14 of Cycle 2.

You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on the study will be over after the follow-up visits.

Study Visits

On Day 1 of each cycle (+/- 4 days)**,** you will have a physical exam.

One (1) time every week during Cycles 1, 2 and 3, and then on **Day 1 of each cycle after that** (+/- 4 days):

- Blood (about 1 tablespoon) will be drawn for routine tests.
- You will have a bone marrow biopsy and aspirate to check the status of the disease, and for biomarker and cytogenetic testing (Day 14 or 21 [+/- 7 days]). If the study doctor thinks it is needed, this will be repeated on Day 28 (in cycle 1). Additionally, you will have a bone marrow biopsy and aspirate to check the status of the disease, for biomarker and for cytogenetic testing at the end of Cycles 2 and 4, then every 3-4 cycles after that, then at any time that the disease appears to get worse.

BPDCN Patients Only

If there is evidence at screening of lymph node or visceral disease**:**
On Day 28 (+/- 7 days) of Cycles 1, 2, 4, 6, 8 and every 6 months during maintenance, you will have a CT or PET/CT scan. You will continue having these scans until there is evidence of relapsed or progressive disease.

If there is no evidence at screening of lymph node or visceral involvement, **at the end of Cycle 2 (+/- 7 days), 28 days (+/- 7 days) after the start of Cycle 8, and then when the study doctor thinks it is needed,** you will have a CT or PET/CT scan.

If there is evidence at screening of skin disease, **on Day 28 (+/- 7 days) of Cycles 1, 2, 4, 6, 8 and every 6 months during maintenance**, you will have a visual exam of skin lesions. You will continue having these exams until there is evidence of relapsed or progressive disease.

If there is no evidence at screening of skin disease, **at the end of Cycle 2 (+/- 7 days), 28 days (+/- 7 days) after the start of Cycle 8, and then when the study doctor thinks it is needed,** you will have a visual exam of skin lesions.

Additional Research Tests

Blood (about 3 tablespoons) will be drawn for biomarker testing at the following time points (within 24 hours). Biomarkers, which may include genetic biomarkers, are found in the blood and tissue and may be related to your reaction to the study drug:

- Baseline (before the first decitabine dose), about Day 3 of Cycle 1, and between Days 21 to 28 of Cycle 1
- At the end of Cycles 2 and 4
- At any point that the disease appears to get worse

You will have a “cheek scrape” at the end of Cycle 1. These cells will be used to compare to cancer cells to look for effects of the study drug. For this test, a small sample of cells from the inside of your mouth will be collected by scraping a special brush against the inside of your cheek a few times, until enough cells are collected.

End-of-Study Visit

Within 30 days after your last dose of study drug(s):

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for routine tests.
- You will have a bone marrow aspirate/biopsy to check the status of the disease and for biomarker and cytogenetic testing.

Follow-up

If the disease responded to the study treatment, you will then be called every 3 to 6 months for up to 5 years and asked about how you are doing. Each call should last about 15-30 minutes.

You may also be asked to be enrolled on the leukemia department long-term follow-up umbrella protocol (DR09-0223).

Other Information
While taking venetoclax, avoid having any grapefruit, Seville (sour) oranges, star fruit, pomegranate and products containing juices of these fruits.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

Venetoclax and decitabine may each cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. Decitabine may cause long-lasting anemia. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Venetoclax Side Effects

Common (occurring in more than 20% of patients)

• swelling (arm/leg) • fatigue • high blood sugar (possible diabetes)	• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) • diarrhea	• nausea • low blood counts (red, platelets, and white) • abnormal liver tests (possible liver damage) • muscle and/or bone pain • upper respiratory tract infection • cough

Occasional (occurring in 3-20% of patients)

• fever • headache • dizziness • skin rash • vomiting • constipation • abdominal pain • mouth blisters/sores (possible difficulty swallowing) • joint pain	• high blood levels of uric acid (possible painful joints and/or kidney failure) • pneumonia • difficulty breathing • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)	• bacteria in the blood • tumor lysis syndrome (TLS)--breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

TLS is a problem that can occur when cancer cells break down rapidly and the body has to get rid of the broken up cell parts. Sometimes your body, especially the kidneys, cannot remove the cell parts quickly enough, so the level of some of these cell products in your blood, such as salts and acids, can rise. This can happen especially in participants with large tumors or a high number of cancerous white cells in the blood. TLS can lead to serious problems, such as effects on your kidneys and heart (including abnormal heart rhythms), seizures, or even death.

If you develop TLS, your urine may look dark, thick, or cloudy. You may have fever, chills, nausea/vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, fatigue, muscle pain, joint discomfort, and/or seizure. If you notice any of these, tell your doctor or nurse right away. Your study doctor will closely watch and treat you as needed to lower the risk of any serious changes in your blood or other complications of TLS. You may need to have extra blood tests or EKGs to check for signs of TLS.

You should wear ear plugs or other hearing protection when involved in a loud activity.

If you notice any rash, hives, itching, or other signs of an allergic reaction such as swelling, wheezing, or you are having a hard time breathing, tell your doctor right away.

At this time, there are no known serious side effects that **occur in fewer than 3% of patients**.

<u>Decitabine Side Effects</u>

Common (occurring in more than 20% of patients)

• swelling (including arm/leg) • pale skin • fever • fatigue • headache • difficulty sleeping • dizziness • high blood sugar (possible diabetes)	• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) • nausea	• constipation • diarrhea • vomiting • loss of appetite • low blood cell counts (red, white, platelets) • shivering • cough • difficulty breathing • infection

Occasional (occurring in 5-20% of patients)

• swelling (face) • abnormal heart sound • low blood pressure (possible dizziness/fainting) • high blood pressure • fast heartbeat • chest pain • heart failure • pain • chills • confusion • anxiety/depression • numbness • skin rash/redness • itching • night sweats • hair loss (partial or total) • dry skin • hives • lymph node swelling • toothache	• mouth blisters/sores (possible difficulty swallowing) • weight loss • abdominal pain • abdominal swelling • heartburn • tongue/mouth pain • lip blisters/sores • difficulty swallowing • upset stomach • fluid in the abdomen • dehydration • hemorrhoids • difficult, painful, and/or frequent urination • bacteria in the blood • high blood platelet count (possible increased clotting) • abnormal liver tests (possible liver damage or yellowing of the skin and/or eyes)	• weakness/tenderness • muscle spasms • joint pain • walking/balance problems (possible falling) • blurry vision • abnormal kidney test (possible kidney damage) • high blood levels of uric acid (possible painful joints and/or kidney failure) • sore throat • low oxygen level in the blood (possible lightheadedness) • fluid in or around the lungs (possible difficulty breathing) • runny or stuffy nose • nosebleed • injection site swelling

Rare but serious (occurring in fewer than 5% of patients)

• irregular heartbeat • enlarged heart • heart attack • heart and lung failure • bleeding around the brain • mental status change • skin condition with fever and skin lesions • blood in the urine	• kidney failure • lung inflammation • blood clots in the lung (possible failure to breathe) • stopped breathing • coughing up blood • enlarged spleen • gallbladder inflammation (possible abdominal pain)	• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Using the study drugs in combination with each other or with standard therapies may cause side effects that are not seen when each is given alone. The drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **bone marrow biopsies/aspirations** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsy/aspiration. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy/aspiration site.

Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: Effective methods of birth control include barrier methods (such as condoms and a diaphragm), spermicidal jelly or foam, oral hormonal birth control ("the pill"), injectable birth control (Depo provera), intrauterine devices (IUDs), or surgical birth control (tubal ligation).

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, on Day 8 of Cycle 1, blood (about 1 teaspoon each time) will be drawn for pharmacokinetic (PK) testing before the dose and then 4 more times over the next 24 hours after the dose. On Days 12 and 16 of Cycle 1, blood (about 1 teaspoon each time) will be drawn for PK testing 24 hours after the dose. PK testing measures the amount of study drug in the body at different time points.

There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have blood drawn for PK testing?

YES **NO**

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Abhishek Maiti, at 346-725-0901) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent

at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- 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 we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

   Blood and/or bone marrow samples may be shipped for research testing to Andrew H. Wei, Department of Haematology, Peter MacCallum Cancer Centre and Royal Melbourne Hospital, 305 Grattan St, Parkville, Victoria 3000, Australia. Your name and other identifying information will be removed from these samples before shipping. No identifiable information will be made available to collaborators or investigators outside of MD Anderson.

Biological samples used in future research may be shared with the following researchers or research facilities, including:

- Dr. Marina Konopleva, Department of Medicine (Oncology), Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, NY
- Dr. Koichi Takahashi, Department of Leukemia, University of Texas MD Anderson Cancer Center
- Dr. Yoko Tabe, Department of Laboratory Medicine, Juntendo University Graduate School of Medicine, Tokyo, Japan
- Dr. John Welch, Dr. David Spencer, Divisions of Hematology & Oncology, Department of Medicine, Washington University School of Medicine at St. Louis
- Dr. Vlad Sandulache Department of Otolaryngology - Head and Neck Surgery, Baylor College of Medicine
- Dr. Andrew H. Wei, Department of Haematology, Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Victoria, Australia
- Dr. Iannis Aifantis, NYU Langone Medical Center, New York
- Dr. Jeffrey W. Tyner, Translational Oncology Program, OHSU Knight Cancer Institute
- Branch Biosciences, Boston, MA
- Notable Labs, South San Francisco, CA
- Janssen Research & Development, LLC, Translational Research – Oncology, Spring House, PA.
- Dr. Kapil Saxena, Department of Leukemia, University of Texas MD Anderson Cancer Center

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2017-0912.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION