

## Kansas City Clinical Oncology Program

### S0535, "A Phase II Study of ATRA, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients With Previously Untreated High-Risk Acute Promyelocytic Leukemia"

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have high-risk acute promyelocytic leukemia (APL) that has never been treated.

#### Why is this study being done?

**The purpose of this study is to learn about the effects of treating your APL with chemotherapy. The chemotherapy for APL has three parts: induction therapy, consolidation therapy, and maintenance therapy. The purpose of the induction therapy is to eliminate the signs and symptoms of your APL from your body. If this happens, your APL will be in "remission". Consolidation therapy and maintenance therapy are intended to make your remission last as long as possible.**

**One of the main purposes of this trial is to study the effects, good and/or bad, of a unique combination and schedule of chemotherapy drugs for people who have difficult-to-treat APL. One of these chemotherapy drugs, gemtuzumab ozogamicin, is experimental.**

#### How many people will take part in the study?

About 70 people will take part in this study.

#### What will happen if I take part in this research study?

Before you begin the study ...

You may need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Medical history and examination
- Blood tests, including tests for your kidneys and liver

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- A bone marrow aspirate and biopsy
- A chest x-ray
- Scans/tests of your heart function

**During the study ...**

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- Physical exam. This will take place twice per week during induction chemotherapy and once per month during the consolidation and maintenance chemotherapy.
- Blood tests, including test for your kidneys and liver. This will take place twice per week during induction chemotherapy and once per week during the consolidation and maintenance chemotherapy.
- Bone marrow aspirate and biopsy. This will take place on Day 42, then every 2 weeks during induction chemotherapy, before the first and third cycles of consolidation chemotherapy, before maintenance chemotherapy, and every 3 months during maintenance chemotherapy.

You will need these tests and procedures that are part of regular cancer care. They are being done more often because you are in this study.

- Heart scans/tests

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body.

- Bone marrow specimens from the aspirates and biopsies will be sent to a special lab for research purposes. This is required as part of the study.

Induction Chemotherapy with ATRA, Gemtuzumab Ozogamicin, and Arsenic Trioxide

You will take ATRA by mouth twice every day with food starting on Day 1 until visible signs of your leukemia go away. Gemtuzumab ozogamicin will be given into your vein over two hours on Day 1. Arsenic Trioxide will be given into your vein starting on Day 10 over two hours every day for five days each week until your leukemia starts getting better. Samples of your bone marrow will be taken 42 days after beginning ATRA. Samples of your bone marrow then will be taken every two weeks if needed until signs of your leukemia are decreased or gone. If signs of your leukemia are decreased or are gone, you will go on to consolidation therapy.

Drug	How Drug is Given	How Often	For How Long
ATRA	by mouth	2 times a day	until visible signs of leukemia are gone
Gemtuzumab ozogamicin	IV for 2 hours	once	on Day 1 only
Arsenic Trioxide	IV for 2 hours	5 days per week, starting on Day 10	until visible signs of leukemia are gone

Consolidation Chemotherapy

After your induction therapy, your bone marrow and blood samples will be tested for signs of APL. This is a standard part of the treatment for APL. You will be in complete remission (CR) if the signs of your APL are gone. If you are in CR after your remission induction therapy, you will receive six cycles of consolidation chemotherapy.

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Consolidation #1 and #2 Chemotherapy with Arsenic Trioxide

You will receive arsenic trioxide into your vein over 2 hours 5 days per week for 5 weeks. You will then have 2 weeks of rest. You will then receive arsenic trioxide into your vein over 2 hours 5 days per week for 5 weeks.

Drug	How Drug is Given	How Often	For How Long
Arsenic Trioxide	IV for 2 hours	5 days per week	five weeks of taking drug, two weeks of rest, five more weeks of taking drug

Consolidation #3 and #4 Chemotherapy with ATRA and Daunomycin

You will take ATRA by mouth twice each day with food on Days 1 - 7. Daunomycin will be given into your vein either in a very short time period or over an hour each day on Days 1 - 3. You will then have 2-8 weeks of rest. You will then take ATRA by mouth twice each day with food on Days 1 - 7. Daunomycin will be given into your vein either in a very short time period or over an hour each day on Days 1 - 3.

Drug	How Drug is Given	How Often	For How Long
ATRA	by mouth	2 times a day	take drug for 7 days, rest for 2-8 weeks, then take drug again for 7 days
Daunomycin	IV (for up to 1 hour)	once daily	take drug for 3 days, rest for 2-8 weeks, take drug again for 3 days

Consolidation #5 and #6 Chemotherapy with Gemtuzumab Ozogamicin

You will receive gemtuzumab ozogamicin into your vein over 2 hours on Day 1. You will then have 2-8 weeks of rest and receive gemtuzumab ozogamicin once again. Samples of your bone marrow will be taken to see if you can go on to maintenance chemotherapy.

Drug	How Drug is Given	How Often	For How Long
Gemtuzumab ozogamicin	IV for 2 hours	once	take drug for 1 day, rest for 2-8 weeks, take drug again for 1 day

Maintenance Chemotherapy

You will take ATRA by mouth twice each day with food for 7 days repeated every other week for 1 year. You will take 6-mercaptopurine by mouth each day for 1 year. You will take methotrexate by mouth once a week for 1 year. Samples of your bone marrow will be taken every 3 months during maintenance chemotherapy.

Drug	How Drug is Given	How Often	For How Long
ATRA	by mouth	2 times a day	take drug for seven days, rest for seven days – repeat this cycle for one year
6-mercaptopurine	by mouth	once daily	one year
Methotrexate	by mouth	once a week	one year

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## How long will I be in the study?

You will be asked to take induction therapy (which could last up to 90 days unless you go into CR sooner), six courses of consolidation therapy (which could last about 6 months but may be longer if you have delays in treatment because of side effects), and maintenance therapy (for 1 year). After you are finished with these courses of treatment, the study doctor will ask you to visit the office for follow-up exams every 3 months for the first year, every 6 months for the second year, then at 3 years from the time you finish treatment. At a minimum, you will have a physical exam and blood tests at each visit. Also, you will have a bone marrow aspiration, every 3 months for 1 year, then every 6 months for 1 year, then at the end of the third year.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the ATRA, arsenic trioxide, daunomycin, gemtuzumab ozogamicin, 6-mercaptopurine, and methotrexate can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped. If you are a female and become pregnant while on the study, you will be taken off of protocol treatment.

## What side effects or risks can I expect from being in the 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, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drugs. In some cases, side effects can be serious, long lasting, or may never go away.

**You should talk to your study doctor about any side effects that you have while taking part in the study.**

**Risks and side effects related to the Induction Therapy (ATRA, Gemtuzumab Ozogamicin, and Arsenic Trioxide) include those that are:**

### Likely

- **Decreased number of a type of white blood cell (neutrophil/granulocyte)**

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- Decreased number of a type of blood cell that help to clot blood (platelet)
- Lack of enough red blood cells (anemia)
- Fever
- Chills
- Headache or head pain
- Nausea or the urge to vomit
- Vomiting
- Diarrhea
- Loss of appetite
- Belly pain
- Constipation
- Irritation or sores in the lining of the mouth
- Inflammation (swelling and redness) or damage to the tissue surrounding where a drug was injected
- Muscle weakness of the whole body
- Shortness of breath
- Fatigue or tiredness
- Difficulty sleeping or falling asleep
- Depression
- Skin rash with the presence of macules (flat discolored area) and papules (raised bump)
- High blood pressure
- Low blood pressure
- Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)
- Increased blood sugar level
- Decreased blood level of potassium
- Low blood oxygen levels
- Chest pain not heart related
- Back pain
- Dryness of the lips
- Dry skin
- Fluid collecting in the lungs
- Sudden or traumatic injury to the kidney
- Toothache
- Sores or irritation of the lips
- Increased blood level of a form of fat called triglyceride
- Nosebleed
- Infection
- Itching

### Less Likely

- Weight gain
- Fluid retention
- Upper respiratory infection
- Damage to the liver, which could cause yellowing of the skin and/or eyes

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- Visual disturbances, eye problems
- Dry nose
- Dry mouth
- Peeling skin
- Severe injury to liver (veno-occlusive disease)
- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Decreased number of all blood cell types Unpleasant sensation of irregular and/or forceful beating of the heart
- Fast heartbeat; regular rhythm
- Irregular heartbeat resulting from an abnormality in one of the lower chambers of the heart (ventricle)
- Noise in the ears, such as ringing, buzzing, roaring, clicking
- Swelling or feeling of fullness and tightness in the abdomen (belly)
- Irritation or sores in the lining of the anus
- Heartburn
- Inflammation (swelling and redness) of the pancreas
- Irritation or sores in the lining of the rectum
- Irritation or sores in the lining of the small bowel
- Swelling of the face
- Swelling of the extremities (arms and/or legs)
- Pain
- Infection associated with a decrease in a type of white blood cell (lymphocyte)
- Bruising
- Increased blood level of a liver enzyme (ALT/SGPT)
- Increased blood level of a liver enzyme (AST/SGOT)
- Increased blood level of a liver pigment (bilirubin) often a sign of liver problems
- Increased blood level of creatinine (a substance normally eliminated by the kidneys into the urine)
- Abnormal electrical conduction within the heart
- Increased blood level of a liver enzyme (GGT)
- Increased blood level of fat-digesting enzyme (lipase)
- Increased blood level of a digestive enzyme (amylase)
- Weight loss
- Decrease in the total number of white blood cells (leukocytes)
- More acid than normal in the blood
- Increased blood level of potassium
- Decreased blood level of magnesium
- Joint pain
- Bone pain
- Shrinking of muscles
- Muscle pain
- Commonly known as “pins and needles”, where part of the body (typically a foot or hand) begins to tingle and becomes numb, or “falls asleep”

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- Weakness or paralysis (loss of muscle function) caused by damage to peripheral nerves (those nerves outside of brain and spinal cord)
- Inflammation (swelling and redness) or degeneration of the peripheral nerves (those nerves outside of brain and spinal cord) causing numbness, tingling, burning
- Anxiety, feelings of dread or danger
- More protein in the urine than usual, often a sign of kidney disease
- Stuffy or runny nose, sneezing
- Sudden constriction of the muscles in the walls of the bronchioles (small airways of the lung)
- Cough
- Irritation or sores in the lining of the voice box
- Irritation or sores in the lining of the throat
- Build up of a large amount of fluid between the layers of tissue that line the lungs and chest cavity
- A collection of symptoms including fever, difficulty breathing, chest pain, fluid in the lung (seen on chest X-ray), fluid around the lungs and heart, and lack of oxygen first seen in patients receiving the drug retinoic acid
- Sore throat
- Irritation or sores in the lining of the windpipe
- Hair loss
- Excess sweating
- Area of bleeding within the skin causing a reddish purple discoloration
- Inflammation (swelling and redness) of the skin
- Thickening of the skin
- Darkening of the skin
- Hives
- Increase in the number and size of the pores in the capillaries (small blood vessels) which causes leakage of fluid from the blood to the tissue spaces, resulting in dangerously low blood pressure, swelling and multiple organ failure
- Sudden reddening of the face and/or neck

### Rare, but Serious

- Severe allergic reaction, which could be life-threatening
- ATRA Syndrome: a combination of heart and lung problems including difficulty breathing, lowered oxygen in the blood, fever, rash, inflammation of the lungs, fluid around the heart and/or the lungs, heart failure

Risks and side effects related to Consolidation #1 and #2 Therapy (Arsenic Trioxide) include those that are:

### Likely

- Fatigue or tiredness
- Nausea or the urge to vomit
- Headache or head pain
- Decreased number of a type of white blood cell (neutrophil/granulocyte)

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- Decreased number of a type of blood cell that help to clot blood (platelet)
- Shortness of breath
- Diarrhea
- Vomiting
- Fever
- Infection
- Itching
- Skin rash with the presence of macules (flat discolored area) and papules (raised bump)

### Less Likely

- Chills
- Weight gain
- Abnormal electrical conduction within the heart
- Increased blood sugar level
- Lack of enough red blood cells (anemia)
- Belly pain
- Chest pain not heart-related
- Dry skin
- Dry mouth
- Build up of a large amount of fluid between the layers of tissue that line the lungs and chest cavity
- Sudden or traumatic injury to the kidney
- Toothache
- Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)
- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Decreased number of all blood cell types
- Unpleasant sensation of irregular and/or forceful beating of the heart
- Fast heartbeat; regular rhythm
- Irregular heartbeat resulting from an abnormality in one of the lower chambers of the heart (ventricle)
- Noise in the ears, such as ringing, buzzing, roaring, clicking
- Swelling or feeling of fullness and tightness in the abdomen (belly)
- Irritation or sores in the lining of the anus
- Constipation
- Heartburn
- Irritation or sores in the lining of the mouth
- Inflammation (swelling and redness) of the pancreas
- Irritation or sores in the lining of the rectum
- Irritation or sores in the lining of the small bowel
- Swelling of the face
- Swelling of the extremities (arms and/or legs)
- Inflammation (swelling and redness) or damage to the tissue surrounding where a drug was injected
- Pain

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- Infection associated with a decrease in a type of white blood cell (lymphocyte)
- Bruising
- Increased blood level of a liver enzyme (ALT/SGPT)
- Increased blood level of a liver enzyme (AST/SGOT)
- Increased blood level of a liver pigment (bilirubin) often a sign of liver problems
- Increased blood level of creatinine (a substance normally eliminated by the kidneys into the urine)
- Increased blood level of a liver enzyme (GGT)
- Increased blood level of a fat-digesting enzyme (lipase)
- Increased blood level of a digestive enzyme (amylase)
- Weight loss
- Decrease in the total number of white blood cells (leukocytes)
- Loss of appetite
- More acid than normal in the blood
- Increased blood level of potassium
- Decreased blood level of potassium
- Decreased blood level of magnesium
- Joint pain
- Bone pain
- Muscle weakness of the whole body
- Shrinking of muscles
- Muscle pain
- Commonly known as “pins and needles”, where part of the body (typically a foot or hand) begins to tingle and becomes numb, or “falls asleep” (
- Weakness or paralysis (loss of muscle function) caused by damage to the peripheral nerves (those nerves outside of brain and spinal cord)
- Inflammation (swelling and redness) or degeneration of the peripheral nerves (those nerves outside of brain and spinal cord) causing numbness, tingling, burning
- Anxiety, feelings of dread or danger
- Difficulty sleeping or falling asleep
- More protein in the urine than usual, often a sign of kidney disease
- Stuffy or runny nose, sneezing
- Sudden constriction of the muscles in the walls of the bronchioles (small airways of the lung)
- Cough
- Nose bleed
- Irritation or sores in the lining of the voice box
- Irritation or sores in the lining of the throat
- A collection of symptoms including fever, difficulty breathing, chest pain, fluid in the lung (seen on chest X-ray), fluid around the lungs and heart, and lack of oxygen first seen in patients receiving the drug retinoic acid
- Sore throat
- Irritation or sores in the lining of the windpipe
- Hair loss

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- Excess sweating
- Area of bleeding within the skin causing a reddish purple discoloration
- Inflammation (swelling and redness) of the skin
- Thickening of skin
- Darkening of skin
- Hives
- Increase in the number and size of the pores in the capillaries (small blood vessels) which causes leakage of fluid from the blood to the tissue spaces, resulting in dangerously low blood pressure, swelling and multiple organ failure
- Sudden reddening of the face and/or neck
- High blood pressure
- Low blood pressure

Risks and side effects related to Consolidation #3 and #4 Therapy (ATRA and Daunomycin) include those that are:

### Likely

- Lower white blood count that may lead to infection, which could be life-threatening
- Lower platelets, which may lead to bruising or bleeding and could be life-threatening. This side effect may require you to receive a transfer of blood platelets from a donor.
- Lower red blood counts that may cause you to feel tired or have shortness of breath and require a transfer of red blood cells from a donor. Low red blood counts could be life-threatening.
- Nausea, vomiting, abdominal pain, or diarrhea
- Loss of appetite
- Sores in the mouth and/or rectum. The sores in the mouth may cause difficulty in swallowing or a sore throat.
- Headache
- Hair loss
- Skin rash
- Fever
- Bone pain
- Flu-like symptoms
- Changes in nail growth
- Taste changes
- Fatigue
- Rash
- Red urine and/or tears while receiving daunomycin
- Eye problems, visual disturbances
- Increased blood level of a fat called triglyceride

### Less Likely

- Heart damage, which could lead to irregular heart beats or heart failure
- Dryness of the skin and lips

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- Damage to the liver, which could cause yellowing of the skin and/or eyes
- Damage to the kidneys, which could result in the need for dialysis
- Chills
- Itching, inflammation, and redness of the skin on the palms of the hands or soles of the feet
- Muscle pain
- Bleeding from the nose, gums, or skin
- Mood changes
- Problems with coordination, speech impairment, seizures, or paralysis

### Rare but Serious

- Inflammation of the lining of the bowel, which could lead to abdominal pain and swelling and require surgery
- ATRA Syndrome: a combination of heart and lung problems including difficulty breathing, lowered oxygen in the blood, fever, rash, inflammation of the lungs, fluid around the heart and/or the lungs, heart failure

Risks and side effects related to Consolidation #5 and #6 Therapy (Gemtuzumab Ozogamicin) include those that are:

### Likely

- Lower white blood count that may lead to infection which could be life-threatening
- Lower platelets, which may lead to bruising or bleeding and could be life-threatening. This side effect may require you to receive a transfer of blood platelets from a donor.
- Lower red blood counts that may cause you to feel tired or have shortness of breath and require a transfer of red blood cells from a donor. Low red blood counts could be life-threatening.
- Fever, chills, headache
- Nausea, vomiting, diarrhea
- Loss of appetite, abdominal pain
- Constipation
- Low levels of potassium in the blood, which may affect the heartbeat or cause muscle cramps
- Sores in the mouth
- Pain at the site of injection/local reaction
- Weakness
- Difficulty breathing
- Fatigue
- Difficulty sleeping
- Fluid in the lungs
- Depression
- Rash
- Changes in blood pressure
- Dizziness

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### Less Likely

- Damage to the liver, which could cause yellowing of the skin and/or eyes
- Severe injury to the liver (veno-occlusive disease), which could be life-threatening

### Rare, but Serious

- Severe allergic reaction, which could be life-threatening

Risks and side effects related to Maintenance Therapy with ATRA, 6-mercaptopurine, and Methotrexate include those that are:

### Likely

- Lower white blood count that may lead to infection, which could be life-threatening
- Lower platelets, which may lead to bruising or bleeding and could be life-threatening. This side effect may require you to receive a transfer of blood platelets from a donor.
- Lower red blood counts that may cause you to feel tired or have shortness of breath and require a transfer of red blood cells from a donor. Low red blood counts could be life-threatening.
- Headache
- Nausea
- Stomach and/or intestinal ulcers
- Vomiting of blood
- Joint pain
- Hair loss
- Skin changes
- Cough
- Sensitivity to light

### Less Likely

- Dryness of the skin and lips
- Bladder irritation and blood in urine (this may be prevented with drinking lots of fluids and/or getting them in an IV and/or with medicine)
- Eye problems, visual disturbances
- Dryness of the skin and lips
- Itching, inflammation, and redness of the skin on the palms of the hands or soles of the feet
- Muscle pain
- Bleeding from the nose, gums, or skin
- Mood changes
- Weight loss
- Diarrhea

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## **Rare but Serious**

ATRA Syndrome: A combination of heart and lung problems including difficulty breathing, lowered oxygen in the blood, fever, rash, inflammation of the lungs, fluid around the heart and/or lungs, heart failure.

In a recent clinical trial using gemtuzumab ozogamicin, in a higher dose than is used in this study and combined with a different chemotherapy, no benefit was seen and there was a higher rate of early death. Due to these findings, the company that makes gemtuzumab ozogamicin has withdrawn the drug from the market. However, every effort will be made to ensure availability of gemtuzumab ozogamicin for this trial. Currently there is no evidence that gemtuzumab ozogamicin at a lower dose (as used in this trial) in combination with ATRA and/or arsenic trioxide causes increased toxicity, although experience is limited. The safety of the study therapy in patients on this trial will continue to be closely monitored.

**Reproductive risks:** You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

Pregnancy testing is required for women with reproductive potential before induction and is strongly recommended before the third course of consolidation therapy and before maintenance therapy.

Women should be fully counseled on the serious risk to the fetus should they become pregnant while undergoing treatment with ATRA. An effective form of contraception should be used for at least one month before and also throughout ATRA therapy, and two months after. If pregnancy does occur during treatment, you should discuss this with your doctor immediately, and you will be removed from protocol therapy.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope the treatment used in this study will be more useful against APL compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about using these drugs as a treatment for APL. This information could help future cancer patients.

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## What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

**Talk to your doctor about your choices before you decide if you will take part in this study.**

## Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The Southwest Oncology Group
- A qualified representative from Pfizer, Inc., the manufacturer of gemtuzumab ozogamicin
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- (For patients registered via the CTSU) The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to clinical trials.

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

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Administration of the drugs will be charged in the usual way. The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research. The research requires that you receive certain standard medical tests and examinations. These standard tests and examinations will be charged in the usual way

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All trans retinoic acid, arsenic trioxide, daunomycin, 6-mercaptopurine and methotrexate are commercially available.

Gemtuzumab ozogamicin is investigational and will be provided free of charge by Pfizer, Inc. for this study.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

### What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, \_\_\_\_\_ [investigator's name(s)], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at \_\_\_\_\_ [telephone number].

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

### What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

### Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor \_\_\_\_\_ [name(s)] at \_\_\_\_\_ [telephone number].

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**For questions about your rights while taking part in this study, call the Kansas City Clinical Oncology Program Institutional Review Board (a group of people who review the research to protect your rights) at 913-948-5588**

Please note: This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say 'no' to taking part in any of these additional studies.

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

1. **Future Contact**

**I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.**

Yes                      No

2. **Banking of specimens for future research**

**About Using Bone Marrow and/or Peripheral Blood for Research**

If you participate in this study, your doctor will remove some blood and bone marrow to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care. As described above, some of your bone marrow will be used for research that is part of this study.

We would like to keep some of the blood and/or bone marrow that is left over for future research. If you agree, this blood and/or bone marrow will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How are Specimens Used for Research?" to learn more about tissue research.

The research that may be done with your blood and/or bone marrow is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your blood and/or bone marrow will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

**Things to Think About**

The choice to let us keep the left over blood and/or bone marrow for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your blood and/or bone marrow can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to

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use your blood and/or bone marrow. Then any blood and/or bone marrow that remains will no longer be used for research.

In the future, people who do research may need to know more about your health. While the Southwest Oncology Group may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes blood and/or bone marrow is used for genetic research (about diseases that are passed on in families). Even if your blood and/or bone marrow is used for this kind of research, the results will not be put in your health records.

Your blood and/or bone marrow will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future.

### **Benefits**

The benefits of research using blood and/or bone marrow include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

### **Risks**

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

### **Making Your Choice**

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No." If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

No matter what you decide to do, it will not affect your care.

1. **My specimens may be kept for use in research to learn about, prevent, treat or cure cancer.**

Yes                      No

2. **My specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer's disease, or heart disease).**

Yes                      No

3. **Someone may contact me in the future to ask me to allow other uses of my specimens.**

Yes                      No

**If you decide to withdraw your specimens from an Eastern Cooperative Oncology**

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**Group Repository in the future, a written withdrawal of consent should be submitted through your treating physician to the Eastern Cooperative Oncology Group Coordinating Center. Upon withdrawal of consent, your specimens will not be considered for use in any future research projects.**

## Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

### Release

By signing this form you authorize KCCOP to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

### Signature

I have been given a copy of all 20 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant \_\_\_\_\_

Date \_\_\_\_\_

Signature of Person Obtaining Consent \_\_\_\_\_

Date \_\_\_\_\_

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## Specimen Consent Supplemental Sheets

### How are Specimens Used for Research?

#### Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by the Southwest Oncology Group. Your doctor does not work for the Southwest Oncology Group, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

#### Why do people do research with specimens?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

#### What type of research will be done with my specimen?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

#### How do researchers get the specimen?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact the Southwest Oncology Group and request samples for their studies. The Southwest Oncology Group reviews the way that these studies will be done, and decides if any of the samples can be used. The Southwest Oncology Group gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. The Southwest Oncology Group will not send your name, address, phone number, social security number or any other identifying information to the researcher.

#### Will I find out the results of the research using my specimen?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

#### Why do you need information from my health records?

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to the Southwest Oncology Group. If more information is needed, the Southwest Oncology Group will send it to the researcher.

#### Will my name be attached to the records that are given to the researcher?

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

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**How could the records be used in ways that might be harmful to me?**

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members.

**How am I protected?**

The Southwest Oncology Group is in charge of making sure that information about you is kept private. The Southwest Oncology Group will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

**Where will my specimens be kept?**

Your blood and/or bone marrow will be kept at:

UNM Cancer Center Research Center, Room 101  
2325 Camino de Salud, NE  
Albuquerque, NM 87131-5636  
Phone: 505/272-8881; or 272-5622  
FAX: 505/272-8047  
E-mail: cwillman@salud.unm.edu

Elisabeth Paietta, Ph.D.  
Our Lady of Mercy Cancer Center  
600 East 233<sup>rd</sup> Street  
6th Floor, Immunology Laboratory  
Bronx, NY 10466-2697  
Tel: 718/920-9992

OR

Mayo Clinic Cytogenetics Laboratory  
970 Hilton  
200 First Street, S.W.  
Rochester, MN 55905  
Tel: 507/284-2950  
FAX: 507/284-0043

**What if I have more questions?**

If you have any questions, please talk to your doctor or nurse, or call our research review board at 913-948-5588.

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