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University of Washington
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A phase 1/2 study of ABI-009 (nab-rapamycin) with pazopanib (VOTRIENT®) in patients with advanced nonadipocytic soft-tissue sarcomas

PROTOCOL NO.: Protocol No.: CC10015

FUNDING SOURCE: Aadi Bioscience, Inc.

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RESEARCHER'S STATEMENT

We are asking you to be in a drug research study. You have been asked to take part in this study because you have been diagnosed with an advanced nonadipocytic soft-tissue sarcoma that has not been cured. The purpose of this consent form is to give you the information you will need to help you decide if you want to be in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. The research team will discuss the requirements for participating in this study. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a signed and dated copy of this form for your records.

This consent form may contain words that you do not understand. Please ask the researcher or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

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.

PURPOSE OF THE STUDY

The purpose of this study is to determine whether ABI-009 (study drug) in combination with an FDA approved standard of care agent, Votrient®, also known as pazopanib, will make your cancer smaller and slow the spread of your cancer. You may receive lower doses than the standard of care or the standard of care may be delayed due to unexpected toxicities of the combination.

ABI-009, human albumin-bound rapamycin, is an experimental drug used to treat patients with advanced nonadipocytic soft-tissue sarcoma in this study. Rapamycin and similar types of drugs have been used in many other tumors, including advanced renal cell carcinoma. The human albumin component of ABI-009 may allow rapamycin to reach cancer cells more effectively.

ABI-009 has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced nonadipocytic soft-tissue sarcoma. The information from this study might help us identify if ABI-009 in combination with pazopanib is a safe and effective treatment for this disease.

Pazopanib has been approved by the FDA for treatment of soft tissue sarcoma. It is also approved for the treatment of kidney cancer. The study drug is a cancer medicine that targets blood vessel growth. It may stop the growth of your soft tissue sarcoma by blocking blood flow to the tumor and blocking some of the enzymes needed for tumor cell growth.
This consent form gives you detailed information about this research study. If you wish to participate in the study, you will be asked to sign and date the informed consent form, and you will be given a complete copy of this informed consent form to keep.

WHY ARE WE DOING THIS STUDY?

We are doing this study to examine the antitumor activity of ABI-009 (also called nab-rapamycin) with pazopanib in subjects with advanced nonadipocytic soft-tissue sarcomas. This combination is investigational, which means it has not been approved for use by the FDA. This study is made up of two parts. Phase 1 and Phase 2.

The first part of the study, the Phase 1 portion, is the dose-escalation Phase. The objective of this Phase is to determine how much ABI-009 can be given safely. Subjects will be treated at different doses of ABI-009 in combination with pazopanib. This is done to determine the maximum tolerated dose of ABI-009. There will be different dosing groups of ABI-009, receiving a dose level that is predetermined for each group. Subjects that join in the beginning of the study may receive a lower or higher dose than subjects who join at a later date. Based on the presence of effects (either good or bad), the dose level can be escalated (raised) or de-escalated (reduced) accordingly. Your study doctor will watch carefully for any side effects.

Once the recommended dose is determined in the Phase 1 portion, the Phase 2 portion of the study will begin. In this part, additional subjects will be enrolled and assigned to the recommended dose level determined in Phase 1, described above. The objective for the Phase 2 portion is to evaluate the effects (good or bad) of ABI-009 in combination with pazopanib in treating subjects with advanced nonadipocytic soft-tissue sarcomas.

PROCEDURES

What is involved in the study?

Before you can receive study treatment, the doctor will perform tests to find out whether you can participate in the study.

In this study, you will receive ABI-009 given through a vein (intravenous) either once weekly on days 1 and 8 of a 21-day cycle, or day 1 only of a 21-day cycle, depending on when you entered the study, in addition to daily pazopanib tablets.

If you were initially enrolled to a day 1 and day 8 dosing, you may switch to a day 1 only dosing schedule at the study doctor's discretion, after you complete at least two full cycles of treatment. If you do switch a dosing schedule, this change is permanent and you may not switch back. If you are initially enrolled on a day 1 only schedule, you may not switch the dosing schedule.

Pazopanib is given in 200 mg oral tablets, so if you are taking a total dose of 400 mg, you would have 2 tablets, for 600 mg you would have 3 tablets, and for 800 mg you would have 4 tablets. Your study team will let you know what dose of pazopanib you will be taking.

You will be required to record when you take pazopanib each day in a medication diary. The medication diary should be returned to your treating physician, along with any leftover pills that you did not take.

Screening Evaluations

Screening evaluations will be performed for all subjects to determine study eligibility. These evaluations must be obtained within 28 days prior to enrollment. Your baseline imaging assessments may be completed on a separate date than the rest of your screening evaluations, in order to have them be as close to initiation of protocol therapy as possible.

The following procedures are to be completed during the screening period:

- Demographics (including date of birth, sex, race, and ethnicity)
- Physical examination including medical/cancer history, weight, and assessment of your general well-being (called an ECOG score)
- Prior and concomitant medications and procedures evaluation to include: all medications taken within 28 days prior to the date of informed consent
- Vital signs (temperature, systolic/diastolic blood pressure, respiration rate, and pulse)
- Electrocardiogram (ECG), a test that measures the electrical activity of your heart
- Left ventricular ejection fraction (LVEF, by echocardiogram or multigated acquisition [MUGA] scan) to measure how well your heart pumps with every heartbeat
- Urinalysis
- Local Laboratory Assessments including a chemistry panel, complete blood count (CBC) with differential, pregnancy test (people who are able to bear children), HIV, hepatitis B surface antigen, hepatitis B core antibody, hepatitis C antibody, lipids, and thyroid function tests
- Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scan to measure the amount of disease in your body

Treatment Period

A subject is considered enrolled on study day 1 when the investigational product, ABI-009, is first administered. ABI-009 is to be administered after all other protocol-specified pre-dose assessments have been performed during each visit that it is required.

Day 1 Assessment

The following assessments will be performed on Day 1 of each cycle, unless otherwise specified:

- Physical examination as per standard of care including assessment of your general well-being (called an ECOG score)
- Height and weight assessment (height to be collected only for Cycle 1 Day 1)
- Concomitant medication and procedures evaluation
- Vital signs (temperature, blood pressure, respiration rate, and pulse)
- Laboratory assessments including a CBC with differential and chemistry panel
- ECG and lipid panel (every even visit: Cycle 2, Cycle 4, etc.)
- Urinalysis

- Adverse event assessment
- Rapamycin levels test (only in Phase 1 at Cycle 1 and 2)
- Observation period of 60 minutes on dosing days for Cycle 1. If there are no infusion related reactions in Cycle 1, the observation period may be omitted moving forward. If at any time an infusion-related adverse event occurs, the observation period will be reinstated.

All Day 1 evaluations for Cycle 1 may be omitted if screening evaluations are performed within 72 hours of Cycle 1 Day 1. All Day 1 laboratory assessments and physical examination for Cycle 2+ may be performed up to 72 hours prior to planned treatment.

Day 8 Assessment

The following assessments will be performed on Day 8 of each cycle, unless otherwise specified:

- Physical examination including assessment of your general well-being (called an ECOG score)
- Weight assessment
- Vital signs (temperature, blood pressure, respiration rate, and pulse)
- Concomitant medication and procedures evaluation
- Laboratory assessments including a CBC with differential and chemistry panel
- Adverse event assessment
- Rapamycin levels test (only in Phase 1 at Cycle 1 and Cycle 2)

All Day 8 laboratory assessments and physical examination may be performed up to 72 hours prior to planned treatment.

Day 15 Assessment

The following assessments will be performed on Day 15 of Cycle 1 and 2 only.

- Physical examination including assessment of your general well-being (called an ECOG score)
- Weight assessment
- Vital signs (temperature, blood pressure, respiration rate, and pulse)
- Concomitant medication and procedures evaluation
- Laboratory assessments including a CBC with differential and chemistry panel
- Adverse event assessment
- Rapamycin levels (only Phase 1, Cycle 1 and Cycle 2)

Response Assessment

CT or MRI scans will be completed at the below time points:

- Within 4 weeks prior to Cycle 1 Day 1 (as close to Cycle 1 Day 1 as possible - screening)

- Every 6 weeks from Cycle 1 Day 1 for the first year. Then every 12 weeks until disease progression or unacceptable toxicity. End of Treatment Visit CT/MRI should be performed only for those subjects that discontinue treatment for a reason other than disease progression.

End of Treatment (EOT) Visit Assessment

The following procedures will be completed at the EOT Visit:

- Physical examination including assessment of your general well-being (called an ECOG score)
- Weight assessment
- Vital signs (temperature, blood pressure, respiration rate, and pulse)
- Concomitant medication and procedures evaluation
- Adverse event assessment
- Urinalysis
- Laboratory assessments including a CBC with differential, chemistry panel, pregnancy test (for people who are able to bear children)
- Imaging Assessment: CT or MRI is to be performed at the end of study visit only for those subjects that discontinue treatment for a reason other than disease progression

30 Day Follow-Up Visit

This visit will be completed 30 days after your last dose of ABI-009 or pazopanib, whichever is later. We will perform the following procedures at the follow-up visit:

- Physical examination including assessment of your general well-being (called an ECOG score)
- Weight assessment
- Vital signs (temperature, blood pressure, respiration rate, temperature)
- Concomitant medication and procedures evaluation
- Adverse Event assessment
- Laboratory assessments including a CBC with differential, chemistry panel, and pregnancy test (for people who are able to bear children)
- Left ventricular ejection fraction (LVEF, by echocardiogram or MUGA scan)

Rapamycin Trough levels

Assays for rapamycin will be performed on subjects in the dose-finding (Phase 1) portion of the study, who received ABI-009 during Cycle 1 and Cycle 2, to determine trough levels, assessed via local lab. The rapamycin sampling schedule is outlined below, based on dosing schedule:

Day 1 and Day 8 ABI-009 Dosing:

- Cycle 1
    - Cycle 1 Day 8: Prior to treatment (within 15 minutes before your infusion)

    - Cycle 1 Day 15: Anytime
- Cycle 2
    - Cycle 2 Day 1: Prior to treatment (within 15 minutes before your infusion)
    - Cycle 2 Day 8: Prior to treatment (within 15 minutes before your infusion)
    - Cycle 2 Day 15: Anytime

Day 1 ABI-009 Dosing:

- Cycle 1
    - Cycle 1 Day 1: End of infusion (within +10 minutes) and Optional 24-hour post dose (Day 2, +/- 2 hours)
    - Cycle 1 Day 8: Anytime
    - Cycle 1 Day 15: Anytime
- Cycle 2
    - Cycle 2 Day 1: Prior to treatment (within 15 minutes before your infusion)
    - Cycle 2 Day 8: Anytime
    - Cycle 2 Day 15: Anytime

Follow-up Period for Survival and Initiation of Anticancer Therapy

Post-treatment survival time and any subsequent anticancer therapy information status will be monitored approximately every 12 weeks (±3 weeks) from the 30-Day Follow-Up visit or more frequently as needed, until death, withdrawal of consent, or the study closes, whichever is earliest. This evaluation may be by record review or telephone contact.

Schedule of Assessments – Day 1 and Day 8 Dosing

Assessments	Baseline Screening	Treatment Phase 21-day (3-week) Cycles Days			End of Treatment (EOT) Visit	30 Day Follow-Up Visit	**Follow-up** every 12 weeks after the 30-Day Follow-Up Visit till study closes or withdrawal of consent
		1	8	15			
Informed Consent	x						
Medical History/Demographics	x						
HIV and Hepatitis Screening	x						
Urinalysis	x	x			x		
Thyroid Function Tests	x						
Optional Biomarker	x						
Pregnancy Test	x				x	x	
Cardiac Assessment (Echo or MUGA)	x					x	
12-lead electrocardiogram	x	x					
Physical Exam (including vital signs, height [C1D1], and weight)	x	x	x	x	x	x	
Blood Chemistry and CBC	x	x	x	x	x	x	
Lipid Panel	x	x					
Rapamycin Level Collection		x	x	x			
ECOG Performance Status	x	x	x	x	x	x	
CT/MRI Disease Assessment	x	Every 6 weeks for the first year, then every 12 weeks					
ABI-009 infusion		x	x				
Pazopanib		Daily					
Adverse Event Assessment and Concomitant Medication Review	Continuous from the signing of the informed consent to 30 days after last study drug						
Long-Term Follow Up							x

Schedule of Assessments – Day 1 Dosing

Assessments	Baseline Screening	Treatment Phase 21-day (3-week) Cycles Days			End of Treatment (EOT) Visit	30 Day Follow-Up Visit	**Follow-up** every 12 weeks after the 30-Day Follow-Up Visit till study closes or withdrawal of consent
		1	8	15			
Informed Consent	x						
Medical History/Demographics	x						
HIV and Hepatitis Screening	x						
Urinalysis	x	x			x		
Thyroid Function Tests	x						
Optional Biomarker	x						
Pregnancy Test	x				x	x	
Cardiac Assessment (Echo or MUGA)	x					x	
12-lead electrocardiogram	x	x					
Physical Exam (including vital signs, height [C1D1], and weight)	x	x	x	x	x	x	
Blood Chemistry and CBC	x	x	x	x	x	x	
Lipid Panel	x	x					
Rapamycin Level Collection		x	x	x			
ECOG Performance Status	x	x	x	x	x	x	
CT/MRI Disease Assessment	x	Every 6 weeks for the first year, then every 12 weeks					
ABI-009 infusion		x					
Pazopanib		Daily					
Adverse Event Assessment and Concomitant Medication Review	Continuous from the signing of the informed consent to 30 days after last study drug						
Long-Term Follow Up							x

How many subjects will take part in the study?

Up to 82 subjects will be entered in this study.

How long will you be in the study?

You may be in the study for as long as your cancer responds to the study treatment, until you experience an unacceptable side effect, you no longer wish to participate, or your study doctor feels that it is in your best interest to stop your participation. You may stop participating at any time without penalty or loss of benefits. However, if you decide to stop participating in the study, we encourage you to talk to your study doctor and your regular doctor first.

RISKS, STRESSES, AND DISCOMFORTS

There may be risks to you if you are in this study. You may have side effects while you are in the study. You will be carefully and regularly monitored by the study doctor for any problems. There may be risks or side effects of the study drug that are unknown at this time. You should tell the study doctor/staff about anything that is bothering you or any side effect you have, even if you do not think they are related to the study drug.

ABI-009 Risks

The following is a list of the most medically significant or most common side effects reported in previous or ongoing studies and considered to be related to ABI-009. In some cases, side effects can be serious, long-lasting, or permanent. Some side effects may go away soon after you stop the study treatment and some may take time to resolve. The study doctor may alter the dosage regimen of ABI-009 or give you medicines to help lessen the side effects. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask the study doctor.

Very common (>10% or more chance that this will happen, based on a previous study with ABI-009):

- Low blood platelets (thrombocytopenia, can increase risks of bleeding)
- Low blood hemoglobin (anemia, which can cause fatigue and may require blood transfusion)
- Low white blood cell count (neutropenia, can increase risk of infection)
- Low potassium levels (hypokalemia)
- Elevated lipid levels (hypertriglyceridemia)
- Elevated cholesterol (hypercholesterolemia)
- Elevated blood glucose (hyperglycemia)
- Diarrhea
- Nausea
- Vomiting
- Inflammation of the mucus membrane (mucosal inflammation)
- Fatigue
- Decreased liver function (elevated aspartate aminotransferase [AST] levels)
- Decreased liver function (elevated alanine transaminase [ALT] levels)

- Weight decrease
- Rash
- Dermatitis (eczema, skin inflammation)
- Headache
- Infection (including candidiasis [yeast], cellulitis [skin], folliculitis [hair follicles], urinary tract)
- Decreased appetite (anorexia)

Common (between a 1% to less than 10% chance that this will happen):

- Edema (swelling)
- Constipation
- Altered sense of taste (dysgeusia)
- Low blood phosphate levels (hypophosphatemia)
- Increased amylase levels (may indicate damage to the pancreas)
- Increased lipase levels (may indicate damage to the pancreas)
- Low magnesium levels (hypomagnesemia)
- Decreased liver function
- Elevated creatinine levels, which may be related to kidney damage
- Elevated potassium levels (hyperkalemia)
- Protein in the urine (proteinuria)
- Low lymphocyte count
- Acid reflux
- Nasal congestion
- Abdominal cramping
- Cough
- Labored breathing (dyspnea)
- Fast heart rate (tachycardia)
- Lung tissue inflammation (pneumonitis)
- Insomnia (trouble sleeping)
- Nose bleeds (epistaxis)
- Dry mouth
- Hair loss (alopecia)
- Nail disorder
- Muscle pain (myalgia)
- High blood pressure (hypertension)
- Fever
- Acute kidney injury
- Failure to thrive
- Inflammation of the stomach and colon (including enteritis, ileitis, colitis)
- Weakness, numbness, or tingling in hand and feet (neuropathy)
- Dizziness (vertigo)
- Unbalanced feeling (ataxia)
- Chest pain (non-cardiac)
- Confusion
- Speaking disorder that affects a person's ability to communicate (dysphasia)

- Change in voice (dysphonia)
- Damage or disease that affects the brain (encephalopathy)
- Frequent urination
- Feeling of discomfort (malaise)
- Nervousness
- Sore throat
- Toothache

Uncommon (between a 0.1 to less than 1% chance that this will happen):

- Alkaline phosphate elevation (liver enzyme)
- Decreased levels of red blood cells, white blood cells and platelets (pancytopenia)
- Alkalosis (an imbalance of pH in the blood)
- Decrease of blood albumin (a protein in the blood)
- Neutrophil count increase
- Double vision (diplopia)
- Decrease in a type of white blood cell (leukopenia)
- Inflammation of the esophagus (esophagitis)
- Inflammation of the stomach (gastritis)
- Hemorrhoids
- Rectum bleeding
- Swelling in the scrotum (hydrocele)
- Swelling around the eyes (orbital edema)
- Jittery
- Limb discomfort
- Swelling caused by inflammation, commonly with tumors (neoplasm swelling)
- Tingling or prickling sensation (paresthesia)
- Pink eye
- A certain type of rash caused by small blood vessels leaking (purpura)
- Discharge from nose (rhinorrhea)
- Scar pain
- Sinus drainage
- Skin disorder
- Skin lesion
- Sore skin
- Non-cancerous mass of tissue on the tongue (benign tongue neoplasm)
- Vitamin D deficiency
- Weakness
- Underactive thyroid (hypothyroidism)
- Dehydration
- Low sodium levels (hyponatremia)
- Infusion site pain
- Thirst
- Suicidal ideas
- Transient chest pain (acute coronary syndrome)
- Painful or difficult urination (dysuria)

In at least one case, a subject receiving ABI-009 developed kidney failure requiring lifelong dialysis. This might have been due to treatment with ABI-009, but this is not clear as other possible causes also existed in that subject.

ABI-009 contains human serum albumin. Human serum albumin presents a small risk of allergic or anaphylactic type reactions. Severe allergic reactions can be life threatening. Tell your doctor if you have ever had a reaction to human serum albumin.

Human serum albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin.

Long term use of Sirolimus, also known as rapamycin, is potentially associated with testicular toxicities, pulmonary toxicities (pneumonitis), and increased risk for cancer.

Pazopanib Risks

Studies in animals indicate that pazopanib may slow or stop bone growth. There is a possibility that pazopanib may affect bone growth in children, adolescents and young adults who are still growing.

Very common, in 100 people receiving pazopanib, more than 20 and up to 100 may have:

- Diarrhea
- Nausea
- Vomiting
- Tiredness (fatigue)
- Bruising, bleeding
- Infection, especially when white blood cell count is low
- Loss of appetite
- Change in hair color
- High blood pressure which may cause blurred vision
- Tumor pain
- Musculoskeletal pain
- Changes in taste
- Weight loss
- Dizziness, headache
- Gastrointestinal pain
- Shortness of breath
- Decreased platelet count
- Decrease in white blood cells (leukocytes, neutrophils, and lymphocytes) which may lead to greater risk of infection
- Elevated liver enzymes

- Increased blood sugar
- Increased bilirubin levels
- Decrease in electrolyte levels in the blood (magnesium, sodium, phosphorus)
- Anemia which may require blood transfusion

Common, in 100 people receiving pazopanib, from 4 to 20 may have:

- Abnormal heartbeat
- Decreased blood sugar
- Pain
- Constipation, heartburn
- Sore in the mouth which may cause difficulty swallowing
- Swelling of arms, legs
- Fever
- Dehydration
- Cough
- Internal bleeding which may cause coughing up blood, black tarry stool, blood in vomit, or blood in urine
- Bleeding from multiple sites including the nose or vagina
- Hair loss, rash, skin changes
- Redness, pain, or peeling of palms and soles

Rare and Serious, in 100 people receiving pazopanib, 3 or fewer may have:

- Anemia
- Blood clot which may cause confusion, paralysis, swelling, pain, or shortness of breath
- Heart failure, heart attack which may cause shortness of breath, swelling of ankles, and tiredness
- Bleeding of the eye which may cause blurred vision with a chance of blindness
- A tear or hole in internal organs that may require surgery
- Liver damage which may cause yellowing of eyes and skin, swelling
- Liver failure
- Change in heart function
- Bleeding in the brain
- Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)
- Kidney damage which may require dialysis
- Damage to the lungs which may cause shortness of breath
- Collapsed lung (pneumothorax) where air may get trapped in the space between your lung and chest wall. This may cause you to have shortness of breath, pain, and may require emergency evaluation and treatment.

Side effects from testing:

Taking blood: may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases, infection may occur. If you have a central venous catheter, the blood sample may be taken from there instead of having a needle inserted into a separate vein.

Electrocardiogram (ECG): patches may cause a skin reaction such as redness or itching. You may also experience localized skin discomforts and/or hair loss associated with the placement of ECG patches.

Tumor biopsy: There are small risks associated with percutaneous (needle puncture) biopsies, these risks include bruising (scarring is usually minimal), infection and hematoma (pooling of blood trapped in the biopsy area). These risks are small, and even when one or more complications do occur they usually resolve within a brief period of time with the proper medical attention.

Echocardiogram (Echo): Echocardiograms are very safe. The gel may feel cold when it is first places. Some people with sensitive skin can develop a rash from the gel.

Radiation Risks

There are some risks from the CT scans used to watch your tumor status and health. These scans will expose you to radiation. A MUGA (multigated acquisition scan) takes images of the beating heart to see how well your heart is pumping blood. A small amount of radioactive material will be injected into your vein and bind to your red blood cells. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called "background radiation." A "millisievert" (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from each of your scans will be about as follows:

- CT scan of the chest: 7 mSv
- CT scan of the abdomen: 8 mSv
- CT scan of the pelvis: 6 mSv
- CT biopsy: 5 mSv
- MUGA scan: 8 mSv

The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans.

Reproductive risks

Taking ABI-009 in combination with pazopanib may involve unknown risks to an embryo fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study, you would have to use an effective method of birth control from the time this form is signed until at least 3 months after the last dose of ABI-009 in combination with pazopanib. If you are already using a method of birth control, you will need to check with the study doctor or a member of the study staff to make sure it is acceptable.

If you became pregnant after joining this study, you will need to notify the study doctor immediately. You would no longer be able to participate in this study. If this happens, you would receive counseling and follow up throughout the pregnancy and for about 6 months after the child is born.

The effects of fathering a child are also unknown. Men who join this study must also agree to use one or more forms of effective and acceptable birth control from the time this form is signed until at least 3 months after the last dose of ABI-009 in combination with pazopanib.

NEW FINDINGS

During the study we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

BENEFITS

You may or may not receive any benefit from being in this study. It is possible that you may get better, stay the same, or get worse. If you take part in this study, other people with soft tissue sarcoma may be helped.

You may receive information from physical examinations, laboratory tests, or other testing that is done in this study but these tests may not have any impact on your health.

Information obtained from this study will benefit the sponsor and funding source of the study and may benefit patients in the future.

COSTS

The funding source of this study, Aadi Bioscience Inc., will provide the ABI-009 study drug to you free of charge. Pazopanib will not be provided by Aadi and will be billed to you or your insurance as a standard of care medication. Study related medical examinations and laboratory tests that are not part of your routine care for your condition will be provided at no charge. Administration of IV drug is considered standard of care and will be billed to your insurance. You may have to pay for some expenses related to this study, such as transportation to the study site, parking, meals, etc. Aadi pays the study doctor to conduct the study and covers the cost of study-related tests and procedures.

You or your insurance company will be billed in the usual manner for examinations, testing, and treatments that are considered routine and required for the management of your cancer. Some examples of standard procedures include routine laboratory blood tests, x-rays, CT scans,

surgeries, blood transfusions, physicians' charges, IV drug administration, and routine medical care.

Ask your study doctor to discuss the costs that will or will not be covered by Aadi. This discussion should include the costs of treating side effects. Examples of medications you could possibly require in addition to the study medications include antibiotics or other medications to manage side effects of treatment. Otherwise, you might have unexpected expenses from being in this study. Your health insurance company might not pay for these charges because you are in a research study. You are responsible for charges your insurance company does not pay.

If you are on a Medicare Advantage Plan, please check with your plan regarding coverage as you may be responsible for certain costs.

PAYMENT FOR PARTICIPATION

You will not be paid for being in the study or for the use of your samples or any information obtained from your samples or medical information. Taking part in this study does not make you an employee of the sponsor or Aadi. You will not be compensated if a commercial pharmaceutical or diagnostic product(s) is developed through the use of your samples or medical information collected during this study.

ALTERNATIVE TREATMENT

Instead of taking part in this study, you may choose to receive standard treatment with other drugs or therapies that may be used to treat advanced cancers. Some of these include chemotherapy, radiation therapy, hormonal therapy, experimental therapy, or surgery. You could also participate in another research study or choose no treatment at all. The risks and benefits of these other treatments will be explained to you by your doctor. The study doctor will answer any questions you have about these other treatments.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home. If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this study is voluntary. You do not have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care or the benefits to which you are otherwise entitled.

You can decide to stop at any time. Tell your study doctor if you are thinking about stopping or decide to stop. Your study doctor will tell you how to stop safely.

It is important to tell your study doctor if you are thinking about leaving the study. This is so you and your study doctor can discuss what follow-up care, testing, and other treatments could be most helpful for you.

If you want to stop participating in the study and you withdraw after you have started, the study staff and the study doctor will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then withdraw, you will not be able to continue to participate in the study or receive any treatment as part of the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study drug.

The study team or the funding source may take you off this study at any time without your consent. There are other reasons that you may be removed from the study including:

- Your study doctor believes it is in your best interest,
- You need treatment that is not allowed in the study,
- You do not follow the study requirements,
- If the study is stopped by the funding source for any reason,
- You do not consent to continue in the study after being told of changes in the research that may affect you or,
- For any other reason.

If the study doctor or funding source ends your participation, or you decide not to continue, you will be asked to return to the study doctor or study site to have the final clinical evaluations and laboratory tests done.

CONFIDENTIALITY AND PRIVACY OF STUDY INFORMATION

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants
- Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children's, and Seattle Cancer Care Alliance
- Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required
- National Cancer Institute
- US National Institutes of Health
- Aadi Bioscience, Inc., the funding source for this study, and their agents

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevent health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA does not help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

COMPENSATION FOR INJURY

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Lee Cranmer (206-606-7439). They will treat you or refer you for treatment. Aadi Biosciences, Inc. will pay for medical expenses relating to your care and treatment of any side effect, adverse reaction, illness or injury resulting from participation in this study provided that the study has been conducted properly. There are no funds to pay you for loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

YOUR RESPONSIBILITIES

If you join this study, you would have some responsibilities:

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

FOR MORE INFORMATION

If you have questions or concerns about this study, you could talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-606-7439 Dr. Lee Cranmer 206-606-6425 Roxanne Moore, Assistant Director
If you get sick or hurt in this study	206-606-7439 Dr. Lee Cranmer 206-598-6190 UW operator and ask to page the oncology fellow on call.
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	The financial services department at Seattle Cancer Care Alliance at 206-606-6226

Emergency number (24 hours): 206-598-6190

You may call the National Cancer Institute (NCI) Cancer Information Service at 1-800-422-6237 or TTY 1-800-332-8615. For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/. This website provides general information on cancer types, treatments, and coping with cancer.

You may also visit one of the websites listed below:

For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/. This website provides general information on what clinical trials are and allows searching for specific clinical trials.

A description of this clinical trial will be available on http://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 website at any time.

When visiting either of these websites, use the search terms "sarcoma, pazopanib, ABI-009" to locate information on this trial.

Biosamples
There is an optional pre-treatment tissue collection for biomarker analysis; either archival tissue or a fresh biopsy sample can be used. If you do not have left over tissue from a previous surgery or biopsy, you may agree to undergo a fresh tumor biopsy if it is clinically feasible and there is no undue risk to you. The risks and side effects for a fine needle aspiration or biopsy are:

Likely (21-100 subjects out of 100) and Not Serious
- Inflammation (redness and swelling) of the area of the biopsy
- Pain
- Bruising
- Bleeding at the site of puncture

Less Likely (Approximately 5-20 subjects out of 100) and Not Serious
- Faintness

Rare but Serious (Less than 5 subjects out of 100)
- Infection at the biopsy site

These tests will not tell if your disease is inherited and will not involve members of your family. The samples will be analyzed for the purposes of the study. They will be stored in a secure storage facility so that we can re-test them or conduct additional analyses on them in order to follow up the safety of the study medication or to better understand the course of the disease or the disease's response to the study medication. The results of these tests may help us improve the diagnosis and the treatment of the disease in the future.

All the samples will be processed without your name, ID number, or any other information which allows your identification. They will be labeled with a code. Only authorized people will have access to the list of names which links your name to the code. Only authorized members of the study doctor's staff or Aadi's personnel or third parties, which assist Aadi with the conduct of the study (e.g., laboratories), will have access to the samples.

The samples will be destroyed 20 years after completion of the study or earlier if required by law. If you leave the study or after your participation has been stopped for any other reason you may ask for all samples that were collected from you to be destroyed or sent back to you. If you decide to withdraw your consent, you can request that all left-over identifiable samples be destroyed to prevent future testing. If you make this decision, you must notify the study doctor in writing. Data collected from analyses already completed cannot be withdrawn.

Please read the sentence below and think about your choice. After reading the sentence, check either "Yes" or "No" box and initial next to your choice. If you have any questions, please contact your study doctor.

> My remaining tumor tissue from a previous surgery or biopsy, or tissue from a fresh tumor biopsy may be stored and used for analysis.

☐ YES _____ Initials ☐ NO _____ Initials

SUBJECT'S STATEMENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to take part in this research study. If I sign this form I will not lose any of the legal rights that I would otherwise have as a subject in a research study.

CONSENT SIGNATURE:

_____
Subject Name (printed):

_____ _____
Signature of Subject (18 years and older) Date

RESEARCHER'S STATEMENT

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____
Printed Name of Person Conducting the
Informed Consent Discussion

_____ _____
Signature of Person Conducting the Date
Informed Consent Discussion

WITNESS OR INTERPRETER

If you served as an interpreter or witness during the consent process, sign below to indicate you attest to the accuracy of the presentation to the participant and the apparent understanding of the research by the participant.

Printed Name	Signature	Date

Copies to: Researcher's file
Subject
Subject's medical record (if applicable)