NCT02990468

BMX-HN-001

version 30 Apr 2019

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	A Phase 1/2 Trial of Concurrent Radiation Therapy, Cisplatin, and BMX-001 in Locally Advanced Head and Neck Cancer
PROTOCOL NO.:	BMX-HN-001 WIRB® Protocol #20161850
SPONSOR:	BioMimetix JV, LLC
INVESTIGATOR:	Name Address City, State, Zip Code Country
STUDY-RELATED PHONE NUMBER(S):	Name Phone Number(s) (24-hour number required)

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

PURPOSE OF THE STUDY

You are being asked to take part in this research study because you have head and neck cancer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed in this document.

Please tell the study doctor or study staff if you are taking part in another research study.

Concise Summary
The purpose of this study is to find out what effects, (good or bad), an investigational drug called BMX-001 may have on patients with head and neck cancers when given in combination with cisplatin and radiation therapy. The word "investigational" means the study drug is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA). It is thought BMX-001 may reduce the bad side effects of radiation therapy to the skin and inside of the mouth of the head and neck region, although there is no proof of this yet. In this study, all subjects will receive investigational agent BMX-001 with radiation therapy and cisplatin. The study will also collect information on your quality of life, side effects of the treatment, and survival.
BMX-001 is injected under the skin. The first dose is given a couple of days before radiation therapy (RT) starts, and BMX-001 is given for eight weeks. There are risks to this study drug that are described in this document. Some risks include irritation at the injection site, feeling tired, and a temporary drop in blood pressure.
If you are interested in learning more about this study, please continue reading below.

[Principal Investigator name] will conduct the study and it is funded by BioMimetix JV, LLC, the sponsor of this study. BioMimetix JV, LLC, will pay [institution/site name] to perform this research, and these funds may reimburse part of [Principal Investigator name] and his/her research team's salaries. The funding coming from BioMimetix JV, LLC is in part supported by a Small Business Innovation Grant funded by the National Cancer Institute to BioMimetix JV, LLC.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, [Principal Investigator name] or one of the other doctors at [institution/site name] will be your doctor for the study. If you choose, your study doctor or a member of the research team can notify your regular health care provider about your participation in this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to find out the effect of the investigational study drug (BMX-001) in combination with radiation therapy and cisplatin. The word "investigational" means the study drug is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA). BMX-001 is thought to reduce the toxicities (bad side effects) of radiation therapy to the skin and mucosa (inside of the mouth) of the head and neck region. BMX-001 is a new class of compound that would be termed "a redox-active metalloporphyrin." This drug was designed to mimic the body's most powerful antioxidant enzymes and is a potent anti-inflammatory that acts by blocking multiple steps in the inflammatory cascade. By inhibiting the inflammatory cascade BMX-001 is expected to protect normal tissues from the inflammatory side-effects of radiation and chemotherapy while at the same time acting as an antioxidant that will have an inhibitory effect on the growth of tumor.

In addition to this study, there are additional studies evaluating this drug with radiation for other types of cancers. Although this compound may be effective in blocking radiation related damage to your skin and mucosal surfaces inside your mouth and throat, providing direct medical benefit

to you is not the main purpose of this study. The main purpose of this study is to learn about the safety of the drug. Please carefully read the sections on risk and benefits below.

This is a Phase 2 study.

Phase 2 will continue to evaluate safety and tolerability of the study drug (BMX-001) in combination with standard radiation therapy and cisplatin for patients with head and neck cancer. It will also explore how the study drug works to improve the side effects of treatment including sore mouth/throat, skin changes and dry mouth.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 48 people will take part in Phase 2 of this study at up to five institutions in the United States.

WHAT IS INVOLVED IN THIS STUDY?
Screening

If you agree to be in this study, you will be asked to sign and date this consent form. You will then need to complete the following tests and procedures to make sure that you are eligible:

- Vital signs, including blood pressure and heart rate
- Past Medical History and physical exam
- An Electrocardiogram (ECG)
- As part of the standard of care for your cancer, you will receive examinations of your throat and voice box (larynx) done with a mirror and/or flexible lighted tube inserted through your mouth. Findings from this examination will be included in the research database for this clinical study.
- As part of the standard of care for your cancer, you will have imaging studies done of your head and neck using CT (computed tomography) and/or MRI (magnetic resonance imaging) and/or a PET (positron emission tomography) scans, which is a computerized image that looks at the activity of tumor cells in your entire body. Findings from these imaging studies will be included in the research database for this clinical study.
- Blood draw (by needlestick) for hematology (blood counts), blood chemistry tests, and a blood test that measures how long it takes your blood to clot.
- Blood pregnancy test, if you are female of childbearing potential, will be done if you are enrolled in the study 48 hours prior to study drug administration
- Review of current medications
- Review of medical and demographic information
- An evaluation of your ability to chew and swallow
- You will be asked about your diet, eating, and speech
- Evaluation of your ability to carry out daily activities
- Measurement of your saliva production, this is a quick test to determine how much saliva your body is producing
- Questionnaires

After completion of the screening process, the doctor will determine whether you are eligible to participate in the treatment part of the study. If you are eligible and you choose to participate, you will be enrolled in the study. If you do not meet the eligibility requirements, you cannot take

part in this study, in which case your doctor will inform you of other options that are available to you.

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. Some are part of regular cancer care.

Weekly during treatment:

- A physical examination
- Information regarding medications you are taking
- Blood tests (about 3 teaspoons of blood will be taken from your vein)
- Evaluation of any side effects from treatment you may be having

During weeks 1 and 4 of treatment, you will have an ECG done before and after (at about 60 minutes) receiving the study drug. During the last week of treatment, we will ask you the questionnaires again.

During treatment, if your study doctor recommends:

- A whole body PET/CT
- CT scans, MRI, or PET/CT of your neck
- A biopsy to check for recurrence of the cancer
- Evaluation of any side effects from treatment more often than weekly, if needed

You will need these tests and procedures in follow-up visits:
These tests and procedures are being done to see how you and your cancer was affected by the treatment you received as well as evaluation of any treatment related toxicity. These tests and procedures are part of regular cancer care.

At about 1 month after you finish treatment:

- A physical examination
- Questionnaires
- Information regarding medications you are taking
- Evaluation of your ability to carry out daily activities
- Blood tests (about 3 teaspoons of blood will be taken from your vein)
- Evaluation of any side effects from treatment you may be having

At about six months and one year after you finish treatment:

- A physical examination
- Questionnaires
- Information regarding medications you are taking
- Evaluation of your ability to carry out daily activities
- Blood tests (about 3 teaspoons of blood will be taken from your vein)
- Evaluation of any side effects from treatment you may be having

Approximately one year after finishing treatment, you will have a chest x-ray completed as part of this study. When you complete the study, we will continue to contact you every couple of months or you will be followed through your Electronic Medical Record (EMR) to see how you are doing for up to two years.

The tests during screening and throughout the study are explained in more detail below:

***Blood Tests**:* In total, approximately 4 teaspoons (20 mL) of blood will be drawn from your arm by a needlestick for the evaluations before starting the study drug during the screening period. These blood tests done at screening will include a complete blood count (CBC), blood chemistry (CMP) and tests of how well your blood clots (PT/aPTT). During the course of the study, complete blood count (CBC) tests and blood chemistry (CMP) tests will be drawn (approximately 3 teaspoons) while you are receiving radiation therapy beginning at Week 1. Following the cessation of radiation therapy, complete blood count (CBC) and blood chemistry (CMP) tests will be drawn (3 teaspoons) at approximately one month, six and twelve months after radiation therapy.

For women of childbearing potential, a blood test to rule out pregnancy will be done during the screening period within 48 hours prior to starting the study drug. Approximately 1 teaspoon of blood will be taken to perform this test.

In total, approximately 34 teaspoons (170 mL) of blood may be drawn during the study period for standard clinical blood tests such as CBC and CMP over a 1-year period.

Evaluation of Oral Mucositis: Mucositis is painful inflammation and ulceration of mucous membranes. Mucositis is typically a side effect of chemotherapy and radiotherapy treatment for cancer. This questionnaire will be completed at every visit.

***Electrocardiogram** (ECG):* ECG is a diagnostic tool that is routinely used to assess the electrical and muscular functions of the heart. This will be done at the screening visit as well as on the first day you receive the study drug and during weeks 1 and 4, before and about 60 minutes after the initial study drug injection.

***Questionnaires**:* Quality of life will be assessed by using patient report outcomes (PROs). PROs refer to the subjective report of symptoms, concerns, and feelings. This will be evaluated using questionnaires. These questionnaires will ask questions about your overall well-being, mood, thoughts, feelings, physical function and thinking.

Additional tests may be done at the discretion of your physician as part of your regular care throughout the study. These exams and tests will be done to monitor the effects of study drugs.

Study Procedures
After screening, the treatment period of the study will consist of 6-7 weeks of radiotherapy and cisplatin with BMX-001, followed by an additional 1-2 weeks of BMX-001. After completion of treatment for your cancer, no further administration of BMX-001 will be given. All subjects in the study will receive the study drug.

You should contact your study doctor at any time to let him or her know of any bad side effects that you might be having.

HOW LONG WILL I BE IN THIS STUDY?
You will receive the study drug, BMX-001 under the skin starting up to 4 days before you start radiation therapy and then 2 times each week for the approximately 6-7 weeks of your radiation therapy. BMX-001 injections are given before, during and after radiation therapy for a total of 17 planned doses. You will then be followed on this study for approximately two years. Thereafter, you will continue to receive routine care as determined by your treating physician. Patients can receive study treatment as long as there is no evidence of disease progression or unacceptable toxicity. The study doctor may also take you off the study if new scientific developments occur that indicate the treatment is not in your best interest, or he/she feels that this treatment is no longer in your best interest.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

The initial study visit and the study visits at the end of your radiation therapy and at 1, 6 and 12 months post radiation therapy will take approximately 2 additional hours to fill out all of the questionnaires. Your other clinical visits during radiation/chemotherapy will be standard of care.

WHAT ARE THE RISKS OF THE STUDY?
Side effects of study drugs and procedures may be mild or they may severe enough to be life threatening. They may resolve (stop) after you stop the study drug or procedure or they may continue.

Adding BMX-001 to standard of care therapy may interfere with the effectiveness of radiation or chemotherapy.

As a result of your participation in this study, you are at risk for the following side effects:

BMX-001 may cause some, all or none of the side-effects listed below. BMX-001 has only been given to animals before. Side effects are dose-dependent and the relatively low doses of this drug planned in this study have not been associated with side effects in animals other than those related to the color of the injected drug.

The most common side effects (expected to occur in more than 30% of subjects) are:

- Red to brown discoloration of the skin at the injection site which may take up to several weeks to resolve
- Irritation at the site of the injection of the drug under the skin
- Transient tachycardia (fast heart beat) after receiving the study drug

Less common side effects (expected to occur in 10-30% of subjects) are:

- Pain at the site of the injections of the drug under the skin
- Local histamine release which could be caused by the study drug. This could cause pruritus (itching), erythema (redness), edema (swelling), urticaria (welts). This is expected to resolve within a couple of hours of injection.

Rare side effects (expected to occur in less than 10% of subjects) are:

- Temporary hypotension (low blood pressure)
- Malaise or "not feeling well" for a few hours
- Prolongation of the QT interval after the loading dose. This is a condition in which your heart muscle takes slightly longer than normal to recharge between beats. This can be seen on an ECG, and is called a prolonged QT interval. We will monitor this by performing ECGs before and after study drug administration the first day you receive the drug and then twice (or more if indicated by your doctor) during BMX-001 treatment. Many drugs are known to cause this. For more information about this please discuss with your study doctor.

After discharge, you should be alert for potential symptoms of low blood pressure, which may include dizziness, fainting, lightheadedness, blurry vision, weakness, nausea, vomiting. These symptoms may occur when you change from lying down or sitting to a standing position. If they occur, you should lie down, elevate your feet and contact your health care provider if these symptoms persist.

An additional possible side effect is:

- Light-activated skin rash in response to sun exposure
- Red to dark color of urine
- It is also possible that previously unobserved and unexpected side effects could occur.

Possible Side Effects Related to Cisplatin: The cisplatin you will receive is considered standard of care for your tumor. The amount of cisplatin you will receive by participating in this study is the same as for patients with the same disease who are not taking part in this study. The cisplatin may be administered either every 3 weeks or weekly, both of which are accepted approaches.

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
• Nausea, vomiting • Infection, especially when white blood cell count is low • Anemia, which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage, which may cause swelling, may require dialysis • Hearing decrease, including ringing in ears • Change in taste

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Allergic reaction, which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion • Difficulty with balance • Numbness in the fingers and toes • Low blood pressure • Low magnesium in the blood, which may cause heart beat irregularities that are possible life threatening

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
• Cancer of bone marrow later in life caused by chemotherapy • Seizure

Possible Side Effects of Radiation Therapy to the Head and Neck: The radiation you will receive is considered standard of care for your tumor. The amount of radiation you will receive by participating in this study is the same as for patients with the same disease who are not taking part in this study.

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 and up to 100 may have:
• Sores in the mouth and/or throat which can be painful and make it very difficult to chew and or swallow foods • Mouth dryness or changes in taste and/or smell that may be permanent • Thick saliva • Hoarseness • Tanning or redness and/or irritation of the skin in the head and neck area being treated with radiation • Ear pain and/or pressure • Fatigue • Weight loss • Permanent hair loss in the area treated with radiation (face, chin, neck) • Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine to prevent you from feeling tired or sleepy • Serious damage to the jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and, rarely, can even be life threatening • Temporary pain or scarring around nerves in the shoulder that could cause numbness and/or weakness • Breathing problems • Difficulty with swallowing and eating for which you might need a long term or permanent feeding tube; possibility of inhaling food and/or liquids into the lungs – which could also result in pneumonia. This side effect is more likely for patients receiving radiation and cisplatin (Group 1). • Serious ear infections and/or hearing loss • Loss of hearing

Use of special techniques to visualize your tumor and normal tissue, called Image Guided Radiation Therapy or IGRT may lead to improved accuracy of radiation treatment compared to regular radiation therapy and eventually, that will be more useful against cancer. At this time, however, there is no proof that using this technique is more useful against cancer than regular radiation treatment without this technique. The dose from these x-ray images is much smaller than the dose used to treat your cancer. However, this dose will cover a somewhat larger region and can spill over to healthy tissues and organs that are not affected by your disease. There is a small risk that the dose from these x-ray images can be harmful, and every effort will be made to minimize this dose to healthy tissues. In this effort, it is important that we have your full cooperation in maintaining your position during treatment. In order to help you stay in position, your doctor will use a special device, sometimes called an immobilization mask. The mask is plastic mesh formed to the head and shoulder area to help stabilize your position during treatment so as to ensure accuracy of radiation treatments daily.

Blood Draws: The collecting of blood samples to monitor your health throughout this study may cause mild discomfort or pain from the needle puncture and possible bruising or mild bleeding. The risk of infection is slight and will be further reduced by keeping the puncture site clean and dry.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical food and drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies that you are taking before you start the study and before taking any of these products while you are on the study.

A CT Scan exposes you to radiation. This is considered standard of care as part of your treatment. Exposure to radiation adds up over a lifetime. The total dose of radiation from a CT scan is about three times the amount of radiation you would normally be exposed to in one year ("background radiation"). The amount of radiation can vary depending on the part of the body that is being examined. If you have more procedures that expose you to radiation, your risk will go up. Risks of harm include getting a cancer, or changes to your genes. Your risk of harm may be as high as 1 in 1,000. Your study doctor can discuss this with you in more detail.

A Positron Emission Tomography (PET) scan exposes you to radiation. This is considered standard of care as part of your treatment. Exposure to radiation adds up over a lifetime. The total dose of radiation from a PET scan is usually around three times the amount of radiation you would normally be exposed to in one year ("background radiation"). The additional exposure from a PET scan largely depends on what part of your body is being examined. If you have more procedures that expose you to radiation, your risk will go up. Risks of harm may include getting a new cancer or changes in your genes. Your risk of harm may be as high as 1 in 1000. If you have an injection into a vein for the PET scan, the needle could cause pain, bleeding, bruising, or infection. The contrast media ("dye") that is injected into the vein can cause an allergic reaction bad enough to cause death. Your study doctor can discuss this with you in more detail.

The MRI may mean some added discomfort for you. This is considered standard of care as part of your treatment. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the MRI. Temporary hearing loss has been reported from this loud noise. You may be asked to wear ear protection. At some time during the test, you may be asked to hold your breath for a while, which can be uncomfortable. Because potential risks to a fetus from a MRI are unknown, pregnant women must not have a MRI.

Chest X-ray: You will be exposed to additional radiation from the required chest X-ray which is a part of this study. The amount of radiation you will receive from a chest X-ray is low — even lower than exposure through natural sources of radiation in the environment. The average dose of the chest x-ray is about 0.1 mSv (millisieverts) and the average annual effective dose of background radiation is about 3 mSv.

Quality of Life Studies: We want to know your view of how your life has been affected by cancer and its treatment. This "Quality of life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete 6 questionnaires at 4 time points: before treatment, at the end of treatment, and at approximately 6, and 12 months after you finish treatment. It takes about 15-20 minutes to fill out these questionnaires.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the 6 questionnaires. You may change your mind about completing the questionnaires at any time.

Confidentiality: There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may

refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

For Those of Reproductive Potential
Female

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you can continue in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study and for 12 months afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B(TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study and followed until the pregnancy has ended.

There may be side effects that are not known at this time.

Male
Your participation in this research may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for 12 months afterward. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B(TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should promptly notify her doctor.

There may be side effects that are not known at this time.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, or for your care, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed

outside of [institution/site name] with the exception that your date of birth and dates of service may be recorded. For all other records disclosed outside of [institution/site name], you will be assigned a unique code number. The key to the unique code number will be maintained electronically on a secure network, which is accessible only to key personnel for the study and is password protected. As part of the study, [Principal Investigator name] and his or her study team will report the results of your study-related tests to the sponsor, BioMimetix JV, LLC. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

Study-related tests would include laboratory tests such as your blood counts and tests to measure the function of your liver and kidneys, neurological tests, and radiographic studies. Research records, records about phone calls made as part of this research, and records about your study visits may also be shared with the sponsor. In addition, your records may be also reviewed in order to meet federal or state regulations.

A Data Safety Monitoring Board (DSMB) will be utilized to review this study. The purpose of this board is to review safety of study procedures, to maintain study integrity, to review adverse events and to review the results of the data from the study.

Reviewers may include representatives from the Food and Drug Administration, The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, Governmental agencies in other countries, representatives of BioMimetix JV, LLC, the DSMB, the Western Institutional Review Board and the principal investigators of all participating institutions. If any of these groups review your research record, they may also need to review your entire medical record. This information may be needed to do the research, to study the results, and to see if the research was done right.

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

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- Qualified representatives of the pharmaceutical collaborator

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.

The study results may be retained in your research record indefinitely. Any research information in your medical record will also be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

You do not have to give permission to use and give out my health information, but then you will not be able to be in this research study. There is no expiration date for the use of this research information.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

You may have the opportunity to review or copy your information, but only after the research is over.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

There is a risk that your information will be given to others without your permission.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
This drug has not previously been given to human subjects and therefore it is unknown whether or not it will benefit you by reducing the side effects of treatment. Potential benefits may include protection against mucositis and xerostomia caused by radiation therapy. We hope that in the future the information learned from this study will benefit other people with your condition.

During this research project, new information regarding the risks and benefits of the study may become known to the investigators. If this occurs, they will tell you about this new information. New information may show that you should no longer participate in the research. New information may also require you to sign a new consent form. If this occurs, the persons supervising the research will stop your participation in it. In either case, you will be offered all available care that suits your needs and medical conditions.

WHAT OTHER OPTIONS ARE THERE?
Instead of being in this study, you have these options:

- You could choose to receive alternative investigational drugs.
- You could choose to receive the same radiation and chemotherapy as in this study or other standard therapy for this disease without BMX-001.
- You could choose to receive the standard therapy for this disease.
- You could choose to receive no therapy at this time and receive care to help you feel more comfortable. If you choose this option, you may reconsider at any time, and this decision will in no way affect the regular care that you receive.

Please talk to your doctor about these and other options.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your charges as long as you are participating in this study. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed. Please ask [Principal

Investigator] if you would like to know more about which tests and studies are being done solely for research purposes.

BMX-001 is provided free of charge by BioMimetix, JV LLC while you are on study. Cisplatin is commercially available and will not be supplied free of charge. Radiation therapy is standard of care and will not be supplied free of charge.
The study sponsor BioMimetix has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

The following are research-related costs and will not be charged to you or your insurance:

1. Blood draw (by needlestick) for a test to check how quickly your blood clots
2. ECGs – at screening and three on the loading dose day of BMX-001, followed by two more during the BMX-001 treatment period.
3. The chest x-ray at approximately 12 months following completion of treatment. If the x-ray is clinically indicated and ordered as standard of care it will be billed to your insurance. If the scan is completed as a required study procedure, the sponsor BioMimetix will pay for the scan.

If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

WHAT ABOUT COMPENSATION?
You will receive no payment for taking part in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at [Institution/Site name] in the event that you are injured as a result of your participation in this research study. However, there is no commitment by [Institution/Site name], BioMimetix, JV LLC, or your physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact [Principal Investigator] at [phone number] during regular business hours and at [24 hour phone number] after hours and on weekends and holidays.

You have not waived any of your rights to legal recourse in the event of research-related harm.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at [institution/site name]. If you do decide to withdraw from the study, we ask that you contact [Principal investigator] in writing and let him/her know that you are withdrawing from the study. His/her mailing address is [mailing address].

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. A reason why this might occur includes new identification of an unexpected problem with the study drug. If this occurs, you will be notified and your study doctor will discuss other options with you.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions, complaints or suggestions about the research, contact [Principal Investigator] at [phone number] during regular business hours and at [24-hour phone number] after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns, complaints or suggestions related to the research, or to obtain information or offer input about the research, contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

CONSENT
I have read 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 be in this research study.

I authorize the release of my medical and research records for the purpose of this study.
By signing this consent form, I have not given up any of my legal rights.

Subject Name (printed)

CONSENT SIGNATURES:

Signature of Subject Date

- I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

Signature of Person Conducting Consent Discussion Date