SUMMARY OF CHANGES

Date: November 9, 2023

Document: NCI Protocol #8264, PhII-96: "Phase II Trial of Single Agent ABT-888 with Post-Progression Therapy of ABT-888 in Combination with Carboplatin in Patients with Stage IV *BRCA*-associated Breast Cancer."

Note: The following is a Summary of Changes between the 6.1.2023 and 11.9.2023 versions of model consent

#	Section	Comments
1.	Footer	Footer was updated to 11.9.23v
2.	Discontinuation of Treatment	Added information regarding the discontinuation of ABT-888 drug program drug being no longer available after December 31, 2024. Patients will need to end their participation by December 31, 2024 or earlier and their physician will discuss other treatment options with a suitable transition.

SAMPLE INFORMED CONSENT

Study Title for Study Participants: Veliparib With or Without Carboplatin in Treating Patients With Stage III or Stage IV Breast Cancer

Offical Study Title for Internet Search on http://www.ClinicalTrials.gov: Phase II Trial of Single Agent ABT-888 with Post-Progression Therapy of ABT-888 in Combination with Carboplatin in Patients with Stage IV BRCA-associated Breast Cancer

I. **PURPOSE OF THIS RESEARCH STUDY**: You have been asked to participate in this research study because you have advanced breast cancer that is associated with a documented inherited mutation in *BRCA1* or *BRCA2*. The purpose of this study is to find the most effective and well tolerated dose-level of ABT-888 when used with carboplatin and to evaluate the effectiveness of ABT-888 alone and in combination with carboplatin in treating BRCA1- or BRCA2-associated advanced breast cancer. Your treatment in this study is expected to last until your disease begins to grow or you have unmanageable side effects. After your treatment is over, your medical condition will be followed on this study indefinitely.

II. **WHAT IS THE USUAL APPROACH TO MY BREAST CANCER?** You are being asked to take part in this study because you have breast cancer that has spread to other places in your body, and has grown worse despite treatment you received. People who are not in a study are usually treated with more chemotherapy.

III. **WHY IS THE STUDY BEING DONE?** Breast cancer is the most common cancer in women. In 2007, approximately 1.3 million women were diagnosed with breast cancer worldwide, and an estimated 465,000 breast cancer-related deaths were expected. Almost 100,000 of these breast cancer-related deaths occur in patients that overexpress HER2 receptors. Metastatic breast cancer (MBC) is incurable, with the primary goal of treatment being to extend life and ease symptoms while maintaining quality of life.

Cells contain a type of molecule called deoxyribonucleic acid, or DNA for short. DNA carries the genetic information for the development of cells. If DNA becomes damaged, chemicals inside the cell try to repair it. One such chemical is the protein PARP-1. ABT-888 is an inhibitor of PARP-1. This means ABT-888 stops PARP-1 from repairing DNA. Functioning BRCA genes in normal cells can repair DNA damage even if PARP-1 is inhibited. However, cells with abnormal BRCA, such as BRCA1 and BRCA2 cancer cells, cannot. ABT-888 is in an early phase of development so there is limited information about the use of ABT-888 in human subjects. In previous studies, ABT-888 has been well-tolerated and has caused less side effects than conventional

chemotherapies. ABT-888 has not yet been approved for use by the Food and Drug Administration (FDA) except in research studies.

In laboratory and animal experiments, ABT-888 was found to enhance the anti-tumor activity of carboplatin. This study is to see if ABT-888 and/or ABT-888 with carboplatin can prevent the survival of *BRCA1*- or *BRCA2*-associated breast cancer cells.

III. **WHAT WILL BE DONE: Screening**: If you agree to take part in this study, you will undergo screening evaluations to see if you are eligible to receive the study drug. You will have at least 2 and possibly more screening visits within a period of 4 weeks.

- You will be asked about current signs and symptoms of your cancer within 28 days and within 7 days before receiving study drug,
- A general health check, including current signs and symptoms of your cancer will be done within 7 days before receiving study drug, including a physical examination, measurement of your height and bodyweight, ECOG (Eastern Co-operative Oncology Group) performance status (the study doctor will question you about you ability to carry out daily tasks), and measurement of your vital signs (temperature, blood pressure, breathing rate and heart rate).
- You will be asked about your date of birth and race, your medical and surgical history (within 28 days before starting study treatment)
- You will be asked about previous cancer treatment you received (within 7 days before starting study treatment; will be done again at visit 1)
- You will be asked about the medications you are currently taking twice (within 28 days and within 7 days before receiving study drug).
- Blood (about 20 ml, which is about 4 teaspoons) will be taken for routine blood counts and tests to see how your organs are working (within 7 days before starting study treatment)
- Tumor assessments: either a computerized tomography (CT) scan (an X-ray that is transmitted onto a computer) or a magnetic resonance imaging (MRI) scan (an imaging procedure using magnetic waves/pulses to take pictures of the inside of your body). Before these scans, contrast medium (like a dye) may be injected into one of your veins to help give clearer images of your cancer. X-rays or other imaging tests may be done also (within 28 days before starting study treatment). You will be asked to sign a separate consent form for any imaging procedure.
- A urine sample will be taken for routine tests to see how your organs are working (within 7 days before starting study treatment)
- If you are capable of bearing children, a urine or blood sample (about 6 ml, which is about 1 teaspoon) will be taken to make sure that you are not pregnant (within 7 days before starting study treatment)
- **Optional**: If you have a tumor that is easy to biopsy, you may be asked to undergo a series of optional biopsies. These would be done: 1) before you start study drug, 2) 4-8 hours after your first dose of ABT-888 on Cycle 2 Day 1, and 3) when you go off of treatment. Your eligibility is not affected by this biopsy. (Please see "Making Your Choice" to mark your selection on this consent form)

If the screening process shows that you are not eligible to receive the study drug, you will be taken off the study and the study doctor will discuss alternatives with you.

Treatment for each Study Group:

What treatment you receive will depend on when you are entered into the study. Each cycle of treatment for all subjects is 21 days long.

Safety Lead-In: If you enter the study during the Safety Lead-In period, each group of subjects will receive a higher dose of ABT-888 than the group before until the highest tolerated dose is found. Therefore, the dose you receive will depend upon when you are entered into this study. Everyone on the safety lead-in will also receive a standard dose of carboplatin.

Phase II: If you enter the study during the Phase II period, you will receive ABT-888 for 3 cycles (63 days). After every 3 cycles you will be evaluated. If your disease has gotten better or stayed the same you will continue on ABT-888. If your disease begins to grow and if you are eligible you will start receiving carboplatin in addition to ABT-888.

When you are assigned to carboplatin, you will receive an intravenous (IV, into a vein) infusion of the drug over 30 minutes on Day 1 of each 21 day cycle. Your dose may be lowered if you experience greater side effects.

All Subjects:

You will start taking drug at Day 1. ABT-888 is provided as capsules containing 100 mg each, which you may take at home. You will take 400 mg twice a day at the beginning. Upon progression of your disease you will start taking 150 mg of ABT-888 twice a day along with carboplatin. You will take the medication once in the morning and again about 12 hours later. Your doctor will tell you how many capsules you will need to take. You will need to swallow the capsules with a glass of water at about the same time each day. It is important that you take the study medication as directed. This drug is yours and should not be taken by anyone else. If you forget to take the capsule at your regular time, you may still take them if it is within 2 hours of your regular time. If you forget to take the capsules more than 2 hours after your regular dosing time, you should not take another capsule until your next regular dosing time, when you should take the capsules as prescribed. You will be asked to complete a patient diary to document when you took each dose or to give a reason if you did not take the capsules. You will be expected to bring the diary and unused capsules to the study doctor at the scheduled visits as described below. If you have side effects, you may have to stop taking the study drug for a while and may need to restart it. The study doctor will provide you with complete instructions if this happens. Any leftover study medication that you do not take and the

container (even if it is empty) must be returned at the end of each treatment cycle to your study doctor.

You must store the study drug capsules below 86 degrees Fahrenheit and protect them from light.

While taking part in the study, you are asked not to take herbal/natural products or other folk remedies without first discussing it with your doctor. Your doctor will discuss with you other medications and treatment that you should not receive while taking the study drug (for example chemotherapy, immunotherapy, hormonal therapy, as well as some other types of drugs). In order to avoid against drug interactions and to best evaluate the effect of the study drug, it is important that you tell the medical staff about any other medication or herbal supplements you have taken before the study and are taking during the study.

You may continue receiving the study drug for as long as your cancer is not getting worse and you are not experiencing unmanageable side effects, or until you decide you want to discontinue taking the study drug. At the end of your treatment on this study, you will have a follow-up visit, and your study doctor will decide how to best manage your cancer.

Required Research Tests: The scientific, diagnostic and/or medical significance of the research to be done is not known. Therefore, neither you nor your doctors will be informed of your individual results, and they will not affect your treatment in any way.

Pharmacodynamics: As part of your participation in this study, you will have a series of blood drawn (about 12 ml, which is about 2-3 teaspoons) on Day 1 before your first dose of ABT-888, then 3 hours after the first dose of ABT-888 for peripheral blood mononuclear cell (PBMC) analysis to show whether the study drug is inhibiting PARP in these cells. On Cycle 2 there will also be a 3-hour blood draw. When you start receiving carboplatin, you will have additional blood draws on day 1 of each cycle before, and 3 hours after, your carboplatin.

Evaluations During Treatment: Below is a table showing the visits during study and the routine and research evaluations that will be done at each visit. Some of the procedures listed for Day 1 may not need to be repeated if the doctor agrees and these eligibility criteria are met within 7 days. On all visits, before you take the study drug in the morning, vital signs will be measured, and blood samples will be taken for laboratory safety tests. So you will be asked to not take your study drug on your visit days, until after these evaluations. If you agree, additional research procedures may be done at some of the visits. These will be described in a separate subsection titled "Optional Research Studies."

Visit Day (+ or – 2 days)	Repeat Review of Previous Therapy	Tumor Biopsy*	Physical examination	Weight Measured	Vital signs Measured	Performance Status	Routine blood tests (20 ml, about 4 teaspoons)	Pharmacodynamic Blood Draw (about 2-3 teaspoons)	Genetic Blood DrawI	Urinalysis	Tumor Assessment (imaging scans as done at screening)	Review of Side Effects & Other Medications you are Taking	Carboplatin Infusion**	Receive New Supply of Drug	Return Unused Drug, Review Drug Diary
1	X	X	X	X	X	X	X	X	X	X		X	X	X	
8					X		X					X			
15					X		X					X			
22		X	X	X	X	X	X	X				X	X	X	X
29					X		X					X			
36					X		X					X			
43			X	X	X	X	X	X			X	X	X	X	X
50					X		X					X			
57					X		X					X			
64								X			X				
Each 21-day cycle visit until study drug discontinued			X	X	X	X	X	X			X	X	X	X	X

When you go off study	X	X	X	X	X	X	X	X			X	X			X

*Optional

**This drug will only be given to those patients that are in the safety lead in, or have disease growth in the Phase II portion of the study.

End of Treatment Visit: If you are not benefiting from treatment or are experiencing unmanageable side effects or if you decide to discontinue treatment, your treatment on this study will be discontinued. You will be asked to come in for an end of treatment visit so that the study doctor can evaluate any side effects you may be experiencing and evaluate your health. The following procedures will be done:

- physical examination including measurement of your bodyweight, vital signs, and ECOG performance status
- blood draw (about 10 ml or 2 teaspoons) for routine blood tests tumor evaluation (imaging scans)
- You will also be asked to describe any changes in your health and the medications you are taking since your last visit, and you will be asked to return all unused capsules to the study doctor or nurse, who will check that your diary has been filled in correctly.

When you have finished taking part in this study, your study doctor will decide how to continue to manage your breast cancer.

Discontinuation of Treatment: Your study doctor may decide that continuing treatment on this study is no longer in your best interest and withdraw you without your consent. Your participation in the study may also be stopped without your consent by the IRB or regulatory authorities. You may also decide that you no longer want to continue treatment on this study, in which case, you are asked to tell the study doctor. If you discontinue treatment for any reason, you will be asked to come in for the End of Treatment visit so that your health can be checked and the effects of the study drug can be evaluated.

As of September 2023, the pharmaceutical collaborator, AbbVie, has discontinued the ABT-888 development program with the NCI Cancer Therapy Evaluation Program (CTEP) and drug will no longer be available after December 31, 2024. You will need stop treatment by December 31, 2024 or earlier.

Your physician will discuss with you alternative treatment options as well as a suitable transition prior to stopping treatment.

Follow-Up Visit: About 30 days after you have taken your last dose of study drug, you will be asked to come in for a follow up visit. On the Follow-up Visit:

- You will be asked about your health and medication you have taken since the last visit.
- If you had abnormal laboratory values at the End of Treatment Visit, you will be asked to give a blood (about 2 teaspoons) and a urine sample for safety laboratory tests.
- If the scans done at the End of Treatment Visit showed that your disease had improved, you may be asked to come in again 4 weeks later to have the imaging scans repeated at the follow up visit.
- If you have any side effects that have not improved by the first follow-up visit, you may be asked to come in for additional follow-up visits at the discretion of your study doctor until the side effects have stopped.

Optional Research Studies: Participation in the following research activities is optional. Your decision not to allow specimens to be taken for biomarker or genetic research or to allow storage of your specimens for future research will not affect your ability to participate in this study. The scientific, diagnostic and/or medical significance of the research to be done is not known. Therefore, neither you nor your doctors will be informed of your individual results and they will not affect your treatment in any way.

Biomarker Research: A biomarker is any biochemical in the body that is useful for measuring or predicting the progress of disease or the effects of treatment. The study team would like to perform biomarker research on samples collected from you during your previous treatment or during your participation in this study. This research will try to identify a way to predict which people will benefit from treatment with the study drug (ABT-888), along with carboplatin, and similar approved drugs.

In order to do biomarker studies, the researchers would like to obtain a portion of any biopsy or surgery specimen obtained during routine procedures before the study that is left over after diagnostic and other clinical tests have been done.

Fresh Tumor Biopsy: If you have a tumor that is easy to biopsy, you may be asked to undergo a series of optional biopsies. These would be done: 1) before you start study drug, 2) 4-8 hours after your first dose of ABT-888 on Cycle 2 Day 1, and 3) when you go off of treatment.

Genetic Research: As part of your participation in this study, you will have blood drawn to study how genetic variations may influence the way people respond to ABT-888 and similar approved drugs. We will not use the blood sample you donate for other purposes. We will draw about 2 teaspoonfuls (approximately 10 mL) of blood from you during screening. DNA will be extracted from your blood sample. In this process, most of the

original blood sample will be used up but a small amount will be kept as a "backup" in case of problems in the testing of your DNA.

The research results from this genetic study may be analyzed along with results from other studies. The purpose of this genetic study is not to provide you with test results. The researchers will not make any results available to you, any insurance company, your employer, your family, the study doctor, or any other physician who treats you now or in the future

Confidentiality: Precautions will be taken to ensure that this biomarker and genetic research will be carried out with a very high degree of confidentiality. To protect your confidentiality, your biological and genetic sample(s) will be labeled with the same code that is given to you in the treatment portion of the study, but not with personal identifiers such as your name or date of birth. The data and results of this biomarker and genetic research may be reviewed with collaborators and published. Neither your name nor any other information that identifies you personally will be available to any collaborators or appear in any publications or reports.

It is possible that the study team may work with other companies to conduct the testing and research and will have access to your de-identified medical information. Your samples will be stored with similar samples at the research laboratory. Samples from this biomarker research may be kept for up to 15 years after the main study is completed. At that time, all remaining samples and preparations derived from these samples, collected and stored by the study team as part of this biomarker research, will be destroyed.

The tests performed on your samples may be done long after (up to 15 years) you finish the study treatment, as new techniques and research tools become available.

The results of research on your biological samples may be compared and combined with results from other research studies for this drug and similar drugs. In addition, the results of research on your biological samples may be compared with your medical information, but only when this information may help our understanding of how people will respond to treatment with the study drug (ABT-888) and similar approved drugs. In addition, these data may be used to develop a diagnostic test.

The DNA sample and the remaining blood sample will be stored with similar samples from other participants at the research laboratory. All DNA and blood samples from this genetic study will be destroyed 15 years after the main study is completed. Your DNA may be studied at any time before this. The pattern of variations in your DNA may be compared with medical information collected in the main study, but only as this information relates to the research goals described above.

At the study site, the code number used to label your genetic blood sample will be recorded next to your name. For this reason, information obtained from your samples, including the results of research on your DNA, is considered protected information. Special precautions will therefore be taken to ensure that the genetic research described in this document will be carried out with a very high degree of confidentiality.

Your genetic blood sample will not be labeled with your name, but, as mentioned above, only with the same code that is given to you in the main study. As an added level of security your DNA, when it is extracted from your sample, and the results of any research on your DNA will receive a second code number. A file linking the first and second codes will be kept in a secure place with restricted access. If you change your mind about participating in this genetic research, this link will allow us to locate your samples and destroy them.

The coding of samples and results is to ensure that genetic research results are kept confidential by keeping your identity and these results separate. Very few people will be able to connect your identity and the results of research on your DNA, and only for special reasons. Study staff whose job it is to make sure the research has been done properly by checking the records, will also be able to identify you from your medical files but will not have access to the results of this genetic research. Regulatory authorities, who also may wish to check that this genetic research has been done properly, will also have access to your files and know your identity.

How the Results of Biomarker and Genetic Research Will Be Used: This research may lead to the development of new patents, diagnostic tests, drugs, or biological products. The biological samples that you donate will not be used to treat or diagnose illness in subjects. Some of this research may result in new inventions or discoveries that may be of potential commercial value and may be patented and license for the development of new products. Donors of blood, tissue, and other biological materials do not retain any property rights to the materials. Any information derived directly or indirectly from this biomarker or genetic research, as well as any patents, diagnostic tests, drugs, or biological products developed directly or indirectly as a result of this biomarker or genetic research, are the sole property of City of Hope (and its successors, licensees, and assigns). You have no right to this property or to any share of the profits that may be earned directly or indirectly as a result of this biomarker or genetic research. However, in signing this form and donating sample(s) for this biomarker or genetic research, you do not give up any rights that you would otherwise have as a participant in research.

Withdrawing Specimens from future Biomarker or Genetic Research: If you agree to allow your specimens to be used for biomarker research, you can change your mind later.

If you change your mind, please ask for the "Withdrawal of Informed Consent for Use of Specimens for Future Research" for IRB #07211 – "*Phase I/II Study of ABT-888 in combination with carboplatin in patients with stage IV BRCA-associated breast cancer*." Please sign this withdrawal form and send it to the principal investigator of this study at City of Hope. Once City of Hope processes your signed withdrawal of informed consent, your specimens will not be used in any new research. At that time, any of your existing specimens will be destroyed. However, if biomarker or genetic research has already been performed, the study team is not obliged to destroy results from this research. In this case only the genetic and biological sample(s) and any preparations from them will be destroyed.

Making Your Choice: Please read each statement listed in the table below and consider the choices you would like to make. After reading each statement, please tick your choice of "yes" or "no". If you have any questions, please talk to your study doctor.

I consent to the use of the following specimens, taken before entering the study and/or during the study as part of my standard care or to meet study endpoints, for biomarker and genetic research:

- Tumor tissue left over after previous routine biopsies or surgeries. Yes ☐ No ☐
- Tumor tissue collected by a core needle biopsy under local anesthesia specifically for research under local anesthesia. Yes ☐ No ☐
  - You will be asked to sign a separate consent form for this procedure.
- Blood drawn to study how genetic variations may influence the way people respond to ABT-888 and similar approved drugs. Yes ☐ No ☐

Amount of Blood Drawn Over the Course of the Study: Overall, spread over all the visits, the maximum blood volume to be taken during the study is about 280 mL (about 58 teaspoonfuls), which is less than half the amount that is taken from blood donors who are giving blood.

IV. **POSSIBLE BENEFITS**: The possible benefits to you from taking part in this study are an improvement in your cancer. However, this cannot be guaranteed. You may not experience any direct health benefits during or after completing this study. Potential benefit to others may result from the knowledge gained from your participation in this research study.

V. **POSSIBLE RISKS AND DISCOMFORTS**: In addition to killing cancer cells, cancer treatment can damage normal tissues and produce unwanted side effects. You will be monitored closely by routine physical examinations and laboratory tests to see if side effects are occurring. By careful adjustments of dosage and schedule, severe side effects can

usually be avoided. The physician may prescribe medication to help keep side effects under control. Study treatment will be discontinued if serious side effects develop that cannot be otherwise controlled. Side effects usually go away when study treatment is stopped, but occasionally problems can persist and cause serious complications. Sometimes a side effect may be fatal.

ABT-888 has been given to humans in a limited fashion, as part of a phase 0 study (a type of clinical trial in which a small amount of an investigational agent is given to a small number of subjects to research the drug's pathway in the body and potential to lead to responses in tumors), and in an ongoing phase I studies. Phase I studies are studies that evaluate the safety of treatments in humans for the first time.

Risk and side effects related to ABT-888:

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss

The ABT-888 used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

The study drug, **ABT-888**, has been tested in the laboratory and in animals. An early phase study of ABT-888 is being conducted in humans. Based on these data no significant safety concerns have been observed to prevent the use of ABT-888 in humans. Experience with ABT-888 in humans is still very limited. So far, subjects who received ABT-888 at doses the same or lower than those used in this study have not experienced significant side effects. Based on the use of this drug in animal and human research to date and experience with other similar drugs, the risks and potential discomforts of ABT-888 are:

COMMON, SOME MAY BE SERIOUS In 100 people receiving ABT-888 (veliparib), more than 20 and up to 100 may have:
• Nausea • Tiredness • Bruising, bleeding
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving ABT-888 (veliparib), from 4 to 20 may have:
• Anemia which may require blood transfusion • Infection, especially when white blood cell count is low • Belly pain • Constipation, diarrhea, vomiting • Weight loss, loss of appetite • Dehydration • Dizziness, headache • Changes in taste • Rash
RARE, AND SERIOUS In 100 people receiving ABT-888 (veliparib), 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions

- A new cancer resulting from treatment of earlier cancer
- Seizure
- Blood clot which may cause swelling, pain, shortness of breath

If you experience side effects associated with ABT-888 your study doctor may prescribe medications to reduce these side effects. It is also possible that future treatment with ABT-888 may be delayed or the dose reduced or stopped permanently. Many side effects of cancer treatments go away shortly after treatment is stopped, but in some cases side effects can be long lasting, permanent or life threatening.

Risk and side effects related to carboplatin (this drug will be given to those subjects that are in the safety lead in or have disease progression on the Phase II portion):

Likely:

- Low white blood cell counts - this may make you more open to infection; may require additional medication, should stop when treatment is stopped
- Low platelet count - this may make you bruise more easily and bleed longer if injured; may require additional medication, should stop when treatment is stopped
- Low red blood cell count which may cause tiredness, shortness of breath or fatigue; may require additional medication, should stop when treatment is stopped
- Fatigue, which is temporary and should get better when treatment is stopped
- Loss of appetite and weight loss; may require additional medication, should stop when treatment is stopped
- Diarrhea, constipation, nausea and vomiting, and abdominal pain; may require additional medication, should stop when treatment is stopped
- Skin rash, which is temporary and may require additional medication
- Changes in taste, which are temporary and should get better when treatment is stopped
- Changes in electrolytes in the blood such as magnesium and potassium
- Decrease in kidney or liver function, which is usually seen on laboratory tests and should get better when treatment is stopped
- Hair loss, should stop when treatment is stopped

Less likely, but serious:

- Numbness or tingling in fingers or toes; may require additional medication, should stop when treatment is stopped
- Ringing in the ears and hearing loss, should stop when treatment is stopped
- Allergic reactions, which may include difficulty breathing, rash, itching, redness or swelling. This is temporary but will require immediate medical attention and additional medication

- Chills and fever with aches and pains, which are temporary and may require additional medication
- Sores in mouth and throat (that can lead to difficulty swallowing and dehydration), which are temporary and may require additional medication
- Altered vision, which is temporary and should get better when treatment is stopped

Rare, but serious:

- Seizures, which are temporary and may require additional medication
- Secondary leukemia - a type of cancer of the blood that may be caused by the drugs you will receive during this treatment. Secondary cancers are very hard to treat and may be fatal.
- Kidney failure requiring dialysis. This may be permanent.
- Deafness, which is permanent
- Death

Unknown Risks: The study medications used in this study may involve other risks, including possible life-threatening reactions that are not known at present. There is always a risk involved in taking new medications but every precaution will be taken to minimize this risk and you are encouraged to report anything that is troubling you. The risk of side effects may increase if you do not follow the restrictions detailed in this consent form, particularly those concerning taking other drugs and use of contraceptives.

Blood Draw: Drawing blood from a vein can cause minor pain and bruising at the site where the needle enters. Some people feel dizzy when blood is drawn. Rarely, infection may occur.

CT Scans: There is a slight risk of developing an allergic reaction to the iodine contrast material that may be given to you. This reaction can be mild (itching, rash) or severe (difficulty breathing or sudden shock). Death resulting from an allergic reaction is rare. Most reactions can be controlled by the use of additional drugs to prevent the allergic type reaction. Be sure to tell your doctor if you have allergies of any kind (such as hay fever, iodine allergy, eczema, hives, or food allergies). The contrast material used during a CT scan can also cause water loss or damage to the kidneys that may lead to kidney failure. This is of particular concern if you have underlying poor kidney function, dehydration, or diabetes. You will be exposed to a limited and medically acceptable dose of radiation during the procedure. There is always a slight risk from being exposed to any radiation, including low levels of X-rays used for a CT scan. You may also experience discomfort related to lying still in an enclosed space for a prolonged period of time.

MRI (magnetic resonance imaging): Risks include possible anxiety and claustrophobia related to being placed in the large body scanner; temporary discomfort related to having to lie still during the procedure; and possible pain, infection and bleeding related to venipuncture if contrast dye is used. Because MRI works through a powerful magnetic field, it cannot be done if subjects have a pacemaker, intracranial aneurysm clips or other metal implants (for example, types of implants used in eye surgery or orthopedic [bone] surgery), artificial limbs and other medical devices that contain iron. Also, there is a risk that metal objects coming near the magnet may become dangerous as they are pulled toward the magnet. The magnetic field will stop a watch that is within several yards of the magnet. Severe injury or death can occur when subjects with implanted neurological stimulators undergo MRI scans. You should discuss any metal devices in your body with the study staff. In addition, when having an MRI scan, iron pigments in tattooed eyeliner or in eye makeup can potentially cause temporary skin irritation and/or swelling around the eye. For subjects that need an MRI scan and have reduced kidney function there is a chance of developing "nephrogenic systemic fibrosis," a condition characterized by thickening and itchiness of the skin, stiffening of the joints and possible reduction in the ability to move around. This condition is associated with the MRI contrast agent gadolinium and occurs mostly in subjects with severe kidney disease. The risk to subjects with mild kidney problems is anticipated to be small. You will be questioned and examined, if necessary, to confirm that you may undergo MRI scanning without additional risk. An x-ray may be performed to rule out the presence of a suspected foreign body before the MRI

For further specific information about any of the procedures in this study, please ask your Study Doctor and/or the specialist doctor (radiologist) who will perform some of these procedures.

Risk to a Newborn or Unborn Child: There might be unknown risks to the unborn child if you are or if you become pregnant during the study. There have been no animal studies to investigate directly the effects of the study drug on the newborn. If you are pregnant, or plan to become pregnant during the research study period, or nursing a baby, you cannot take part in this study. If you are of childbearing potential, a urine or blood pregnancy test will be obtained before treatment is started. If you are sexually active and capable of bearing a child, you and your partner must agree to use one of the following forms of contraception throughout the treatment period and for 3 months after discontinuation of treatment: oral contraceptives or other hormonal therapy (e.g. hormone implants), intra-uterine device, diaphragm with spermicide or condom with spermicide.

If at any time during this study you think you might be pregnant, or later learn that you were pregnant during the study, you must contact the study doctor immediately for further instructions about your participation in this study and follow-up.

VI. **ALTERNATIVE TREATMENTS**: Alternative treatments include other types of chemotherapy or other experimental therapies. Your physician has discussed alternative to participation with you.

VII. **CONFIDENTIALITY OF INFORMATION**: Any information learned from this study in which you might be identified will be confidential and disclosed only with your permission. By signing this form, however, you allow the researchers to make your information available to the City of Hope Institutional Review Board (IRB) Office; the Cancer Protocol Review and Monitoring Committee (CPRMC); the Office for Human Research Protections (OHRP); the National Cancer Institute (NCI) will obtain information from this clinical trial under data collection authority Title 42 U.S.C. 285; Theradex, auditing organization for the NCI, the Food and Drug Administration (FDA); Pharmaceutical Collaborator; participating institutions in this study, and any other party as required by law. If information learned from this study is published, you will not be identified by name.

VIII. **OFFER TO ANSWER QUESTIONS AND RESEARCH INJURY NOTIFICATION**: The principal investigator, Dr. Mortimer or a colleague, Dr. _____, responsible for your care or treatment, has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact Dr. Mortimer at (626) 256-HOPE (4673).

IX. **INVESTIGATIONAL DRUG (IND)**: This research study involves the use of an investigational drug called ABT-888 registered with the Food and Drug Administration (FDA), IND# 77,840 by the NCI.

X. **SPONSOR OF THIS RESEARCH**: The National Cancer Institute is the sponsor of this research study.

XI. **COSTS TO THE SUBJECT FOR PARTICIPATION**: The investigational drug ABT-888, drug will be provided free of charge by the National Cancer Institute (NCI). Should this drug become commercially available during the course of your treatment, you and/or your insurance carrier may be asked to pay for the costs of the drug.

You and/or your insurance carrier will be responsible for the other costs of treatment and diagnostic procedures. You and/or your insurance carrier will be billed for the costs of treatment and diagnostic procedures in the same way as if you were not in a research study.

XII. **PAYMENT TO THE SUBJECT FOR PARTICIPATION**: You will not be paid for taking part in this study.

XIII. **EXPLANATION OF TREATMENT AND COMPENSATION FOR INJURY**: It is the City of Hope policy that in the event of physical injury to a research subject, resulting from research procedures, appropriate medical treatment will be available at City of Hope to the injured research subject but financial compensation will not be available.

XIV. **VOLUNTARY PARTICIPATION WITH RIGHT OF REFUSAL**: You have been informed that your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at City of Hope.

XV. **IRB REVIEW AND IMPARTIAL THIRD PARTY**: This study has been reviewed and approved by the Institutional Review Board (IRB). A representative of that Board, from the Research Subjects Protection Office, is available to discuss the review process or your rights as a research subject. The telephone number of the Research Subjects Protection Department is (626) 256-HOPE (4673) ext. 62700.

XVI. **FINDINGS RELATING TO WILLINGNESS TO CONTINUE PARTICIPATION**: Your physician has explained to you that you will be informed of any significant new findings related to this study which might affect your willingness to continue to participate.

XVII. **EXPERIMENTAL SUBJECT'S BILL OF RIGHTS AND CONSENT FORM**: You will be given a signed copy of this consent form and the "Experimental Subject's Bill of Rights" and have read them.

XVII. **SIGNATURE FOR CONSENT**: The above-named investigator has answered your questions and you agree to be a research subject in this study.

Print Subject's Name: _____

Subject's Signature:_____

Date: _____

(date must be in subject's handwriting)

* Subject's Legally Authorized Representative _____

Date: _____

(if subject unable to sign) (date must be in representative's handwriting)

Witness's Signature: _____

Date: _____

Investigator's Signature: _____

Date: _____

(If applicable) I have translated this form into the
_____ language.

Translator's Signature: _____

Date: _____

* If signed by other than subject, indicate relationship (e.g., mother, father, husband, wife, daughter, son, etc.):

_____