Official Title:	A single arm phase II study to evaluate efficacy of T-DM1 with Palbociclib in the treatment of patients with metastatic HER2 positive breast cancer
NCT number:	NCT03530696
Document Type:	Consent Form
Date of the Document:	Version 02/15/2021, IRB approved 7/15/2021

Consent to Participate in Research

Study Title: A single arm phase II study to evaluate efficacy of T-DM1 with Palbociclib in the treatment of patients with metastatic HER2 positive breast cancer

Protocol Identification: Palbo T-DM1

Principal Investigator: Pavani Chalasani MD, MPH

Sponsor: University of Arizona Cancer Center

Funding Source: Pfizer

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

The University of Arizona receives compensation from the Pfizer for the conduct of this study. If you have any questions, please discuss this with your study doctor.

Why is this study being done?

The purpose of this study is to see if combination of T-DM1 with palbociclib is safe and assess if it has signal of efficacy for metastatic HER2 positive breast cancer. Palbociclib is considered investigational in this combination because this combination has not been approved to be used for treatment in the United States by the Food and Drug Administration (FDA), at this time. However, Palbociclib is currently approved in combination with hormonal therapy for treatment of hormone receptor positive but HER2 negative metastatic breast cancer.

What will happen if I take part in this study?

You will be asked to:

- sign this consent form;
- give your health history. The study staff will review your medical history and test results to see if you can be part of this study.
- tell the study staff if you take any over-the-counter or prescription drugs, vitamins, or herbs.

The study staff will discuss what is required for you to be part of this study. If you have HER2+ metastatic breast cancer and meet all study entry criteria you may be able to participate in this study.

Screening Visit

- Physical examination
- Measure of your vital signs (blood pressure, heart rate, temperature, respirations) including height and weight
- Electrocardiogram (ECG) and Echocardiogram (ECHO) to evaluate your heart (if not done previously in the past 28 days of signing the informed consent form)
- Blood sample of about 3 tablespoons to assess blood counts and chemistry analysis (if not done previously within 14 days of signing the informed consent form)
- Blood sample of about 1 tablespoon for a pregnancy test if you are a person of childbearing potential
- Complete review of your medical history
- Review how well you perform daily tasks
- Review all medications (including any herbal or nutritional supplement you may be taking). Please bring all medications, vitamins, and supplements that you are taking to this visit for review.
- CT Scan or MRI or Bone Scan or X-ray, or PET Scan of your chest, abdomen, and pelvis (if not done previously within 14 days of signing the informed consent form)
- Assessing availability of archival tumor tissue sample for research. If available, 5-10 unstained slides will be used for research purposes. If no archival tissue is available, you will still be able to participate in this trial

<u>Study Treatment Groups</u>
This study will have only 1 group for research subjects like you. All subjects will be treated with T-DM1 in combination with study drug Palbociclib.

T-DM1 is delivered through your vein. This is known as an infusion. You will receive an infusion lasting anywhere between 30-90 minutes, depending on tolerability, once every cycle (Day 1 of a cycle). A cycle is 21 days (3 weeks). Palbociclib is provided in tablets taken orally. You will be taking this for 14 days of the 21-day cycle starting on Day 5 of a cycle (day 5-18 of 21 days).

<u>Day 1 of every cycle</u>
If after all screening tests and procedures your study doctor determines that you are eligible for participation in the study, you will come to the clinic for your first visit. This is considered Cycle 1 Day 1. It is not expected that you will need to stay in the hospital during this study.

The following procedures will be done on Day 1 of every Cycle, but some might not need to be repeated if they have previously been done close enough to Day 1 (within 14 days).

- Physical examination
- Vital signs including weight

- Blood sample of about 3 tablespoons to assess blood counts and chemistry analysis
- Blood sample of about 2-3 tablespoons for biomarker study for research (Only for Cycle 1)
- Blood sample of about 1 tablespoon for a pregnancy test if you are a person of childbearing potential (every 2nd cycle)
- Review how well you perform daily tasks (Only for Cycle 1)
- Review all medications (including any herbal or nutritional supplement you may be taking)
- Complete a Quality of Life questionnaire (Only for Cycle 1)
- Receive infusion of T-DM1
- Receive a patient diary and Palbociclib for use on Days 5-18 of a cycle
- Review patient diary from previous cycle to ensure compliance with dosing of Palbociclib
- Review any signs or symptoms you might be experiencing

<u>End of Treatment</u>

This visit will take place within 14 days of your last dose of T-DM1 or Palbociclib (whichever is last)

- Physical examination
- Vital signs
- Blood sample of about 2-3 tablespoons for biomarker study for research
- Review how well you perform daily tasks
- Review all medications (including any herbal or nutritional supplement you may be taking)
- Complete a Quality of Life questionnaire
- Review any signs or symptoms you might be experiencing
- Review patient diary from previous cycle to ensure compliance with dosing of Palbociclib

<u>Routine Follow Up</u>

- After you have stopped treatment on this study, you will be followed every 6 months until final patient is completed or study is terminated, whichever is first. This may be done by review of your medical records or a phone call. We will be collecting information about treatments you are receiving and survival.

<u>Additional Procedures</u>

Every 3 months (12 weeks) before starting the next cycle you will have a CT Scan (Computed Tomography) of your chest, abdomen, and pelvis as well as any other areas of known disease or MRI (Magnetic Resonance Imaging) of the same to measure tumor size. This might also be repeated at the End of Treatment Visit if greater than 12 weeks from previous scans. You will also get your heart function assessed (by Echocardiogram or MUGA scans) every 3 months.

Your Responsibility

- You will have to go to the study visits, complete the study assessments, and follow the instructions the doctors give you
- You will need to agree to receive and take the treatment as directed
- You must not take part in other studies while you are taking part in this study
- You and your partner must be willing to avoid pregnancy during the study and for 6 months after the last dose of drug by using adequate contraception. Please reference the Reproductive Risks section on page 8 of this consent form for a thorough explanation of approved methods of contraception.
- You agree not to breastfeed while you are taking part in the study
- You will need to contact the study doctor or nurse if you feel any discomfort while you are taking part in the study
- You will need to inform your study doctor or nurse of any changes in your medication
- Upon study completion or early withdrawal, it is important for you to speak with your study doctor to arrange follow-up care

How long will I be in this study?

If you are interested in this study and would like to participate, you will need to come to clinic for a screening visit, which might last 4-8 hours to determine if you are eligible to be in the study. If after screening you are eligible for participation and are enrolled in the study you will start treatment and can remain on study until your disease progresses, you decide to withdraw consent, your physician removes you from treatment due to intolerable side effects, or the study is terminated by the sponsor, whichever comes first. Follow up visits while you are on study are part of your routine clinical care.

Once you are no longer actively being treated on the study, study staff will conduct follow up visits with you every 6 months to check on your cancer and to see if you are receiving any new treatments. These follow up visits will continue until the last patient on the study has completed treatment.

How many people will take part in this study?

Approximately 46 individuals will be enrolled in this study nationwide in the United States. We expect to enroll about 5-7 subjects at our site.

What risks, side effects or discomforts can I expect from being in the study?

Discomforts and risks may vary from person to person. Everyone in the study will be watched carefully for side effects; however, we do not know all the discomforts and risks that may happen. You may experience some, none, or many of these discomforts. Also, there is the risk of a rare or previously unknown side effect occurring. These may be mild or severe and can be

life-threatening or fatal. If any side effects occur, you must tell your study doctor who may give you treatment to ease the undesirable affects you may experience.

You will be monitored closely for all side effects. Palbociclib has been given to approximately 1674 patients with breast cancer who received palbociclib together with hormonal treatment in Pfizer sponsored clinical trials. The following side effects reported with the hormonal treatment and palbociclib:

- 30% or more: decreases in neutrophil blood cells (may increase the risk of infection), decreases in while blood cells (infection fighting cells), infections, fatigue
- 10 to less than 30%: decreases in hemoglobin (may cause weakness), decreases in platelets (may cause bleeding and/or bruising), inflammation of the mouth, diarrhea, constipation, nausea, vomiting, joint pain, back pain, pain in hands and feet, hair loss, rash, cough, shortness of breath, headache, dizziness, decreased appetite, hot flush, insomnia (inability to sleep), fever, common cold
- 5 to less than 10%: abdominal pain, indigestion, dry mouth, fever, asthenia (general weakness), swelling of hands and feet, irritation or sores in the lining of hollow organs like mouth, throat, stomach, bowels; pain, influenza (flu) like illness, muscle pain, pain in the muscles and bone including around the chest and neck, muscle cramps, increases in blood liver markers that may indicate liver damage, dry skin, itching, mouth/throat pain, nosebleed, impaired sense of taste, high blood pressure, depression, fall, anxiety, acid reflux (heart burn), increased creatinine level (may indicate abnormal kidney function)
- The following side effects have been reported in less than 5% of patients, but are still deemed important: Fever associated with dangerously low levels of a type of white blood cells (neutrophils), blurred vision, increased tearing, dry eye. In addition, interstitial lung disease (an inflammation of the lungs which can cause cough and shortness of breath) can occur. If you were to develop a dry cough or shortness of breath while at rest or with low levels of activity please contact your study team immediately.
- Serious and life-threatening infections have been observed in some patients treated with Palbociclib. Severe, life-threatening, or fatal ILD and/or pneumonitis can occur in patients treated with cyclin-dependent kinase 4/6 (CDK 4/6) inhibitors, including palbociclib when taken in combination with endocrine therapy.

Palbociclib is also being evaluated in a number of clinical trials run in a variety of tumor types given alone or together with other drugs. The side effects reported in these studies to date are similar to those mentioned above.

In a rat study where palbociclib was administered for the lifespan of the rat, microglial cell tumors (this a type of cell located in the central nervous system) were seen when palbociblib in their blood was at a higher level than those used to treat humans. It is currently unknown what these findings observed only in male rats mean for patients treated with palbociclib over time.

T-DM1 is standard of care treatment for metastatic HER2+ breast tumor. Your study physician will review the side effects in detail with you. Briefly, in clinical trials, T-DM1 has been evaluated as single-agent in 884 patients with HER2-positive metastatic breast cancer. Side effects from T-DM1 include:

- More than 25% reported fatigue, nausea, musculoskeletal pain, hemorrhage (bleeding), thrombocytopenia (low platelet count which can increase risk of bruising or bleeding), headache, increased liver enzymes, constipation and nose bleeds
- Heart issues: a decrease in heart pumping function (measured by left ventricular ejection fraction) to <40% has been observed in 1.8% of patients treated with T-DM1
- Inflammation of the lungs (pneumonitis) has been reported in 0.8% of patients treated
- Reactions during infusion or hypersensitivity reactions of T-DM1 have been reported in 1.4% of patients. There has been only 1 case of a serious allergic reaction to T-DM1.
- Peripheral neuropathy (all grades 21.2%), severe neuropathy was reported in 2.2% in T-DM1 group
- Hepatotoxicity (severe liver injury and/or failure) has been reported in clinical trials with T-DM1 . Rare cases of nodular regenerative hyperplasia (a form of liver side effect) have been seen in the trials (0.003% cases were reported in clinical trials, 0.001% were fatal)

The combination of T-DM1 with different doses of palbociclib (200mg, 150mg and 100mg) was studied in a small trial of 9 patients. The most frequent side effects noted (more than 30%) were anemia, thrombocytopenia, neutropenia and decrease in lymphocyte count. The incidence of these side effects was higher at the higher dose levels of palbociclib (200mg and 150mg than the 100mg dose)

<u>Other risks and effects of the testing of the study</u>
You may feel discomfort during some of these tests or may experience some inconveniences. Some may also have risks, which may include:

Blood Draws:
The risk of drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely, infection.

Routine blood tests to check your overall health require a little more than 1 tablespoon of blood (about 15 mL), although efforts will be made to collect smaller amounts of blood where possible. Blood tests to check how much study drug is in your system, to check whether your body is making antibodies towards the study drug, and for biomarker testing requires approximately 2 tablespoons of blood altogether (about 30 mL).

Generally, blood samples will be drawn by single needle-sticks. However, when multiple samples are to be taken in one day a member of the study team may insert a thin, flexible tube (called a catheter) into one of the veins (probably in your arm) so you won't need to be stuck with a needle many times on the same day.

Electrocardiograms (ECGs):
To perform the test, stickers will be placed on your skin to record your heart's activity. No pain or other side effects are expected to be associated with these tests, but you may feel some discomfort, similar to pulling off an adhesive bandage, when the technician removes the electrodes after the procedure. The adhesive patches can also cause skin irritation or rash in some patients.

MUGA scan:
The MUGA heart scan (used as an alternative to echocardiograms) will be done using a radioactive tracer. The radioactive tracer will be injected through a needle placed in the vein of your arm. The amount of radiation is very low and does not cause radiation sickness. The Radiology staff will check you closely for an allergic reaction, which is rare but could be life-threatening.

X-Rays:
The amount of radiation that you receive during an x-ray is very small, so the risk of damage to cells in your body from an x-ray is very low. The total radiation exposures you will receive from the X-rays in this study are not expected to negatively affect you or the treatment of your disease.

Bone Scintigraphy (also known as a Bone Scan):
Bone scans are used to determine the presence and/or extent of cancer in your bones and require the injection of a small amount of radioactive substance into your vein. The radioactivity means there is exposure to radiation. The amount of radiation is very small so your radiation exposure is very low and the radioactivity does not affect the normal processes of your body. There is a chance that you may experience discomfort, pain or swelling at the injection site and, as is the case with any injection, there is an increased risk of infection at the site. Rarely, some people may have a life-threatening allergic response to the radioactive material. If you have any trouble breathing during the test, you should tell the scanner operator right away. A few people may experience a rash or swelling. There is a slight risk of bleeding when the needle goes into your vein.

Computed Tomography (CT) Scans:
A CT scan is non-invasive, but involves exposure to radiation. There is a potential risk of radiation exposure from CT scans; this risk is considered small. Sometimes, an intravenous (in the vein) contrast dye is given with a CT scan. Contrast (or dye) given through an IV may cause a slight burning sensation at the IV site. It can also cause a metallic taste in the mouth. Some people complain of a warm flushing of the body. These sensations are all normal and go away within a few seconds. This contrast dye is iodine based.

A person who has allergies is more likely to have an allergic reaction to the dye. This reaction may be mild, such as skin rash or hives, to severe, such as breathing difficulties or shock. You will be closely monitored and treated should this occur. A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death. You should

discuss any history of allergies or concerns with your doctor. You may also experience discomfort related to lying still in an enclosed space for a prolonged period of time. The study staff prior to performing the procedure will provide additional instructions to you.

Magnetic Resonance Imaging (MRI) Scans:
Having an MRI (Magnetic Resonance Imaging) scan involves lying still on a table that slides into a tunnel slightly wider than your body. People who feel uncomfortable in confined spaces may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces please tell your study doctor. Your study doctor may give you a medication to make you feel more comfortable. MRI uses powerful magnets to make images. Therefore, people with certain metal implants, such as pacemakers, should not have an MRI. If you have an implant or any metal in your body, please check with your study care doctor to know whether you can have an MRI or not. For people without metal implants, there are no known health risks associated with exposure to the magnet. As images are taken, a loud banging noise is produced. Earplugs or headphones will be available if needed. The MRI can be stopped at any time at your request, but the scan may not be complete.

Positron Emission Tomography (PET) Scans:
A PET/CT scan with sodium fluoride F 18 injection (18F NaF) is a nuclear imaging test that scans the entire skeletal system and produces images of the bones for detecting cancer that has spread to the bone from a tumor that started in a different organ, such as the breast. The risks to you associated with PET/CT scans that are part of normal cancer care are small. A radiotracer chemical is used in a PET or some CT scans; the amount of radiation you are exposed to is low and is considered so small that it does not affect the normal processes of the body.

The PET radiotracer may expose the fetus of patients who are pregnant or infants of women who breastfeed to radiation. Women who are pregnant, plan on becoming pregnant, or are breastfeeding are not allowed on the study. You and your doctor need to consider this risk compared with the need for and potential information to be gained from the PET or CT scan.

Genetic Test/Research:
The sponsor cannot absolutely guarantee that your genetic research result could never be linked to you, meaning there is risk for loss of privacy or confidentiality. If disclosed to unauthorized persons, this could mean a possible risk for discrimination by employers or insurance providers.
Please talk to the study doctor or staff about any questions or concerns that you may have about the procedures required for this study.

Reproductive Risks:
You should not become pregnant or breastfeed a child while in this study. Naturally, the best way not to become pregnant is not to have vaginal sex (intercourse). If you are sexually active, you should talk with your study doctor about the types of birth control that are best for you and your partner. Tell your study doctor right away if you become pregnant or think you are pregnant.

Taking part in this study can result in risks to an unborn child or breastfeeding child. You must use birth control for 7 months after the last dose of the study drug if you are sexually active. The form of birth control you use must not be hormonal. Ask your study doctor if you have any questions.

Some methods of birth control which are taken orally, are applied as a patch, or given by injection (medication that travels throughout your blood stream), might be less effective due to a possible interaction with palbociclib. Barrier methods of birth control used with a spermicide should not be affected by study drugs taken by mouth or injection. The method of birth control that you use must be approved by your study doctor.

Male reproductive organ effects were seen in some of the rats and dogs that were given palbociclib for at least 3 weeks. These effects include degeneration of seminiferous tubule structure (tubes in the testes where sperm is produced) and a decrease in semen fluid secretion (ability of semen to flow). These effects on male reproductive organs were minimal to severe, depending on the dose given. These toxicities were observed at drug levels that are used in clinical research studies. Partial to complete reversal of these effects were seen at least 4 weeks after palbociclib dosing stopped. It is currently unknown what these findings mean for patients treated with palbociclib over time. If you are a male patient and want to have children at a later time, it is recommended that you preserve your sperm prior to beginning therapy.

Exposure to T-DM1 during pregnancy or within 7 months prior to conception can result in fetal harm. Women of reproductive potential are recommended to use effective contraception during treatment and for 7 months following the last dose of T-DM1

Other Risks:
In addition to the side effects already described, palbociclib, T-DM1 and other drug(s) required by the protocol and the combination of the study drugs, and the study procedures may have other unknown risks. There may be unknown risks of possible harmful interaction with other medication you may be taking. You should not give the study drug to other people. Only you should take the study drug. It must be kept out of the reach of children or anyone else who may not be able to read or understand the label.

If new information becomes available that is relevant to your willingness to participate in the trial, you will be informed.

What benefits can I expect from being in this study?

You may or may not receive any benefit from being in this study. If you take part in this study, other people with metastatic breast cancer may be helped. Information obtained from this study may benefit study participants in the future.

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.

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

Please keep in mind that the treatments and procedures that are part of this study may involve risks to you (or to your unborn child should you become pregnant) which are currently unforeseeable.

If you are injured as a result of taking part in this study or for questions about a study-related injury, you may contact the Principal Investigator, Dr. Pavani Chalasani. You can tell the doctor in person or call her at 520-626-0191.

If you suffer an injury from taking part in this study, you should seek treatment. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. If you do not have insurance, you will be financially responsible for those expenses. Neither the University of Arizona, Pfizer, nor Criterium have funds set aside to pay for a research-related injury, added medical costs, loss of a job, or other costs to you or your family.

If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Can I stop being in this study?

Your taking part in this study is entirely voluntary.

You may refuse to take part in the study, or you may stop your participation in the study at any time. Whatever your decision, you may do so without a penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your future relationship with your physicians. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

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

Currently, standard of care treatments for patients with your type of metastatic breast cancer include chemotherapy. You doctor will be able to discuss these with you. You have option of participating in other clinical trials too.

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.

When may participation in the study be stopped?

Your participation in this study can be stopped because

- *Your disease progresses while on study*
- *You experience a deterioration of your condition*
- *Requirement for other anti-tumor therapy*
- *Non-compliance to taking the study drug in accordance with instructions provided*
- *Pregnancy*
- *Death*
- *Lost to follow up*
- *Any other reason that, in the opinion of your physician, justifies your removal*
- *Sponsor terminates the study for any reason*

If you decide to withdraw from the study, please discuss with your study doctor. Withdrawing from this study will not interfere in your relationship and care by your physicians.
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.

If you stop being part of this study, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation.

What are the costs of taking part in this study?

Pfizer will be supplying the investigational drug, palbociclib, for this study. Research only procedures/services involved in this study will also be paid for, however some of the tests, procedures, and treatments that you will receive in this study are the same that will occur during a standard of care treatment for your cancer. T-DM1 is standard chemotherapy and will be billed to your insurance

You and/or your insurance will be financially responsible for any treatment, test, or procedure that is considered to be standard of care for your cancer. Your study doctor will go over the costs that are involved in your care during this study. You will be responsible for copays and coinsurance costs.

You may be responsible for payment of any bills that your insurance may refuse to pay due to your participation in this research study.

Will I be paid for taking part in this study?

You will not receive any payment for participating in this study.

Will my study-related information be shared, disclosed, and kept confidential?

It is anticipated that there will be circumstances where your study related information and PHI will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups include:

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- Representatives of the U.S. Food and Drug Administration (FDA)
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Banner University Medical Group and Banner Health
- The University of Arizona (UA) and the UA Institutional Review Board
- The University of Arizona Cancer Center (UACC), Pfizer
- The sponsor supporting the study, their agents or study monitors (Criterium)
- Your health insurance company
- Your primary care physician or a specialist taking care of your health.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

Your genetic research data may be shared with researchers who are not participating in this study or submitted to government or other health research databases for broad sharing with other researchers. You will not be identified by name or any other personally identifying information.

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

- Health insurance companies and group health plans may not request your genetic information from this research.
- If health insurance companies and group health plans do somehow receive your genetic information from this research, they may not use it to make decisions about your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Those persons who receive your health information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws that apply to them.

If information from this study is presented publicly or published in a medical journal, you will not be identified by name. Your blood samples and extracted medical records information will be labeled with a coded identification number only.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, questionnaires and diaries.
- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Tissue samples and the data with the samples
- Billing or financial information

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL

NOT create, collect, or disclose this type of information for the purposes of this research study. Study related data is entered into online database and will be shared with collaborating entities (Pfizer) through data protected electronic transfers.

When will my authorization expire?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective. Identified study related data is stored for 6 years after completion of study. After that, de-identified data is stored long term for future research purposes.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under “Who can answer my questions about the study” at the end of this document.

Will access be limited to your research study record during this study?

You can ask your study team to provide access to your research data files. You may ask for corrections in personal information that you deem incorrect. You will not have access to other participant records.

Will my data or specimens be stored for future research?

There may be some specimens (blood, tissue, etc) remaining after the study is complete. If you are willing to allow the remaining specimens to be used for future research studies, you must specify your consent below. Consent for future use of your remaining samples is entirely voluntary and may be withdrawn at any time.

If you decide now that your tissue can be kept for research, you can change your mind at any time. Contact your study doctor and let him or her know that you do not want us to use your

tissue (or collected blood sample, body fluid, if appropriate), and it will no longer be used for research. If your specimen has already been used for research it will not be possible to get it back.

In addition to the treatment study, researchers are also interested in studying tissue, body fluids, or other specimens that were, or may be, obtained from you in the normal course of your treatment and care. These research tests may be developed during the time you are on treatment, or years later.

We would like to keep any of the tissue that is left over after diagnosis for future research. This will be stored in a central facility (called a "tissue bank") which is located at the University of Arizona Cancer Center. Your sample will be stored there permanently and will not be available for use in making health care decisions for you. At some time in the future, pieces of this stored tissue may be used by other researchers for other tests that are not known at this time. In most cases, you will not be told what your sample is being used for.

When your sample(s) is sent to the researchers, samples will be identified by a unique study code only. Researchers to whom the University of Arizona sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are. If research results are published, your name and other identifiable information will not be used.

Please read each sentence below and think about your choice. After reading each sentence, mark an X in the box for "Yes" or "No." No matter what you decide to do, it will not affect your care. You can participate in the treatment part of the study without participating in all or part of the tissue (or collected blood sample, body fluid, if appropriate) research studies. If you have any questions, please talk to your doctor.

1. My tissue (or collected blood sample, body fluid, if appropriate) may be used in future research to learn about preventing or treating breast cancer.

_____ Yes _____ No

2. My doctor may contact me in the future to ask me to take part in more research.

_____ Yes _____ No

Future Use of PHI

Future research activity is part of this project. If you choose to participate in the future research activity your PHI will be included in this future research activity.

By initialing the line below, you agree to allow your information to be used and/or disclosed for the optional future research referenced above.

_____ Initials

Who can answer my questions about this study?

Contact your study doctor, Pavani Chalasani, M.D., at 520-694-2873 or 520-694-6000 (pager # 9940 - 24 hours) or the Oncologist on call at 520-694-6000 (24-hour pager) for any of the following reasons:

- if you have any questions about this study or your part in it;
- if you feel you have had an injury or bad reaction, or any other unusual health event; or
- if you have questions, concerns, or complaints about the research study.

If you are injured, the study doctor will treat you or refer you for treatment.

You should contact the study doctor first if you have questions, complaints, or concerns about the study.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at http://rgw.arizona.edu/compliance/human-subjects-protection-program. Please note that your contact with the University of Arizona Human Subjects Protection Program online can be anonymous.

If you have any questions or concerns about the authorization for access to your PHI, you should contact Sue Colvin, Banner Research Regulatory Affairs Director, at (602) 839-4583 or sue.colvin@bannerhealth.com. You may also request and will be provided a copy of the Notice of Privacy Practices.

To cancel your authorization for access to PHI you must notify the *Principal Investigator/Research Team* in writing at the following address:

Pavani Chalasani MD, MPH
1515 N Cambell Ave, PO 245024
Tucson, AZ 85724

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

FOR STUDY PARTICIPANT TO COMPLETE

_____ _____

Signature of Study Participant Date

_____

Study Participant Name (print or type)

FOR INDIVIDUAL CONDUCTING INFORMED CONSENT DISCUSSION TO COMPLETE

I have explained the study (such as the purpose, risks, benefits, and the procedures) to the study participant before the study participant voluntarily agreed to participate

_____

Name of individual conducting informed consent discussion (print or type)

_____ _____

Signature of individual conducting informed consent discussion Date

Signatures for Impartial Witness

In case the trial study participant is unable to read or write, the signature of an impartial witness to this process is required.

I witnessed that the information in the consent and any other written information was accurately explained to, and apparently understood by, the study participant, and that informed consent was freely given by the study participant.

_____

Impartial Witness Name (print or type)

_____ _____

HSPP Use Only:
B–UM/UA T503a v 2016-10