RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Phase II subjects ONLY

TITLE:	An Expanded /Phase II, Multi-Center, Randomized, Open-Label, Study to Evaluate the Safety and Tolerability of Proxalutamide (GT0918) in Subjects with Metastatic Hormone Sensitive Prostate Cancer (mHSPC) and Metastatic Castrate Resistant Prostate Cancer (mCRPC) who Failed Either Abiraterone or Enzalutamide
PROTOCOL NO.:	GT0918-US-1002 – Expanded phase II WIRB® Protocol #20152501
SPONSOR:	Suzhou Kintor Pharmaceutical, Inc.
ICF VERSION #:	V5.0, dated 18Mar2021
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Phone Number(s) (24 Hours) [24-hour number required]

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject.

SUMMARY
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 you fully understand this document and all of your questions are answered. You may want to discuss it with your family, friends or family doctors before you sign.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) drugs or procedures that are being tested for a certain condition or illness. An investigational drug is one that has not been approved by the US Food and Drug Administration (FDA). The investigational drug that is being used in this study is known as GT0918 (proxalutamide).

- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed, then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study may or may not affect your current or future insurance coverage.

PURPOSE OF THE STUDY

You are being asked to take part in this research study as your prostate cancer has not responded to or progressed on hormonal therapy abiraterone or enzalutamide.

Prostate cancer requires testosterone to grow and spread. Goal of the treatment of prostate cancer is to remove the source of male hormones, either surgically (castration) or by giving drugs to both stop the production of male hormones and to block the effect of male hormones on the prostate cancer.

The current approved drugs, XTANDI® (enzalutamide), or Zytiga® (abiraterone) can block the male hormone activity; however, the medication does not work for everyone or for all time. Now if your disease gets worse or you have serious side effects from either of these drugs, you may be qualified for this study.

There are 2 parts (stages) to this research study and first part of study has finished. This is the second part of the expanded/Phase 2 study. It is to learn if the drug is safe in more patients who are administered the drug and to find the best dose to take with the least side effects.

There are 60 patients who will participate in this study and will be randomized (like the flip of a coin) to orally receive study drug at 400 mg, or 500 mg daily. If you are enrolled into the current study, you will be asked to take GT0918 tablets every day by mouth on an empty stomach (or 2-3 hours after a meal) for up to 6 months, have blood drawn, and safety tests performed at multiple times through-out your participation in this study. All participants will be evaluated by the study doctor and the doctor's staff for side effects.

While taking the study drug, if your study doctor sees that you are receiving clinical benefits, you may continue on the study after you finish the first 6 months of study drug.

PATIENT RESPONSIBILITIES

During the study, you will have the following responsibilities:

- Report to your study doctor or study nurse immediately if you feel allergic to the study drug, fatigue/lethargy, dizziness, pain or edema in hands and feet, loss of appetite, and symptoms that have significant impact on your daily activities. If the study drug dose is deemed too high for you, your doctor may ask you to take a couple of days off or/and reduce the dose of study drug.
- Attend all scheduled visits.
- Take the study drug as directed.
- Return any unused study drug and containers as instructed by the study staff.
- Follow the study doctor's instructions about whether you may continue to take your regular prescribed medications or over-the-counter medicines during the study period.
- Tell the study doctor all drugs you are taking, any changes to your current medications, illnesses or injuries, unexpected or troublesome side effects, or problems that are not mentioned above.
- Tell the study doctor if you plan to have an elective surgery or any other medical treatment or procedure.

- You should continue to make regular visits to your primary doctor or any other special doctors whom you were seeing before starting the study, since being in the study does not replace regular medical care.
- Make sure that the study drug is kept out of the reach of children and people who have a limited capacity to read or understand. You are the only person who should take the study drug. Contact the study doctor if you find you have any questions about the study after you sign this form.
- You and/or your partner must use a reliable form of contraception during the study and for at least 3 months after you are off from the study drug. If your partner becomes pregnant while you are in the study, be sure to tell the study doctor as soon as possible.

PROCEDURES

The doctor in charge of this study or a member of the study staff will have discussions with you regarding the requirements for participation in this study. In order to participate in this expanded/phase II study, one of the selection criteria is prior therapy of abiraterone or enzalutamide, not both. As a subject in this study, you will receive active study drug. You should take the study drug by mouth on an empty stomach (or 2-3 hours after a meal).

Expanded / Phase II Study

Screening

You will first visit the clinic and sign an Informed Consent form before you complete any study related procedures.

After signing the Informed Consent Form, the doctor or staff will ask you questions about your medical and surgical history, how you are doing, and any medications you are taking. You should have a computed tomography (CT) or magnetic resonance imaging (MRI), or/and bone scan, to assess your disease. If the previous assessment was more than 42 days ago, you may be asked to have another CT or MRI or bone scan. All scans and tests must be performed within 6 weeks before starting study drug.

You will have the following study procedures completed:

- vital signs taken (heart rate, breath rate, blood pressure and body temperature) and height taken,
- a complete physical exam performed,
- your physical capability (ECOG) assessed,
- blood and urine taken for laboratory tests, and
- an ECG will be performed.

Week 1, Day 1 (Baseline)

You will visit the clinic. The study doctor and staff will confirm that you remain eligible to participate in this study. The doctor and study staff will ask you questions about any changes in your medical and surgical history, medications you are taking , how are you are doing and any side effects you may have since your last screening visit. Your physical capability (ECOG) will be assessed, vital signs taken, a brief physical exam performed, blood taken (about 4.5 to 6.5 tablespoons) for laboratory and exploratory marker tests (about 3 tablespoons blood) to be drawn, and a urine sample will be collected. The ECG performed within 30 minutes of taking study drug. Instruction of what and how to take study drug will be given to you in the clinic and you will be given a supply of 14 days of study drug. You are required to take the study drug on the same time every day. You will be discharged from the clinic after all procedures are completed.

Day 15 (Week 3)

You will visit the clinic. The study doctor and staff will ask you questions about medications you are taking how you are doing, and any side effects since the previous visit. You will also have vital signs taken, a brief

physical exam, and your physical capability (ECOG) assessed. Additionally, you will bring any unused study drugs and empty box of study drug when you visit the doctor office. The study staff will count your pills and check your diary to ensure that you are taking study drug daily and do so at the same time each day. You will be given a supply of 2 weeks (for Day 15) of study drug to take home. You will be discharged from the clinic after all procedures are completed.

Day 29, also known as Cycle 2 Day 1
You will visit the clinic. The study doctor and staff will ask you questions about medications you are taking, how you are doing and any side effects since the previous visit. You will also have vital signs taken, a complete physical exam performed, your physical capability (ECOG) assessed, blood taken (about 3 to 5 tablespoons) for laboratory tests, and a urine sample will be collected for testing. A single ECG will be performed. Study drug of 28 days of supply then will be given to you in the clinic following all procedures are complete. You will be discharged from the clinic after all procedures are completed.

Cycles 3-6, (Day 57, 85, 113, and 141)
You will visit the clinic if qualified to continue in subsequent cycles. The study doctor and staff will ask you questions about medications you are taking how you are doing, and any side effects since the previous visit.

You will also have part or all of the following tests performed:

- vital signs taken
- a physical exam performed
- physical capability (ECOG) assessed
- disease status assessed (will be measured by radiologic methods (CT and/or MRI) on Day 85
- blood taken for laboratory tests, hormone test at Cycle 4 (Day 92), exploratory marker tests every 3 month and a urine sample collected for testing
- single ECG performed monthly with repeat ECGs if abnormal readings seen

Additionally, the study staff will count your unused pills and/or empty boxes to ensure that you comply with the protocol. Study drug of 28 days then will be given to you. You will be discharged from the clinic after all procedures are completed.

Additional Study- (Additional 24 Months After Cycle 6 Day 28)
If you have completed all 6 cycles of the study, your disease is not worsening, and the study doctor and sponsor agree that you are likely to have continued benefit from participation in the study, you will have the option to continue in the study until either you show signs of disease worsening, the doctor determines you need to end the study, or you have completed the 24 months of the additional study. You will be required to visit the clinic monthly. The study doctor will ask you questions about medications you are taking, how are you doing and any side effects since the previous visit. You will also have vital signs taken, a brief physical exam for all visits except for the very last visit on Cycle 30 Day 28 at which time a complete physical exam will be performed, your physical capability (ECOG) assessed, blood taken (about 3 to 5 tablespoons) for laboratory tests and exploratory marker tests (every 3 months, 84 +/- 7 days) and a urine sample will be collected for testing. Disease status will be assessed (measured by radiologic methods [CT and/or MRI]) every 3 months (84 +/- 7 days). The study staff will count your pills to ensure that you comply with the protocol. After all study procedures are completed, you will be given a supply of study drug to last until your next visit (unless this is the last visit of the extension study, 24 months after Cycle 6 Day 28). You will be discharged from the clinic after all procedures are completed.

End of Study or Early Termination
You will visit the clinic after your last dose of study drug, and the study doctor and staff will ask you questions about medications you are taking, how you are doing, and any side effects you may experience since the previous visit. You will also have vital signs taken, a brief physical examination performed, and

your physical capability (ECOG) assessed. The study staff will count your pills if not already completed to ensure that you comply with the protocol. You will have blood drawn (about 2 to 3 tablespoons) for hormone and exploratory marker testing. You will be discharged from the clinic after all procedures are completed.

If you are unable to attend the End of Study visit in person, a phone call will be made to ask you questions about medications you are taking and any side effects since the previous visit. You may also be asked questions to assess your physical capability (ECOG).

Safety Follow-up

You will visit the clinic or be called 30 days after your last dose to check any experimental drug-related side effect you may have.

Unscheduled Visits

Your study doctor may at his/her discretion arrange for you to have an unscheduled visit, especially in the case of disease conditions or/and side effects that require follow-up or considered by study doctor.

RISKS AND DISCOMFORTS

There may be risks to you if you participate in this study.

Study Procedure Risks

Blood Tests

For many subjects, needle punctures for blood draws do not cause any serious problems. Some side effects that may be seen are bleeding, bruising, discomfort, infections, dizziness, and/or pain at the needle site.

Imaging Tests

Some imaging techniques that may be used to follow your cancer include CT, MRI, positron emission tomography, and x-rays. These tests will expose you to a moderate to high doses of ionizing radiation. Some people may also get claustrophobic (feel closed in) from being in the imaging machine, which is sometimes in the shape of a tube.

Potential Risks and Discomforts Associated with GT0918

This is an Expanded /Phase 2 study is to find best dosing with less side effects in more number of study subjects. Thus, there may be side effects that are not known at this time.

From limited subjects in clinical study that occurred with this study drug and common in patients with cancer, you may expect or experience any of the following adverse events (side effects) during your treatment, possibly, fatigue, lethargy, headache, nausea, vomiting, dizziness, loss of appetite, weight loss, diarrhea, hot flushes, hypercholesterolemia, hyperglycemia, hypertriglyceridemia, peripheral edema, constipation, back pain, anemia, pain in extremities, arthralgia, elevated creatine kinase, transaminase elevation, liver injury, hepatic failure, hepatic cirrhosis. Should any of these side effects occur, you should immediately notify your doctor or/and study staff.

As a study subject, you should not get your sexual partner pregnant while taking the study drug. The effects of the study drug on sperm, embryos, or fetuses are not known. If you think that your partner may have gotten pregnant during the study, you must tell your study doctor immediately.

Other Risks

The study drug is a CYP 3A4 inhibitor and has shown some level of drug interactions with CYP 3A4 components in some patients during this trial. For example, several patients on simvastatin 40 mg or higher daily resulted in elevated lab results of ALT, AST, CK, muscle pain, rhabdomyolysis (damage to skeletal muscle), etc. Please discuss with your doctor the list of potential interactions

Your condition may not get better or may get worse during this study.

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.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study in a timely manner. You may be asked to sign a new consent form if this occurs.

BENEFITS
The benefits are not known yet. It cannot be promised that you will receive any medical benefits from being in this study. Information from this research may help people with mCRPC in the future.

COSTS
Suzhou Kintor Pharmaceutical, Inc. will provide the study drug free of charge during this study. Tests and procedures that are out of standard of care and done only for the study will not be billed to you or your insurance company.

You or your insurance company may be billed for any standard medical care given during this research study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION
You will not be paid for being in this study.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there are other treatment choices available to you. Please ask your study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your demographic and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Study records and source documents must be preserved for at least 15 years after the completion or discontinuation of/withdrawal from the study or 2 years after the last approval of a marketing application in an ICH region, whichever is the longer time period.

Who may use and give out information about you?
The study doctor and the study staff

Who might get this information?
The sponsor of this research will get unidentified medical information under HIPAA. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or employee (such as study team) of the sponsor.

Information may be given to:

- The US FDA,
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board.

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are used or made public, **information that identifies you will not be used**.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

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 or join the study again at a later time.

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

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Confidentiality
Information from this study will be given to the sponsor. “Sponsor” includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the US FDA. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- Suzhou Kintor Pharmaceutical, Inc., the sponsor,
- Syneos Health an agent for the sponsor,

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA,
- DHHS agencies,
- governmental agencies in other countries, and
- Institutional Review Board.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
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 otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- discovery that you do not meet the study requirements
- if it is in your best interest
- if you do not consent to continue in the study after being told of changes in the research that may affect you
- any change in your medical condition that might make continuation in the study harmful to you
- your failure to follow the study doctor's instructions
- Cancellation of the study

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.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, Suzhou Kintor Pharmaceutical, Inc., will pay for this research study.

QUESTIONS
Contact [name] at [number(s)] for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may 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

An Institutional Review Board (IRB) is a group of people who independently review research.

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

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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.

REQUEST FOR AUTHORIZATION TO STORE BLOOD SAMPLES FOR FUTURE TESTING

The study sponsor would like to store your blood samples for future testing. The future testing would be related to the purpose of the study protocol- to test the safety of the study drug and to get a better understanding of prostate cancer. Your samples will not be labeled with your name or other directly identifying information. Your samples will have a code instead. The list that matches the code with your name will be stored separately from your samples.

You have the option to choose not to allow your samples to be utilized for future testing. You may withdraw your consent for the use of your blood samples in future testing at any time during or after the study by contacting the study doctor.

Please INITIAL one response below:

_____ I allow that my samples can be used for future testing.

_____ I request that my samples not be used for future testing.

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)

_____ _____
Signature of Subject Date

INVESTIGATOR: I, _____, acknowledge that the purpose of this research study, the procedures required, the potential risks and benefits associated with participating in this study, and alternatives to participation in this study and the potential risks and benefits associated with these alternatives have been discussed with this individual. All of the participant's questions have been answered and he has voluntarily agreed to participate. A signed and dated copy of this document will be given to the participant.

_____ _____
Printed Name of Investigator Date

_____ _____
Signature of Investigator Date

_____ _____
Printed Name of Person Conducting Informed Consent Discussion (if different from Investigator above) Date

_____ _____
Signature of Person Conducting Informed Consent Discussion (if different from Investigator above) Date

Authorization to Use and Disclose Personal Health Information

The United States government has issued a Privacy Rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "protected health information" or "PHI"). PHI collected in this study may include your medical history, the results of physical exams, laboratory tests, x-ray exams, and other diagnostic and treatment procedures as described in the "Procedures" section of this consent form as well as basic demographic (age, gender, ethnicity) information.

By signing this form, you allow the study doctor and/or study staff to disclose your information to the sponsor, Suzhou Kintor Pharmaceutical, Inc., and the sponsor's representative(s). The data sent by the study doctor and/or study staff to the sponsor do not include your name, address, or social security number.

Your information may be reviewed and/or copied by the sponsor or sponsor's representative(s), FDA, IRB, or by other regulatory agencies in this country or in other countries to ensure the quality of the study or for other uses allowed by law.

Federal and state laws require the study doctor and/or study staff to protect the privacy of your information. However, absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. After the study doctor and/or study staff shares your information with the sponsor or others, the law may no longer protect the privacy of the information, and it may be further disclosed.

You have the right to see and copy your records related to the study for as long as the study doctor has this information in his or her possession. However, by signing this form you agree that you might not be able to review some of your records related to the study until after the study has been completed, at which time your right of access will be restored.

This Authorization does not have an expiration date. If you do not revoke (cancel) this Authorization, then it will remain in effect indefinitely.

You can revoke (cancel) this Authorization at any time by giving written notice to the study doctor at the address listed on page 1. If you revoke this Authorization, then you will no longer be able to participate in the study, and no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All the information that has been collected prior to revoking the Authorization and any new information about a side effect related to the study may still be used and disclose to the above-mentioned parties.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

If you do not sign this Authorization, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, the Western Institutional Review Board, the FDA, and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

_____

Subject Name (printed)

_____ _____

Signature of Subject Date

_____

Name of Study Staff Member Administering Consent (printed)

_____ _____

Signature of Study Staff Member Administering Consent Date