MODEL INFORMED CONSENT FORM

VERSION LOG

Version	Date	Reason for Change
1.0	*13 April 2021*	*Not applicable*
2.0	*09July 2021*	*Protocol Amendment 1 – 08Jul2021*

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Title of Study	**A Randomized, Double-blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Proxalutamide (GT0918) in Outpatients with Mild to Moderate COVID-19 Illness**
Protocol Number	**GT0918-US-3001**
Aligned with protocol version and date	**Version 2.0, 08Jul2021**
Sponsor	**Suzhou Kintor Pharmaceuticals, Inc.**
Investigator	(to be filled in at each site)
Title of Investigator	(to be filled in at each site [delete, if study subjects are located outside Japan])
Subject	(to be filled in at each site)

CONCISE SUMMARY

Being a participant in this research study is voluntary; it is your choice. If you join this study, you can still stop at any time. Do not join this study unless all your questions are answered.

You are being asked to take part in this study because you recently tested positive for SARS-CoV-2, which is the virus that causes the COVID-19 illness. This study is being done to find out if a new investigational drug, GT0918 (proxalutamide), helps your COVID-19 better than other drugs or types of treatments that are currently available and approved to be sold in the market.

By participating in this study, you may reduce the chance of progressing to severe illness and needing to go to the hospital.

There are treatments, referred to as “standard of care,” that are available to treat your COVID-19 that your doctor will use if you do not want to join this research study.

Researchers believe that this new drug GT0918 might work better because it has been shown to be effective in inhibiting the entry and spread of the SARS-CoV-2.

You will undergo a 1-day screening that includes a physical examination, measurement of vital signs, blood draw, and nasopharyngeal swab. Once screening is complete, you will be assigned to one of two groups to receive GT0918 plus standard of care or placebo plus standard of care. You will take the study medication daily for 14 consecutive days and will complete a daily diary and questionnaire. You will have 3 study visits during which you will have measurement of vital signs, a blood draw, and a nasopharyngeal swab. You will have a follow-up visit, with a measurement of vital signs, a blood draw, and a nasopharyngeal swab, 14 days following your last dose of study medication. You will have a safety follow-up phone call 14 days after that. The total duration of the study is about 6 weeks.

There are risks that may affect you due to GT0918. You may experience fatigue, decreased appetite, diarrhea, stomach pain, and confusion or dizziness. A comprehensive list of risks and discomforts is described later in this document.

It is not known whether GT0918 will have any benefit for you different from the treatment that your doctor would normally choose. By participating in this research study, you may help doctors answer this question.

Being in the study will not cost anything, although you or your insurance will be billed for standard medical care.

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, the pronouns “you” and “your” should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject’s representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

1 WHY HAVE I BEEN GIVEN THIS FORM?

You are invited to review this consent form because you recently tested positive for SARS-CoV-2 which is the virus that causes the COVID-19 illness.

Coronavirus disease 2019 (COVID-19) emerged in late 2019 and spread rapidly, resulting in a global pandemic. COVID-19 is caused by a novel coronavirus (SARS-CoV-2), and infected persons can have a wide range of disease severity, with many patients showing mild or moderate disease. Although many therapies have been and are being explored in various stages of

COVID- 19, for the large population with mild and moderate COVID-19, limited treatments are available.

The study drug, GT0918 (proxalutamide), is a new androgen receptor (AR) antagonist that has been shown to be effective in inhibiting virus entry and replication. GT0918 is an investigational drug, which means that it is still being studied and has not been approved by the United States Food and Drug Administration (FDA), European Medicines Agency (EMA) in Europe, the National Medical Products Administration (NMPA) in China, or any other regulatory authorities to be prescribed by doctors. Throughout this information consent form, GT0918 will be referred to as the "study drug."

This clinical research study is being sponsored by Suzhou Kintor Pharmaceuticals, Inc. (hereafter referred to as the Sponsor).

Before you decide if you want to take part in this study, it is important for you to understand why the research is being is done and what the study will involve.

2 DO I HAVE TO TAKE PART?

You are invited to take part in a clinical research study. To help you decide, you should understand the study and what it will involve for you. To make an informed decision to take part, you should know the purpose of the study, the procedures, the benefits and risks of the study, the discomforts and the precautions taken. This process is called "informed consent."

If there is anything you do not understand or if you would like more information, please ask the study doctor or study staff. You may also discuss the study with family members, friends, and your own doctor if you wish. Once you have decided that you want to take part, you will be asked to sign and date this informed consent form. You will be given a copy of this signed and dated form to keep, and the original will stay at the study center.

It cannot be promised that the study will help you, but in the future the information we get from this study may help improve the future treatment of people with the same condition.

A clinical research study is an experimental investigation designed to answer specific questions about potential new drugs or existing drugs. These questions may include how safe and effective a particular study drug is, or what is the best dose of the study drug. All new drugs must undergo thorough testing in clinical research studies before they may be prescribed by doctors. Without clinical research studies, no new drugs could be developed, and few medical advances would be made.

Taking part in a clinical research study is completely voluntary and your participation will be kept private. You can choose not to take part in the study if you wish, and you can decide to stop taking part at any time, without giving a reason. The decision you make will not change the legal rights or the treatment options you have.

The study doctor can withdraw you from the study at any time if he or she feels it is in your best interest or if you cannot comply with study requirements.

Your participation in the study may also be stopped at any time by the Sponsor (for medical or business reasons), the regulatory authorities, or independent ethics committees such as the Institutional Review Board or Institutional Ethics Committee. These committees ensure that your rights are not violated. The reason(s) for stopping the study will be explained to you, and you will be given advice about continued care for your condition, if this is appropriate.

If you leave (or withdraw from) the study, you will be asked to go through study withdrawal procedures detailed in Section 4 and information about you will be handled as detailed in Section 12.

3 WHAT IS THE STUDY ABOUT?

There are no FDA approved treatments available for patients with confirmed SARS-CoV-2 with mild or moderate COVID-19 illness. Mild to moderate COVID-19 symptoms can include fever, cough, headache, shortness of breath, and other symptoms your study doctor considers mild to moderate. Because there are no approved treatments available for mild to moderate COVID-19 illness, this study is to evaluate the study drug effects for a larger population.

The study drug has completed the Phase I, first-in-human study, to confirm the recommended study drug dose is safe. The study drug has also completed the Phase II to evaluate whether or not the study drug works well for some subjects. The study drug has also completed a Phase III study to evaluate whether or not the study drug works well for many subjects.

The Phase I and Phase II studies were not evaluated on COVID-19 subjects; they were conducted using both healthy volunteers and cancer subjects. A Phase III study in Brazil enrolled 262 male COVID-19 positive subjects. Of the subjects given study treatment with the study drug plus standard of care, none were hospitalized. Among the group of subjects who received placebo (inactive substance) plus standard of care, 27.3% required hospitalization over the course of the full 30-day participation. The subjects in Brazil were given 200 mg tablets of the study drug every day for 15 consecutive days by mouth. The same study dose (200 mg/day) is being tested in this study. The study drug dose is fixed, regardless of body mass or weight.

This is a Phase III study which the Sponsor plans to implement in the USA and other countries. There will be approximately 100 study sites participating globally, and it is expected that about 668 subjects will be enrolled.

Because we do not know if GT0918 is better than the current standard of care for treating COVID- 19 we need to compare them. For this reason, we will put people into 2 groups: a group receiving the study drug plus standard of care and a group receiving placebo plus standard of care. To make the comparison as fair as possible, this study is “double-blinded.” This means that neither you nor the study doctor will know whether you are taking GT0918.

The purpose of this study is to test the study drug against placebo for:

- How effective the study drug works with your disease, which includes reducing virus in your body, relieving your COVID-19 symptoms, and reducing the chance of your COVID-19 illness getting worse.
- How safe the study drug is and how long it may work for you.

4 WHAT WILL HAPPEN TO ME DURING THE STUDY?

4.1 Screening

If the study is right for you and you agree to take part, you will be asked to sign and date this information consent form. After you have signed and dated the consent form, you will be asked to complete a series of screening assessments. Screening assessments will include procedures such as:

- Review of inclusion and exclusion criteria
- Demographics, medical history, tobacco use and pre-existing conditions
- Review of any prior treatments within the last 30 days, including over-the-counter and prescribed treatments
- Physical examination
- Vital signs, including body temperature, pulse rate, blood pressure and respiratory rate
- Nasopharyngeal swab
- Laboratory blood tests

Screening procedures may also include:

- Chest X-ray, Computed Tomography (CT) Scan or Electrocardiogram (ECG), if your study doctor deems any of these clinically necessary.
- Also, if you are female regardless of child bearing potential, you must do a pregnancy test with your blood samples.

If the study doctor decides that you are not eligible to take part in this study, then he/she will discuss with you other treatments for your condition.

4.2 Randomization

Once you have signed and dated this consent, and your study doctor confirms you are eligible to take part, and you want to continue, you will be assigned, by computer, to 1 of 2 groups. This is called “Randomization.” Randomization means group assignment is completely random and unknown to your study team. There is a 1 in 2 chance of being assigned to either group, like flipping a coin.

The first group is a study treatment group. This group will receive the study drug plus standard of care. The second group is the placebo group. This group will receive the placebo plus standard of

care. The term 'placebo' means the tablets you receive will look the same as the study drug but will not have active ingredient.

Neither you nor your study team will know to which group you have been assigned. Your study doctor will not tell you to which group you have been assigned. If for reasons associated to any medical emergencies during or after the study treatment period, the study doctor will be able to request the information regarding your group assignment.

- Group 1: Standard of care with oral administration in tablet form, 200 mg of study drug (two 100 mg tablets), taken once a day, every day for 14 consecutive days.
- Group 2: Standard of care with oral administration in tablet form, placebo (identical to study drug), taken once a day, every day for 14 consecutive days.

4.3 Study Treatment Period

4.3.1 Study Medication

The study treatment period of this study is 14 consecutive days, or earlier if you decide to stop your participation to this clinical study. If your disease worsens and you are hospitalized, you may continue per your study doctor's discretion. Signs of disease progression can include increased severity of COVID-19 symptoms or developments of unacceptable side effects.

Your study doctor will provide you with enough study drug/placebo for accurate dosing throughout the 14 consecutive days study treatment period. You will need to take the doses around the same time each day (+/- 2 hours) around 30 mins after a meal for 14 consecutive days. For example, if you take the first dose (two 100 mg tablets) on Day 1 at 1 PM after your lunch (you finish your lunch around 12:30 PM), you should take your remaining daily doses between 11 AM- 3 PM, 30 mins after your meal on the subsequent days (Day 2, Day 3, etc.) through Day 14. Swallow the tablets whole and do not chew or crush them.

Your doses will not be increased and your schedule (how often you receive the study drug) will not be changed.

4.3.2 Daily Diary and Daily Questionnaire

During your participation you will need to keep a daily diary. This diary captures:

- When you take your tablets (14 consecutive days)
- How many tablets/doses you take
- Any missed doses you have

The study doctor will show you how to use this daily diary. You will either be provided information to access an electronic or a paper version of the diary. The electronic version can be accessed either through a computer/Web-based portal, or by smart phone application. If you are unable or unwilling to complete the daily diary electronically, your study doctor will provide you with a printed, paper diary that you can complete in writing and bring back to your study site staff or home visit staff. Each time you visit the clinic or meet your home visit staff, you must bring the

daily diary, study drug containers, and any remaining tablets. You will need to complete the daily diary from first day you take the study drugs until the last day you complete your study treatment.

In addition to answering questions about the study medication, you will be asked to fill out a form with questions/ questionnaire about your physical and emotional well-being, mostly focused on the COVID-19 related symptoms (such as, fever, diarrhea, cough, etc.). The questionnaire helps you and your study doctor keep track of any changes to your symptoms. This questionnaire form can either be completed on paper or electronically for you to self-evaluate every day from the day you start the study to 14 days after your last dose of your study medication (Day 28 per schedule of activities). The form will take about 5-10 minutes to complete each day. You don't have to answer any question that makes you feel uncomfortable. If you are completing the daily paper questionnaire, please let your study doctor know of any important changes to your symptoms like going to the hospital or a need for home oxygen.

4.3.3 Study Visits

Before you begin the study, your study doctor will review the results of your screening exams, tests, and procedures. This helps your study doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health. We will use them to carefully follow the effects of the study drug, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Blood tests and physical exams done before you begin the study.
- Blood tests done on Day 7, the last day of study drug taken (Day 14) and 14 days after last dose (Day 28).
- Nasopharyngeal swabs taken for virus tests before you start the study, Days 3, 7, 14, and 28. The study doctor may be required by law to report the result of these tests to the local health authority.
- Chest X-ray or CT Scan, physical exams or 12 ECG tests may need to be done per your study doctor's decision.
- Daily diary completed from first day you take the study drug to the last day you finish your study treatment (Day 14).
- COVID-19 related symptoms questionnaire (subject self-evaluation) daily since you start the study to 14 days after last dose (Day 28).
- Pregnancy test with blood sample for all female subjects regardless of childbearing potential before you begin the study and urine sample on Day 28 will be done if you are the childbearing-potential female subjects

During your participation in the study, you will be asked not to take certain medications (called "prohibited medications"). These will be prohibited during all periods of the study. You will also be asked to use caution with some medications including some over-the-counter medications or other anti-COVID-19 drugs and/or treatment procedures. The study doctor will review this with you. If you choose to take part in this study, you will be asked to fill out a form with questions/ questionnaire about your physical and emotional well-being, mostly focused on the COVID-19 related symptoms (such as, fever, diarrhea, cough, etc.). Researchers will use this information to learn more about how the COVID-19 illness progresses and the study drug treatment affects people. This questionnaire form can either be completed on paper or electronically for you to self-evaluate every day from the day you start the study to 14 days after your last dose of your study drugs. The form will take about 5-10 minutes to complete each day. You don't have to answer any question that makes you feel uncomfortable.

If you have any serious health issues or other concerns, please talk with your study doctor or study nurse right away.

A subject study calendar/schedule of activities is included as an Appendix at the end of this document for your quick reference. It shows how often these exams, tests, and/or procedures will be done.

4.4 Follow-up Period/ Post-study Treatment

After you finish the 14-day study treatment period, your study doctor will continue to follow your condition for another consecutive 14 days and watch you for side effects. That is called post-study treatment. You will continue to fill out the questionnaire about your physical and emotional well-being, mostly focused on the COVID-19 related symptoms, until Day 28. The post-study treatment visit will occur on Day 28 or last dose +14 days. This visit can be either in home health visit or in-office visit with study doctor. This is determined at your study doctor's discretion.

4.5 Safety Follow-up Period

After you finish the 14-day post-study treatment period, your study doctor will continue to follow your condition for another 14 days or last dose +28 days (whichever occurs first) and to watch you for side effects. This is called the safety follow-up. The safety follow-up visit will occur by phone. This means you will be seen or contacted by your study doctor for approximately 6 weeks.

You also should understand the continued scientific importance of your data. In order to prevent missing data even if you are taken off of the study early, you and/or your close contacts may be contacted via telehealth visits or other approaches (for example, telephone calls, texts, and emails).

4.6 Early Withdrawal

You can decide to stop taking part in the study at any time, without any penalty. If you decide to stop, you should notify your study doctor know as soon as possible. It is important that you discontinue your participation safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing. Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may decide to withdraw you from the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- You become pregnant
- The study is stopped by the Sponsor, IRB/IEC, or regulatory agency.

If you withdraw early from this study for any reason, you will complete the Early Withdrawal visit within 2 days of the day you withdraw. You will go to the safety follow-up period for 28 days after your last dose.

4.7 Drug Access after Study Completion

You will only be given GT0918 while the study is going on but not after it has ended.

4.8 Blood Tests

The total amount of blood that will be taken over the entire study is about 120 mL, which is much less than what you would give as a blood donor (500mL).

5 WHAT WILL I HAVE TO DO DURING THE STUDY?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell your study doctor about:
    - All medications and supplements you are taking
    - Any side effects you may experience
    - Any doctors' visits or hospital stays outside of this study
    - If you have been or are currently in another research study
- Complete the daily diary each time you take the study drug
- Complete the daily questionnaire
- Follow recommendations for reducing reproductive risks
    - Remain abstinent or have birth control for the duration of the study and until 90 days after the last dose of study drug.

- Advise all of your female partners of the need for them to use contraception during your participation in this study and until 90 days after your last study dose.

6 WHAT ARE THE POSSIBLE RISKS?

If you choose to take part in this study, there is a risk that the study drug with standard care may not be as good as the usual approach for relieving or reducing COVID-19 illness. You also may have the discomfort of spending more time in the laboratory or study doctor's office.

As with all research studies, the study medication and study procedures may involve unknown risks. Any medication can have temporary and permanent side effects and can cause unforeseen adverse reactions. The study drug may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

Here are important things to know about side effects:

- The study doctor does not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor immediately. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may take you off the study drug to try to reduce side effects.

6.1 Study Drug Risks

Risks are possible side effects from the study treatment and from tests done during the study. You should tell the study doctor if you have any unusual complaints, behaviors, or side effects, or had other doctor visits or hospitalizations outside of the study.

The tables below show the most common and most serious side effects of the study drug that doctors currently know about. Keep in mind that there might be other side effects doctors do not yet know. If important new side effects are found, the study doctor will discuss these with you.

6.1.1 The study drug risks experience based on previous studies in subjects with breast or prostate cancers.

VERY COMMON, SOME MAY BE SERIOUS
In 100 subjects receiving the study drug GT0918 (proxalutamide), more than 10 may have (greater than or equal to 10%):

- Feeling tiredness
- Decreased appetite
- Gastrointestinal disorders including diarrhea, abdominal (stomach) discomfort, pain, distension
- Nervous system disorders including confusion, dizziness, heart beats faster than normal while at rest, shortness of breath, changes in taste, loss of the sense of smell
- Weight decrease, weakness
- Liver damage that may cause yellowing of eyes and skin
- Infection, especially when white blood cell count is low
- Anemia (low red blood cell count) which may require blood transfusion
- Blockage of internal organs which may cause vomiting or inability to pass stool, or straining to have bowel movements
- Hot flush
- Kidney damage may cause protein in your urine
- Breast enlargement or pain

COMMON, SOME MAY BE SERIOUS
In 100 subjects receiving the study drug GT0918 (proxalutamide), more than one but less than 10 people may have (greater than or equal to 1% and less than 10%):

- Increased creatine phosphokinase which may cause heart damage
- Low potassium level (hypokalemia) which can cause heart rhythm problems, weakness, muscle cramps
- Low calcium level (hypocalcemia) which may cause bone or other problems
- Low blood sugar (hypoglycemia) which may cause dizziness
- Lipoproteins increased which may cause heart, liver or other problems

6.1.2 The study drug risks experience based on a previous study in subjects with COVID-19 illness.

VERY COMMON, SOME MAY BE SERIOUS
In 100 subjects receiving the study drug GT0918 (proxalutamide), more than 10 may have (greater than or equal to 10%):

- Diarrhea, nausea, abdomen pain

VERY COMMON, SOME MAY BE SERIOUS In 100 subjects receiving the study drug GT0918 (proxalutamide), more than 10 may have (greater than or equal to 10%):
• Dyspepsia may cause burning or discomfort in the stomach or upper abdomen, full feeling
COMMON, SOME MAY BE SERIOUS In 100 subjects receiving the study drug GT0918 (proxalutamide), more than one but less than 10 people may have (greater than or equal to 1% and less than 10%):
• Abdominal discomfort • Heartburn • Vomiting • Skin Lesions

6.1.3 Additional Study Drug Risks

The study drug could interact with other drugs such as moderate/strong inhibitors or inducers of CYP3A4/2D6 an important enzyme in the body, mainly found in the liver and in the intestine that helps small organic molecules, such as toxins or drugs, so they can be removed from the body. Nutritional supplements such as St. John's Wort, grapefruit or extracts of grapefruit, and immunosuppression medicine should be used with caution. Your study doctor will give you information that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

6.2 Reproductive Risks

The study drug could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention you must use during the study and for 90 days after you have completed the study.

If you are male, regardless of your fertility status, you must agree to either remain abstinent (if this is your preferred and usual lifestyle), or use condoms for the duration of the study and until 90 days after the last dose of study drug. As a condom alone is not considered adequate contraception for this study, you are also strongly recommended to advise all of your female partners of the need for them to use at least one of the methods of contraception listed below. Female partners should be advised of the need for them to use contraception during your participation in this study and until 90 days after your last study dose.

Women of child-bearing potential who are completely abstinent or in a same sex relationship, as part of their preferred and usual lifestyle, must agree to either remain abstinent or stay in a same sex relationship without sexual relationships with males.

All other women of child-bearing potential must agree to use two forms of effective contraception, where at least one form is highly effective (less than 1% failure rate), for the entirety of the study.

Recommended methods of method of contraception for females, use of one of the following combinations (a+b or a+c or b+c):

a) Use of oral, injected or implanted hormonal methods of contraception or other forms of hormonal contraception that have comparable efficacy, for example hormone vaginal ring or transdermal hormone contraception.

b) Placement of an intrauterine device (IUD) or intrauterine system (IUS)

c) Barrier methods of contraception: Condom or Occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/vaginal suppository

Do not father a baby or become pregnant while taking part in this study. Your study doctor will discuss with you what qualifies as acceptable contraception during this study. Also, you should not donate eggs, semen/sperm during the study or within 90 days after your last dose.

Tell the study doctor right away you get pregnant (for female participants) or you get you partner pregnant (for male participants) or thinks she may be pregnant during the study or within 90 days after your last dose of study drug. The study doctor or study staff will advise you of the possible risks to the fetus and baby. The study doctor must follow-up and keep a record of the course and the outcome of all pregnancies, even if you withdraw from the study or if the study has finished. If your partner becomes pregnant during the study, the study doctor or his/her staff will ask to contact you/your partner and your/your partner's doctor for information about the pregnancy and the child until 3 months after the birth. Your partner will be asked to sign a consent to report information regarding pregnancy outcomes.

6.3 Procedure Risks

There is also a risk that you could have other side effects from the study procedures, such as blood draws, nasopharyngeal swabs, etc.

Blood Tests

For most people, needle punctures for blood draws do not cause any bad problems. However, sometimes they may cause bleeding, bruising, discomfort, infections and/or pain where you had the blood drawn. You may also feel dizzy.

Nasopharyngeal Swabs

There may be some pain and discomfort when receiving a nasopharyngeal swab (a swab that goes into your nostril). There is a small risk of bleeding.

Electrocardiogram

Electrocardiogram (ECG, a recording of the heart's rhythm). An ECG (electrocardiogram) will be done. An ECG traces the electrical activity of the heart. You may have mild irritation, slight redness, or itching at the sites on your skin where the recording patches are placed.

Computed Tomography (CT) Scan

A CT scan is a computerized x-ray picture of your internal organs. You may feel some discomfort or anxiety when lying inside of the CT scanner.

Chest X-Ray

X-rays involve exposure to radiation. The amount of radiation exposure you may receive from these standard diagnostic tests is considered small and will not adversely affect the treatment of your disease.

Discomfort with Questionnaires

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

Risks with Electronic Transmission of Personal Information

As part of this research study, you will have the option to use an electronic daily diary and/or a daily diary app downloaded onto your personal smartphone. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information.

7 WHAT ARE THE POSSIBLE BENEFITS?

The study drug is an experimental treatment and there is no proven benefit to taking the study drug. There is preliminary evidence that this study drug plus usual care may be effective in reducing the chance of progressing to severe illness requiring hospitalization. It is not possible to know now if the study drug GT0918 with standard care will reduce your COVID-19 illness compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

8 ARE THERE ALTERNATIVE TREATMENTS?

You do not have to be in this study to get treatment for your COVID-19. We are doing this study because we want to find out if the approach used with this study drug is better or worse than the usual approach for your COVID-19 illness. The usual approach to treating COVID-19 illness with mild or moderate symptoms is also called standard of care.

The current standard of care for people with COVID-19 is rapidly changing and includes a number of medicines and experimental treatments, which may vary from site to site. It may also

include infection prevention and control measures and supportive care, including oxygen and ventilatory support when indicated. Your doctor can discuss your treatment options with you.

9 WILL I INCUR ANY EXPENSES OR RECEIVE ANY PAYMENTS?

9.1 Expenses

The study drug or placebo will be provided to you at no cost. You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. These include the extra samples taken of blood or nasopharyngeal swabs.

You and/or your insurance plan will need to pay for the costs of usual medical care you get during this study, just as you would if you were getting the usual care for your COVID-19 illness. This includes the costs of tests, exams, procedures, and drugs that you get in addition to the study drug during the study to monitor your safety and prevent and treat side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical study. Also, you should find out if you need approval from your insurance before you can take part in this study.

Ask your study doctor or study nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

9.2 Compensation for Participation

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your COVID-19. You may need to take more time off work and have other additional personal costs.

You may get compensation for every visit up to $XXX _and/or reimbursement for the travel and parking costs.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ["following each completed visit", "monthly", "quarterly", "at the end of your participation in the research study", "following each completed visit or at the end of your participation in the research study, whichever you prefer"].

If you have any questions regarding your compensation for participation, please contact the study staff.

The research may lead to new tests, drugs, or other products for sale. You will not be entitled to compensation related to these during or after your participation in this research study.

10 WHAT IF I AM INJURED DURING THE STUDY?

If you experience any unexpected symptoms or injury, and if emergency medical treatment is required, please report it immediately to:

_____ (Site to insert contact name and number).

Any compensation payable for any injury caused to you by taking part in this study will be in line with local guidelines. The Sponsor will pay for the cost of medical treatment for any injury that is directly due to study treatment with the study drug or study procedure (that has been used as described in the study plan). The Sponsor will not compensate you where the injury has happened because a procedure has been carried out that is not in line with the study plan or where the study doctor has acted negligently.

The Sponsor has taken out an insurance policy to cover compensation for any personal injury resulting from you taking the study drug, provided such personal injury is not due to fault or negligence of the study doctor or his team. To pay medical expenses, the Sponsor will need to know some information about you like your name and date of birth.

If you have medical insurance, please check with your insurance company that taking part in this study will not affect your policy. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

11 WHAT WILL HAPPEN IF THERE IS ANY NEW INFORMATION?

The study doctor or his/her staff will tell you in a timely manner if any new information becomes available which may influence your decision to stay in this research study.

12 WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

By signing this form, you consent to the study doctor and his or her staff collecting and using your personal and study data for the study.

- Personal data include: your gender, your ethnic origin, your date of birth (day, month and year), information on your physical or mental health or condition.
- Study data are information collected from you including results from the tests and examinations performed during this study.

The data shared with the Sponsor is protected using a code specifically assigned to you. The study doctor is in control of the code needed to connect your personal data to you.

All data that identify you by name will be held confidential and will not be made publicly available. This means that such data will be kept in locked electronic files with appropriate levels of security. Only staff with proper approvals will be able see or refer to these files. However, the study doctor, the authorized personnel from the Sponsor and its representatives, the study monitor (who checks how the study is going and makes sure that the information is being collected and used properly) and, under certain circumstances, the regulatory authorities and members of the ethics committees will be able to inspect confidential data that identify you by name. This will be done without violating your confidentiality to the extent permitted by the applicable laws and regulations.

By signing this consent form, you grant permission for personal data and medical information about you obtained during this study (your study data) to be made available to authorized or

approved representatives of the regulatory authorities and other government agencies. You also grant permission for your personal data to be made available to the Sponsor auditors, the study monitor, other study personnel, and ethics committees.

Your coded data and study data may be sent to other countries) since some of the recipients are based outside of your country. When your personal data is sent to another country, it is either controlled by a contract approved by government agencies supervising protection of your data (data privacy authorities) or by the Sponsor's rules which have been approved by data privacy authorities (called Binding Corporate Rules). Your personal information will still be kept completely confidential, no matter which country it goes to, even if that country does not have the same level of protection for personal information as <Country>.

The data collected during this study, including your personal data, may be further used in analyses by the Sponsor or other researchers to answer additional scientific questions related to GT0918 and COVID-19. The Sponsor will take appropriate measures to protect your information and will only use and share coded data for such additional research.

Your data may be used by the Sponsor or contract research organization on a coded basis for administrative purposes. For example, such coded data may be used to track the overall progress of this study and to improve the manner in which future clinical trials are conducted. Your data may also be stripped of any information that could be used to identify you or combined with other data by the Sponsor or contract research organization as part of their efforts to protect personal information.

If you withdraw your consent for participating in this study, your personal and study data that were collected before you withdrew your consent may still be used as described above. Once you have withdrawn your consent for participating in the study, no further data will be collected about you for the purposes of this study unless you agree otherwise, for example, you agree to have further tests and examinations. If you do agree to have further data collected after you have withdrawn your consent, these study data may also be used as described above. By signing this consent, you explicitly agree that if you decide to withdraw from the study, your medical data (and samples) collected prior to withdrawal may still be processed along with other data collected as part of the study. If you prefer any previously retained samples destroyed, you must notify your study doctor in writing.

Please note that you have the right to view and access your personal data and to ask for correction as allowed by <European Union regulation /national law. > [delete "national law" if subjects are located in European Economic Area (EEA) member state; otherwise delete "European Union regulation"]. If you wish to make a request, then please contact the study doctor, who can help you contact the Sponsor, if needed.

You can also request that the Sponsor completely delete any personal data that was collected from you. However, it may not always be possible to meet such requests. If deleting your personal data makes the results from this study undependable or if the Sponsor is required to keep such personal

data for legal reasons, then they will not be deleted. In this regard your coded personal data will be retained for a period of <xx> years after the end of the study [delete this paragraph, if study subjects are located outside the EEA].

If you wish to exercise these rights, <or file a complaint> [delete, if study subjects are located outside the European Economic Area], please contact your study doctor <or the data protection officer (staff who makes sure that personal data is kept confidential) of your study site> [delete, if study subjects are located outside the EEA]. You can find out more about how <Sponsor> keeps personal information at <insert url>.

<You have the right to lodge a complaint to your data protection authority. In case you decide to do so, the Sponsor is very interested to understand your perspective and, therefore kindly asks you to inform them via your study doctor when you lodge a complaint.> [delete, if study subjects are located outside the EEA].

The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, e.g., photo) in any of these publications. Researchers from for example the Sponsor, other companies, and universities might ask to use information from this study, including your coded data and samples for other medical, healthcare or scientific related research. The researchers may combine the results from this study with results from other studies. If the Sponsor lets them have your personal data, the Sponsor will make sure that they cannot find out who you are and that such research is in line with this document. You may have a right to object to the use of your personal data for this additional research for reasons specific to you. If you wish to object to such use, please contact your study doctor.

The blood samples that you donate will be used in this research study and will not be used for medical diagnosis or treatment decision-making. Unless required by law, you will not get copies of the results. If you decide to stop taking part in this study, your samples that we have already collected will still be used in the ways that you agreed to when you started in the study. Once you have withdrawn your consent for participating in the study, no further data will be collected about you for the purposes of this study. If you withdraw consent to take part in the study, you can request for your samples to be destroyed. We will try to destroy samples, but if the samples are no longer linked to you or if the samples were sent to a third party, this might not be possible.

In future, identifiers associated with your data and/or specimens could be removed from the data and specimens. The de-identified data and specimens could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

Your samples may be analyzed or safely stored in another country but will always be coded. <Some> samples will be destroyed when they have been used for the purpose of the study <or be kept longer, up to <xx> years, if you agree>. The Sponsor will be the owner of the study results.

[If applicable, explain whether the subject will be informed about clinically relevant research results, and if so, under what conditions.]

"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.

For applicable clinical trials that are conducted in the EU and the European Economic Area (EEA) or Clinical trials conducted outside the EU / EEA that are part of an EU Paediatric Investigation Plan (PIP), include:

"A description of this clinical trial will be available through the public website https://www.clinicaltrialsregister.eu. This Web site will include information on the trial and summary of the results but will not include any information that can identify you. You can search this Web site at any time."

For trials in China, include:

A description of this clinical trial will be available on www.chinadrugtrials.org.cn. 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.

For trials in Japan, include:

A description of this clinical trial will be available on Medical Information Database of Japan Pharmaceutical Information Center (JAPIC) according to the Sponsor's request: http://www.clinicaltrials.jp/user/cteSearch.jsp. You can search this Web site at any time.

[Include any Sponsor-specific websites where information may be available, if applicable.]

13 WHAT IF I HAVE QUESTIONS?

If you have questions about the study, or have a problem related to the study, you may contact the study doctor or his/her staff at the telephone number below.

Name:_____Telephone: (_____) _____

Title of Investigator: _____

If you are calling after hours or on a weekend, you may contact the individual below.

Name:_____Telephone: (_____) _____

If you have questions about your rights as a research participant, you should contact the individual below.

(Note: Insert name of IRB/IEC chairperson and/or name of IRB/IEC, [For Japan, type of IRB/IEC (eg. specialized IRB)], address, and telephone number.)

Name:_____Telephone: (_____) _____

Address: _____

(Note: Insert name of data protection officer of the site, address, and telephone number.)

Name:_____Telephone: (_____) _____

Address: _____

14 CONSENT STATEMENT OF SUBJECT

I have received verbal information on the above study and have read the attached written information. I have been given the chance to discuss the study and ask questions.

I voluntarily consent to participate in this study, including all assessments, lifestyle restrictions, contraception requirements, and taking of blood samples.

I understand that I am free to withdraw at any time. I understand that if I choose to not participate or to withdraw, my current medical care will not be affected by this decision.

I agree that my primary doctor may be told of my participation in this study.

I agree that my primary doctor may be asked to give information about my medical history.

I agree that my personal data, including data relating to my physical or mental health or condition, and ethnic origin, may be used as described in this consent form.

I agree and authorize that my coded personal data may be transferred within and outside [Country] to countries, where personal data may not have the same level of statutory protection as in [Country].

I agree and authorize that samples collected from me for the purposes described in this consent form will be processed in coded form within and outside [Country], where personal data may not have the same level of statutory protection as in [Country], by the Sponsor, its affiliates, representatives and collaborators for scientific and regulatory purposes and that these samples may be stored up to [insert number] years after the conclusion of the study for further research.

I understand that I will get and may keep a copy of this signed and dated consent form.

By signing and dating this consent form, I have not given up any of the legal rights that I would have if I were not a participant in a medical research study.

Signature of Patient	Date (mm/dd/yyyy)	Printed Name of Patient
Signature of Legal Representative	Date (mm/dd/yyyy)	Printed Name of Legal Representative
Relationship of Legal Representative to Patient		
Signature of Witness	Date (mm/dd/yyyy)	Printed Name of Witness

15 STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I, the undersigned, certify that to the best of my knowledge, the patient signing this consent form had the study fully and carefully explained and clearly understands the nature, risks, and benefits of participation in this research study.

Signature of Investigator (or other Person Obtaining Consent)	Date (mm/dd/yyyy)	Printed Name of Person Obtaining Consent

16 Appendix: Subject Calendar/ Schedule of Activities (SoA)

Assessments obtained previously as part of routine clinical care may be used as the screening assessment if they were done no more than 1 day before randomization. Visits may be conducted as a telephone call, outpatient clinic visit, or home visit if the study plan SoA is followed and in compliance with local regulatory requirements.

	Screen	**Study Treatment Period**				**Early Withdrawal[16]**	**Post-study Treatment**		**Safety Follow Up[17]**
Study Day (Visit Window ± days)	**Day -1**	**Day 1**	**Day 3**	**Day 7 (±1)**	**Day 14 (+1)**	**(+2)**	**Day 15**	**Day 28 (±2)**	**Day 42 Phone Call (±2)**
Informed Consent	**X**								
Inclusion/Exclusion Review[1]	**X**								
Demographics[2]	**X**								
Pre-existing Conditions and Medical History[3]	**X**								

NIAID Ordinal Scale[4]	**X**	**Daily**							
Prior Treatment [5]	**X**								
Tobacco Use	**X**								
Physical Examination [6]	**X**	**Symptom Directed PE only if Clinically Indicated**							
Vital Signs [7]	**X**		**X**	**X**	**X**	**X**		**X**	
Nasopharyngeal swabs [8]	**X**		**X**	**X**	**X**	**X**		**X**	
Randomization [9]	**X**	**X**							
Hematology [10]	**X**			**X**	**X**	**X**		**X**	
Chemistry [10]	**X**			**X**	**X**	**X**		**X**	
Biomarkers [10]	**X**		**X**		**X**	**X**		**X**	
Coagulation [10]	**X**				**X**	**X**		**X**	
Drugs and Diary Dispense [11]	**X**	**X**							

GT0918 or Placebo Administration [11]		**Daily from Day 1 to Day 14**					
Subject Diary [11]		**Daily from Day 1 to Day 14**					
Questionnaire (Symptoms; Overall Clinical Status;) [11]	**Daily**						
Chest X-ray or CT Scan [12]	**Clinically Indicated**						
12-ECG [12]	**Clinically Indicated**						
Hospitalization events [13]		**Daily**					
Clinical status and concomitant procedures if subject is hospitalized [14]		**Daily if hospitalized**					
Adverse Events [15]	**X**						
Concomitant Medications [16]	**X**						
Pharmacokinetics [17]		**X**	**X**	**X**	**X**	**X**	
Pregnancy test [18]	**X**						**X**
COVID-19 vaccination status	**X**						

Annotation:

1. Inclusion/Exclusion review: every subject needs to meet all inclusion and exclusion criteria. The eligibility checklist needs to be signed by the investigator or sub-investigator.
2. Demographics: includes age, gender, race, and ethnicity.
3. Pre-existing conditions and medical history: obtained from interview or available information and including timing of exposure and onset of symptoms suggestive of SARS-CoV-2 infection.
4. NIAID ordinal scale to be completed daily through Day 28 or 14 days after last dose. This information can be collected from questionnaire; reported events; or directly from the patient.
5. Prior treatments within last 30 days.
6. Physical exam (PE): Full physical exam should be done at screening visit. For the subsequent visits, symptom directed PE can be done per investigator's discretion. If the result is clinically significant, the PE result should be recorded in eCRF.
7. Vital sign: documentation of hospital-based exam is acceptable. Vital signs include body temperature, pulse rate, systolic and diastolic blood pressure, respiratory rate. For screening visit, SpO_2, and supplemental oxygen flow rate, FiO_2 if known and method of delivery if applicable, also need to be recorded. Record blood pressure and SpO_2 while subject is at rest.
8. Nasopharyngeal (NP) swabs: Only NP swab sample is acceptable. The method of taking samples should be consistent for each subject during the whole period of this study. This does not need to be the same before screening visit, when the subject is first time confirmed SARS-CoV-2 positive at local laboratory and/or Point of Care testing. Sample for first positive test must be collected within 3 days prior to start of dosing. Local laboratory and/or Point of Care testing are acceptable.
9. Randomization: randomization should be via the Interactive Voice/Web (IxRS) Response System. Randomization should be done after confirmation the subject meets all inclusion/exclusion criteria. Drugs and Diary Dispense should occur after randomization. It is allowed for the subject to take the drug on the same day of the screening visit after confirmation of eligibility and randomization (the screening visit is counted as D1 too). The Subject Diary should start to be completed.
10. Laboratory tests: Hematology, Chemistry (including Creatinine Kinase), Biomarkers (including Procalcitonin, C-reactive protein, D-dimer, Ferritin, Troponin, Testosterone), Coagulation. For details refer to Section 7.2.2 and 7.2.4.
11. GT0918 or placebo administration: GT0918 or placebo will be given orally once daily on Days 1-14 during the study period after a meal (±2 hours for medication scheduling). The drug taken time should be recorded with subject diary. If the screening day is also D1, the subject does not need to follow the drug taken window on screening day/D1. For details refer to Section 6.1.

    Subject Diary should be completed every day since first dose until the last dose.

    Questionnaire should be completed every day since screening visit to the end of post-treatment by Day 28. For details refer to Section 7.2.6.
12. Chest X-ray or CT-Scan or 12-ECG can be done per investigator's discretion. If investigator deems the result is clinically significant, the result should be recorded with eCRF.
13. Hospitalization events: if the subject is hospitalized, the treatment may be continued to the 14 days per PI. Hospitalization is defined as ≥24 hours in hospital of care. For details refer to Section 7.1.2.

    Record if the following events occur:

- Emergency room visits

- Hospitalized
- ICU admittance
- Discharge
- Extended care facility admittance(refers to long term care for chronic diseases or prolonged rehabilitation, which is not defined as hospitalization)

14. Documentation from hospital records is acceptable.
    Includes:
    - Limitation on activities due to COVID- 19
    - Ongoing hospital medical care
    - Supplemental oxygen
    - Non-invasive ventilation or high flow oxygen device
    - Mechanical ventilation
    - ECMO, or
15. Adverse events: any events that occur after signing the informed consent are considered AEs as defined in Section 10.3.
16. Concomitant medications: all medications administered within 30 days prior to the first dose of study treatment through 30 days after the last dose of study treatment will be recorded in the concomitant medications, for details refer to Section 6.4.
17. Pharmacokinetics (PK) samples only need to be taken for at least 100 subjects, who will be assigned according. For details refer to Section 7.2.3.
18. All women regardless of childbearing potential must complete a serum pregnancy test at screening visit, urinary pregnancy test on day 28 as per the schedule of assessment for women of childbearing potential. Local laboratories will be used for the analysis of serum and urinary pregnancy tests.
19. Early withdrawal (EW): if the subject is early withdrawn from this study for any reason (Section 7.1.4), the subject should complete the EW visit, and the visit should occur within 2 days of the EW day. The subject will go to the safety follow-up period for additional 28 days after his last dose.
20. D42 (or 28 days ±2 post last dose if subject is withdrawn early) safety follow-up visit is phone call visit.