RESEARCH SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

TITLE: A Phase 2b/3, Randomized, Double Blind, Placebo Controlled, Adaptive Design Study to Evaluate the Efficacy and Safety of Leronlimab for Patients with Severe or Critical Coronavirus Disease 2019 (COVID-19)

PROTOCOL NO.: CD12_COVID-19
IRB Protocol#20200923

SPONSOR: CytoDyn, Inc.

<<CF-Main Header Block - Investigator>>
STUDY RELATED PHONE NUMBER(S): <<CF-Main User Defined #1>>

In this consent form “you” generally refers to the research subject. If you are being asked as the legally authorized representative to permit the subject to take part in the research, “you” in the rest of this form generally means the research subject.

INTRODUCTION

You are being invited to take part in a clinical research study because you have been diagnosed with Coronavirus Disease 2019, known as COVID-19. This research study is using an investigational drug as a possible treatment for this diagnosis.

The name of the study drug involved in this study is:

- Leronlimab (PRO 140). It belongs to a class (group) of drugs called CCR5 antagonist.

For purposes of this research, you will be referred to as a "participant".

CytoDyn, Inc., a pharmaceutical company is supporting this research study by providing funding for this research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

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

WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Phase 2b/3 clinical trial. Phase 2b/3 clinical trials test the safety and effectiveness of an investigational drug to learn whether the drug works in treating a specific disease.

Your study doctor and medical team are conducting a research study with CytoDyn, Inc. This study will help determine the safety and efficacy of leronlimab (PRO 140) in the treatment of coronavirus disease 2019 (COVID-19).

The safety of leronlimab (PRO 140) has been previously evaluated in over 750 people in previous studies. The product you will be using is an investigational drug. "Investigational" means that the drug is being studied. The FDA (the U.S. Food and Drug Administration) has not approved this drug, leronlimab (PRO 140) as a treatment for any disease. The results of these studies will be used to design future studies to improve treatment of patients suffering from COVID-19.

In the Randomized part of this study, 390 subjects were randomly assigned (by chance, like drawing straws) to receive two doses of leronlimab (PRO 140) or placebo. Patients

had 2 chances in 3 (67%) of receiving the study drug and 1 chance in 3 (33%) of receiving the placebo. Neither patients nor the study doctor were aware of the treatment assignment. About 390 subjects were enrolled in the randomized study across 30 centers.

After the completion of enrollment in the Randomized Phase of the study, an Open-label Phase is added to provide access to leronlimab for the eligible patients while waiting for the results for the randomized portion of the study. If you are eligible, you will be assigned to receive Leronlimab (PRO 140) in this open-label phase of the study. Approximately, 100 patients are expected to be enrolled in this open-label phase. Enrollment will remain open until the decision is made by CytoDyn and/or regulatory authorities to close the recruitment.
You will be allowed to continue to receive the standard treatment in combination with leronlimab (PRO 140) or placebo. This includes hydroxychloroquine or chloroquine with or without azithromycin, Veklury (remdesivir), Dexamethasone (or other corticosteroids), monoclonal antibodies (such as bamlanivimab, casirivimab, imdevimab), immunomodulatory agents (such as baricitinib, sarilumab, clazakizumab, tocilizumab, anakinra), or Convalescent plasma therapy if already prescribed to you by your doctor.

HOW DOES Leronlimab (PRO 140) WORK?

Leronlimab (PRO 140) belongs to the monoclonal antibody class of medicines. Monoclonal antibodies are synthetic versions of the disease-fighting proteins (antibodies) that are naturally produced by the body. Antibodies that are normally circulating in the blood typically react to any foreign organisms or materials that enter our body. However, leronlimab (PRO 140) binds to a protein (CCR5) that is present on the surface of one kind of our blood cells. By doing so, it is hoped that it prevents the bad inflammation and damage to the lungs that result from infection with the coronavirus, and thus might be useful in the treatment of COVID-19.

In the disease COVID-19, the body may respond to the viral infection by overproducing immune cells and their signaling molecules in a dangerous phenomenon called cytokine storm, which is often associated with a surge of activated immune cells into the lungs. This can lead to acute respiratory distress syndrome (ARDS).

In ARDS, fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. The fluid keeps your lungs from filling with enough air, which means less oxygen reaches your bloodstream. This deprives your organs of the oxygen they need to function. ARDS has known to be one of the main reasons for death in patients with COVID-19.

Leronlimab (PRO 140) does not kill the novel coronavirus. It acts as a CCR5 antagonist by blocking pro-inflammatory cytokines, which prevents cytokine storm and thus could be useful in treatment of COVID-19.

A small Phase II study of 86 patients with mild to moderate coronavirus disease 2019 (COVID-19) did not meet its study goal to demonstrate difference between Leronlimab and placebo as the vast majority of the patients with mild to moderate COVID-19 recover with supportive care. However, some additional analyses of the data indicated a possibility of benefit in more severe patients. Safety results showed no new safety risk was identified in patients receiving Leronlimab.

This document uses words such as treatment, drug, medication, and patient. Please remember this is a research study and the use of these terms does not mean the use of the leronlimab (PRO 140) has been found to be safe or effective for your condition.

WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. There is no specific antiviral treatment recommended for COVID-19. Instead of being in this research study, you have other options which may include the following:

- Other standard supportive care to help relieve symptoms
- Take part in another research study being explored for antiviral treatment

Please talk to the research doctor about your options and their risks and benefits before you decide whether you will take part in this research study.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

- You will take once weekly dose of 700 mg leronlimab (PRO 140) for two weeks.
- Leronlimab (PRO 140) or placebo will be injected via a very thin needle slightly below the surface of your skin in your stomach, by the research staff or visiting nurse. You will receive two injections (of 2 mL) or four injections (of 1 mL), every week for two weeks. Placebo was used in the randomized part but is not used in the open-label part of this study,
- Your participation involves 3 periods:
    - Screening will take up to 1 week and may include more than one visit.
    - Treatment will last for two weeks and include four visits. You will receive treatment with leronlimab (PRO 140) twice during the two-week Treatment Phase.
    - Follow-up phase will last for four weeks. The follow-up phase includes two visits, two weeks apart. Visits during the follow-up phase can be conducted as telephone or video contact visits.
- In total, the expected study duration is 42 days (6 weeks).
- At visits conducted at the hospital, you and the study staff will be provided the appropriate protective gear (e.g., masks, gloves) to prevent the spread of the infection. If you are discharged from the hospital at any point during the study, study visits can be conducted at your home by a visiting nurse or a trained member of the study team.

- Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

Before the research starts (screening):
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can participate in the research study. If you have had some of these tests or procedures recently, they may not have to be repeated.

The screening period may last up to seven days (1 week).

Screening Visit
The following procedures will be done at the screening visit:

- You will be asked a number of general questions about your age, race, ethnicity, your medical and surgical history, including any illnesses or health problems, and your prior or current medications.
- Your study doctor will give you a Physical Exam.
- Your height, weight, heart rate, temperature, blood pressure, and breathing rate will also be assessed.
- Your study doctor will assess your clinical status based on your hospitalization status and if you have any limitations.
- Your study doctor will measure the ratio between the oxygen level in your blood and the amount of oxygen you breathe in.
- You doctor will perform a test (pulse oximetry) to measure your blood oxygen level
- If you are intubated within 72 hours of this visit (using a tube to help you breathe), your doctor will measure the pressure in your lungs.
- Your doctor will perform an assessment (Sequential Organ Failure Assessment (SOFA) Score) to determine the severity of your health status. The assessment score is based on lab results and clinical status.
- Your doctor will determine your National Early Warning Score 2 (NEWS2) by checking your blood oxygen levels as well as assessing your breathing, your need for oxygen, heart and breathing rate, and your consciousness level. (Not done in the open-label part of this study)
- Your study doctor will perform an ECG (electrocardiogram – a test to check your heart).
- A series of blood tests will be performed. The amount of blood needed for these tests is about 3-4 teaspoons.

    - A blood test for general health screening, such as chemistry and complete blood count.

- If you are a female and able to become pregnant, a pregnancy test will be required. If the pregnancy test is positive, you will not be able to be in the study.

- A urine sample will be needed for lab tests.
- A nasal swab will be taken to test for the level of coronavirus in your body. (*Not done in the open-label part of this study*)
- If needed, you will have a computed tomography (CT) scan, or chest X-ray test done to allow your study doctor to take images of your body or lungs.
- An assessment to test your requirement for breathing or oxygen assistance, renal replacement therapy, or any hospital stay.

Note that all of the procedures listed above may not be done if at any point during the evaluation, you fail eligibility. If you are not eligible for the study, your study doctor will explain the reasons and arrange for your prescribed standard care to continue.

Within this 1-week period, you will be informed if you are eligible to enter the study. If Visit 2 takes place on the same day as the Screening Visit, scheduled assessments performed under screening (V1) do not need to be repeated.

Treatment Period

Visit 2 (Day 0)
The treatment will start within 1 week of the Screening Visit.

Before you receive any study treatment, your study doctor will reconfirm your study eligibility by completing the following procedures:

- Your pulse rate, respiratory rate, temperature, and blood pressure will be assessed.
- Your study doctor will measure your weight and give you a physical exam based on any changes reported in your health.
- Your study doctor will assess your clinical status based on your hospitalization status and if you have any limitations.
- Your study doctor will measure the ratio between the oxygen level in your blood and the amount of oxygen you breathe in.
- You doctor will perform a test (pulse oximetry) to measure your blood oxygen level
- If you are intubated (using a tube to help you breathe), your doctor will measure the pressure in your lungs.
- Your doctor will perform an assessment (Sequential Organ Failure Assessment (SOFA) Score) to determine the severity of your health status. The assessment score is based on lab results and clinical status.
- Your doctor will determine your National Early Warning Score 2 (NEWS2) by checking your blood oxygen levels as well as assessing your breathing, your need for oxygen, heart and breathing rate, and your consciousness level. (*Not done in the open-label part of this study*)

- A blood test to check the levels of certain proteins and substances in your blood cells (*Not done in the open-label part of this study*)
- A blood test to check level of CCR5 receptors on the specialized white blood cells (Treg and macrophages) and any changes to the CCR5 gene (polymorphism). (*Not done in the open-label part of this study*)
- A nasal swab will be taken to test for the level of coronavirus in your body. (*Not done in the open-label part of this study*)
- An assessment to test your requirement for breathing or oxygen assistance, renal replacement therapy, or any hospital stay.

Once all of the above assessments have been completed, your study doctor will perform for the following procedures:

- You will receive your treatment injections of leronlimab (PRO 140) or placebo.
- Your essential body functions like pulse rate, temperature, respiration rate, and blood will be recorded
- You will be asked to report any symptoms that you experienced.

Leronlimab (PRO 140) will be given under your skin as two 2mL shots on opposite sides of the stomach or as four 1mL injections at the clinic or at your home.

Visit 3 (Day 3)

The following assessments will be performed at Visit 3:

- Your doctor will perform a physical exam based on any changes reported in your health
- You will be asked about any change in current medications
- Your pulse rate, respiratory rate, temperature, and blood pressure will be assessed.
- Your study doctor will assess your clinical status based on your hospitalization status and if you have any limitations.
- Your study doctor will measure the ratio between the oxygen level in your blood and the amount of oxygen you breathe in.
- You doctor will perform a test (pulse oximetry) to measure your blood oxygen level
- If you are intubated (using a tube to help you breathe), your doctor will measure the pressure in your lungs.
- Your doctor will perform an assessment (Sequential Organ Failure Assessment (SOFA) Score) to determine the severity of your health status. The assessment score is based on lab results and clinical status.
- A nasal swab will be taken to test for the level of coronavirus in your body. (*Not done in the open-label part of this study*)
- An assessment to test your requirement for breathing or oxygen assistance, renal replacement therapy, or any hospital stay.
- You will be asked to report any symptoms that you experienced

- A series of blood tests will be performed. The amount of blood needed for these tests is about 3-4 teaspoons.

    - A blood test for general health screening, such as chemistry and complete blood count
    - A blood test to check the levels of certain proteins and substances in your blood cells (*Not done in the open-label part of this study*)
    - A blood test to check level of CCR5 receptors on the specialized white blood cells (Treg and macrophages) and any changes to the CCR5 gene (polymorphism). (*Not done in the open-label part of this study*)

Continuation of Treatment, Visit 4 (Day 7)
For Visit 4, the following assessments will be performed:

- Your study doctor will give you a physical exam.
- You will be asked if there have been any changes to the medications you are taking
- Your weight, heart rate, temperature, blood pressure, and breathing rate will also be assessed.
- Your study doctor will assess your clinical status based on your hospitalization status and if you have any limitations.
- Your study doctor will measure the ratio between the oxygen level in your blood and the amount of oxygen you breathe in.
- You doctor will perform a test (pulse oximetry) to measure your blood oxygen level
- If you are intubated (using a tube to help you breathe), your doctor will measure the pressure in your lungs.
- Your doctor will perform an assessment (Sequential Organ Failure Assessment (SOFA) Score) to determine the severity of your health status. The assessment score is based on lab results and clinical status.
- Your doctor will determine your National Early Warning Score 2 (NEWS2) by checking your blood oxygen levels as well as assessing your breathing, your need for oxygen, heart and breathing rate, and your consciousness level. (*Not done in the open-label part of this study*)
- A nasal swab will be taken to test for the level of coronavirus in your body. (*Not done in the open-label part of this study*)
- Your study doctor will check your clinical symptoms regarding any fever, muscle pain, breathing difficulties, and cough.
- A series of blood tests will be performed. The amount of blood needed for these tests is about 3-4 teaspoons.

    - A blood test for general health screening, such as chemistry and complete blood count.
    - A blood test to check the levels of certain proteins and substances made by a kind of your blood cells (*Not done in the open-label part of this study*)

    - A blood test to check level of CCR5 receptors on the specialized white blood cells (Treg and macrophages) and any changes to the CCR5 gene (polymorphism). (*Not done in the open-label part of this study*)
    - A urine sample will be needed for lab tests

- You will be asked to report any symptoms that you experienced
- You will receive your treatment injections of leronlimab (PRO 140) or placebo.

Visit 5, End of Treatment (Day 14)
One week after your last treatment, you will be asked to visit the clinic for the end of treatment (EOT) visit during which the following assessments will be performed:

- You will be asked to report any symptoms that you experienced
- You will be asked if there have been any changes to the medications you are taking
- Your study doctor will give you a Physical Exam.
- Your weight, heart rate, temperature, blood pressure, and breathing rate will also be assessed.
- Your study doctor will assess your clinical status based on your hospitalization status and if you have any limitations.
- Your study doctor will measure the ratio between the oxygen level in your blood and the amount of oxygen you breathe in.
- You doctor will perform a test (pulse oximetry) to measure your blood oxygen level
- If you are intubated (using a tube to help you breathe), your doctor will measure the pressure in your lungs.
- Your doctor will perform an assessment (Sequential Organ Failure Assessment (SOFA) Score) to determine the severity of your health status. The assessment score is based on lab results and clinical status.
- Your doctor will determine your National Early Warning Score 2 (NEWS2) by checking your blood oxygen levels as well as assessing your breathing, your need for oxygen, heart and breathing rate, and your consciousness level. (*Not done in the open-label part of this study*)
- A nasal swab will be taken to test for the level of coronavirus in your body. (*Not done in the open-label part of this study*)
- A urine sample will be needed for lab tests
- A series of blood tests will be performed. The amount of blood needed for these tests is about 3-4 teaspoons.

    - A blood test for general health screening, such as chemistry and complete blood count.
    - A blood test to check the levels of certain proteins and substances made by a kind of your blood cells (*Not done in the open-label part of this study*)

- If you are a female and able to become pregnant, a pregnancy test will be required. If the pregnancy test is positive, you will not be able to be in the study.
- A blood test to check level of CCR5 receptors on the specialized white blood cells (Treg and macrophages) and any changes to the CCR5 gene (polymorphism). (*Not done in the open-label part of this study*)
- If needed, you will have a computed tomography (CT) scan, or chest X-ray test done to allow your study doctor to take images of your body or lungs.
- An assessment to test your requirement for breathing or oxygen assistance, renal replacement therapy, or any hospital stay.

Follow-Up Period

Visit 6 and Visit 7 (Day 28 and Day 42)
The follow-up period will last up to four weeks and include two visits. The following assessments will be performed at each visit:

- You will be asked to report any symptoms that you experienced.
- You will be asked if there have been any changes to the medications you are taking.
- Your study doctor will give you a physical exam.
- Your heart rate, temperature, blood pressure, and breathing rate will also be assessed.
- Your study doctor will assess your clinical status based on your hospitalization status and if you have any limitations (Visit 6 only).
- A urine sample will be needed for lab tests
- A series of blood tests will be performed. The amount of blood needed for these tests is about 3-4 teaspoons.
    - A blood test for general health screening, such as chemistry and complete blood count.
- A nasal swab will be taken to test for the level of coronavirus in your body. (*Not done in the open-label part of this study*)

HOW LONG WILL I BE IN THIS RESEARCH STUDY?
This research study lasts for a total of 42 days. You can participate for as long as you do not have serious side effects and your disease does not get worse.

You may be taken off the research study for many reasons including if:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- Your condition worsens

- Or for other unforeseen reasons that make it necessary to stop your participation in the research study
- You become pregnant
- If you miss two consecutive doses of the investigational drug
- The study is canceled by the sponsor or the FDA

If you are removed from the research study, the research doctor will explain to you why you were removed.

In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

WHAT ARE THE RISKS/SIDE EFFECTS OF TAKING PART?

There are risks to taking part in any research study. One risk is that you may get a study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your essential body functions- blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

In other studies of leronlimab (PRO 140), possibly related side effects observed in subjects receiving the 700 mg dose included:

- Reactions at the site of the injection such as:
    - Bruising
    - Redness of the skin
    - Fluid leakage
    - Itch
    - Rash
- Headache
- Diarrhea
- Fatigue

All of these side effects occurred in less than 2% of subjects.

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Side effects that you could experience during or after the leronlimab (PRO 140) treatment:

- The most common potential study drug-related side effect that has been seen using the drug formulation that you will be using is mild headache. Other side effects likely to be related to the drug include mild to moderate diarrhea, nausea, and fatigue. There may be other side effects associated with leronlimab (PRO 140) that we do not know about.
- Leronlimab (PRO 140) belongs to the monoclonal antibody class of drugs. Monoclonal antibodies are sometimes associated with allergic reactions (fatigue, diarrhea, fever, vomiting, headache, nausea, pain at the site of injection, low blood pressure, rash, itching, and chills) or flu-like reactions such as fever, chills, and aches. These events usually do not last long if they occur at all. Severe allergic reactions, however, can be life-threatening.
- Rare severe acute hypersensitivity reactions or anaphylaxis can occur. If anaphylaxis or severe allergic reactions occur, therapy with leronlimab (PRO 140) will be permanently discontinued and appropriate medications (e.g., epinephrine) and supportive care will be provided.
- People who take leronlimab (PRO 140) or other monoclonal antibodies can also develop an immune response to leronlimab (PRO 140) that may affect their ability to receive monoclonal antibodies, or to benefit from diagnosis or therapy with a monoclonal antibody in the future.
- Side effects that may be associated within a short period of time after receiving drugs similar to leronlimab (PRO 140) through an injection include chills, headache, backache, overall feeling of being ill, fever, skin rash, nausea, tingling and high blood pressure. Your study doctor may give you medicine to help with these side effects.
- People who lack a functional CCR5 gene are at increased risk for severe infection by West Nile virus. Please ask your study doctor about this.
- Local pain, redness, tenderness, bruising, itching and rarely, an infection might occur at the site of injection in your stomach or at the site of the needle stick in your arm for blood draws or you may faint when blood is taken.
- The nasal swab procedure to test for the level of coronavirus in your body may be uncomfortable. (*Not done in the open-label part of this study*)

- Studies on leronlimab (PRO 140) to determine its capability to cause harm to an unborn child have not been performed. If you are a woman of childbearing potential, you will be tested for pregnancy at the beginning of the study.
- It is unknown if leronlimab (PRO 140) can pass through breast milk and it is unknown if this can cause harm to your child.

In addition to the risks or discomforts listed here, there may be other risks that are currently not known.

Reproductive Risks:
The drug used in this research study may affect a fetus. While participating in this research study, you should not become pregnant and should not nurse a baby. We can provide counseling about preventing pregnancy. You must use at least one highly effective method of birth control (hormonal contraceptives such as implants, injectables, combined oral pills, patches or rings; intrauterine devices (IUDs), tubal ligation (two fallopian tubes that connect ovaries and uterus are blocked, tied, clamped, sealed, or cut) or sexual abstinence) throughout the course of this study. Let your doctor know immediately if you or your partner become pregnant.

If you or your partner become pregnant during the course of this study, you will be followed until 3 months after the birth of the child. This will consist of telephone contact to determine what side effects may have happened

Non-Physical Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?
We do not know if taking part in this study will help you. This study may help researchers learn information that could help people in the future. If you receive leronlimab and it is effective, it may help prevent the bad inflammation and damage to the lungs that result from COVID-19 infection

WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?
You will not be paid for participating in this study.

The study sponsor may reimburse you for qualifying study-related travel costs and/or expenses. Study staff will review the reimbursement plan and any requirements for reimbursement with you.

Patients will receive $XX for each completed study visit. If you do not complete the study, you will be paid for the visits which you have completed. You will be paid at the end of the designated study visits.

OR You will not receive any payment for taking part in this research study.

<<CF-Main Payment for Part. Paragraph>>

WHAT IF SOMETHING IS DEVELOPED FROM THIS RESEARCH?
We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

ARE THERE COSTS FOR PARTICIPATING IN THIS STUDY?
Taking part in this research study might lead to added costs to you or your insurance company.

You will not be charged for leronlimab (PRO 140). It is possible that leronlimab (PRO 140) may not continue to be supplied free for some reason. If this would occur, your research doctor will talk with you about your options.

You or your insurance company will be charged for portions of your care during this research study that are considered standard care. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services of the hospital for information. You should also check with your insurance to see what services will be covered by your insurance and what you will have to pay.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?
If you think you have been injured as a result of taking part in this research study, tell the study doctor as soon as possible. The research doctor's name and phone number are listed in this consent form. The study doctor will treat you or refer you for care.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments will be billed to you or your insurance company. You will be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data. The information collected about you usually will not directly identify you (for example, by name, address, or social security number). Instead, your initials and a code number will be used for your information.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file.

If you consent to take part in this study, your medical records may be reviewed by relevant employees of CytoDyn, Inc., the company sponsoring the study, or [redacted] LLC (Amarex), the company to which CytoDyn has given the management of this study, for purposes of analyzing the study results and monitoring the study. Regulatory authorities such as the U.S. Food and Drug Administration (FDA), the Institutional Review Board (IRB)<<CF-Main SMO Company 1>><<CF-Main Affiliated IN Language 1>> and other foreign regulatory bodies may review study results and subject records to check that the study is being conducted correctly. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law. Your identity and medical records will be kept confidential and will not be disclosed outside of the hospital/clinic/family physician's office.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance.

Additional information can be found at http://www.genome.gov/10002328.

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.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

During the course of a research study, new information may become available about your disease or the treatment that is being studied that might change your decision to be in this study. If this happens, your study doctor will discuss this with you and whether you want to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your prescribed standard care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

In addition, on receiving new information your study doctor might consider it to be in your best interest to withdraw you from the study. Your study doctor will explain the reasons and arrange for your prescribed standard care to continue.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

This study is expected to start in 2020. Once the study has finished, the information will be analyzed and a clinical report will be written to record the results. This process can take about 6 months. Your study doctor will be kept informed of the results from the study, and a paper detailing these results will probably be published in an appropriate medical journal. You can also ask your study doctor for the results of the study.

RESEARCH FUNDING

The company sponsoring and funding this research is CytoDyn, Inc.

The study center and/or your study doctor are receiving financial support from the sponsor for holding this study. <<CF-Main Financial Disclosure>>

CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping leronlimab (PRO 140). In some cases, the abrupt stopping of a drug can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888)-303-2224 or (800) 562-4789, irb@cgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

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 received satisfactory answers to all of your questions.

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

If you choose to participate in this study, please read the following and sign where indicated.

CONSENT

I confirm that I have read this consent form (or it has been read to me) and have had the opportunity to ask questions. I agree to participate in this study and comply with the requirements to the best of my ability.

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

By signing this consent form, I have not given up any of my legal rights. I will receive a signed and dated copy of this consent form<<CF-Main California Bill of Rights>>.

_____

Printed Name of Subject

_____ _____ _____

Subject Signature *Date* *Time*

_____

Printed Name of Legally Authorized Representative, if applicable

_____ _____ _____

Signature of Legally *Date* *Time*
Authorized Representative

_____

Relationship of Legally Authorized Representative to Subject

STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I, the undersigned, certify that to the best of my knowledge that subject named above or the subject's legally authorized representative had the study fully and carefully explained, including the nature, risks, and benefits of his/her participation in the research study; and all questions were answered to his/her satisfaction. I confirm that the he/she freely and voluntarily gave consent to participate in this research study

before any study-related procedures were performed. A medical problem or language or educational barrier has not precluded this understanding.

I reviewed the consent form with the subject or the subject's legally authorized representative and answered his/her questions. The subject or his/her legally authorized representative appeared to have understood the information and was able to answer the following questions correctly:

- What is the purpose of this study?
- If you decide to be in the study, what will you be asked to do?
- What is the possible benefit of participating in this study?
- What are the possible risks of participating in this study?
- If you decide not to participate in this study, what options do you have?
- Will participating in this study cost you anything? If so, what will you have to pay for?
- Do you have to be in this study?
- If you decide to be in the study, can you leave the study when you want to?

_____	_____	_____
Signature of Person Conducting Informed Consent Discussion	*Date*	*Time*

_____

Name of Person Conducting Informed Consent Discussion

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject or the subject's legally authorized representative because he/she is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative. He/she freely consented to be in the research study.

_____

Printed Name of Impartial Witness

_____	_____
Signature of Impartial Witness	*Date*

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject or the subject's legally authorized representative.

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

Original for researcher; one copy for subject; one copy to be kept with medical records.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

While you are participating in this research study, the study doctor and his study staff will collect and create personal health information about you and record it on study forms. This information may include health histories, examinations and results of tests. The study doctor will keep this information in study records. He may also gather information regarding your past, present, and/or future medical conditions from your primary medical doctor. These records may also include personal information such as your birth date, social security number, or medical record numbers which could be used to identify you. This type of information is called "Protected Health Information" (PHI).

The terms "you" and "your" in this Authorization refer to the research subject.

Under a federal law called the "Privacy Rule" or Health Insurance Portability and Accountability Act of 1996 (HIPAA), your PHI that is gathered and obtained during research cannot be used to conduct the research or be given to anyone for research purposes without your permission. Because of this rule, you may not participate in this study unless you give your permission to use and disclose your PHI. You do not have to sign this form, but if you do not, you cannot participate in this study.

By signing this consent form, you are giving permission for the study doctor and his study staff to use your PHI to conduct this study, to monitor your health status, and possibly to develop new tests, procedures and commercial products.

You are also agreeing to allow your PHI to be disclosed to the study sponsor and any representatives working with them. The sponsor may also give your PHI to the FDA or other regulatory agencies which are responsible for ensuring that the research is being done correctly.

Study staff will assign a code number to you for this study. This will help to protect your identity; however, the sponsor may look at your complete study records which will identify you. The sponsor will also send representatives to your study doctor's office to oversee how the study is

being conducted. These representatives will review your PHI to make sure the information is correct. The Institutional Review Board (IRB)<<CF-Main SMO Company 2>><<CF-Main Affiliated IN Language 2>> may also have access to your PHI. These disclosures help to make sure that all information related to the research is available to those who need it.

Your identity will remain confidential and except for the disclosures described above and detailed specifically in the consent page, will not be shared with others, unless it is required by law. If your PHI is given to the parties listed above or to anyone who is not required to follow federal law, your PHI will no longer be protected by the “Privacy Rule” and could possibly be used or disclosed in ways other than are listed here.

You have the right to see and make copies of your PHI. You are agreeing, however, not to see or make copies of your PHI until all of the sponsor work has been completed. At that time, you may ask to see your records.

This permission will be good until December 31, 2068. You have the right to cancel or withdraw this authorization at any time. If you cancel this authorization, your PHI will no longer be used for this study, unless it is necessary (based on your earlier authorization) to complete analysis (test) and reports for this research. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

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

In the event of an adverse drug reaction/serious side effect following revocation of Authorization, your information may still be used and disclosed as necessary for study purposes.

To cancel your permission to use PHI, you must send a written notice to your study doctor’s office stating that you are canceling your authorization to use or disclose your protected health information. If you cancel this authorization, you will not be allowed to continue 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 otherwise entitled.

AUTHORIZATION

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. I will receive a signed and dated copy of this Authorization.

_____

Printed Name of Subject

_____ _____ _____

Subject Signature *Date* *Time*

_____

Printed Name of Legally Authorized Representative, if applicable

_____ _____ _____

Signature of Legally Authorized Representative *Date* *Time*

_____

Relationship of Legally Authorized Representative to Subject

Statement of the Witness (when applicable*)
The information in the authorization was accurately explained to, and appeared to be understood by the subject or the subject's legally authorized representative. Authorization was freely given.

Printed Name of Impartial Witness

Signature of Impartial Witness **Date**

*Impartial Witness: If the subject or the subject's legally authorized representative cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject or the subject's legally authorized representative.