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FOR SITES BEFORE USE
AS MODIFIED
Jul 07, 2021

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

TITLE:	A Phase II, Multi-center, Two-Part (Part 1: Randomized, Double-Blind, Placebo-Controlled with Leronlimab 700mg and placebo; and Part 2: Open-Label, Single-Arm with Leronlimab 350mg), Three-Arm, Dose-Ranging Study of the Safety and Efficacy of Leronlimab (PRO 140) in Adult Patients with Nonalcoholic Steatohepatitis (NASH)
PROTOCOL NO.:	CDI-NASH-01 IRB Protocol #20203731
SPONSOR:	CytoDyn, Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in this study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **No one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;

- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

Introduction

You are being invited to take part in a clinical research study. 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. This consent form may contain words that you do not understand. Please take the time to read the following information carefully and feel free to take home an unsigned copy of this consent form to discuss this information with your family, friends, relatives and/or your study doctor or other Primary Care Physicians (PCP). Please ask the study doctor or one of the study staff to explain any words or information that you do not clearly understand. Feel free to request more information about the study.

Once you have this information, understand the study procedures, and have had all your questions answered, you will need to decide if you will participate in this study. If you decide to participate, you will be asked to sign and date this consent form. Signed and dated copies of the consent form will be provided to you.

Although an Institutional Review Board (IRB) has approved the information provided in this informed consent form and has granted approval for the study doctor to conduct the study, this does not mean IRB has approved your participation in the study. IRB is an independent committee established to help protect the rights of research participants. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

What is the purpose of the study?

Your study doctor and his/her study staff are conducting a research study with CytoDyn, Inc., which is a pharmaceutical company supporting this research study by providing funding for this research study. You are being invited to take part in a clinical research study because you have been diagnosed with Nonalcoholic Steatohepatitis (NASH). Steatohepatitis is a type of liver disease known as fatty liver where the cells in the liver have abnormal accumulation of fat. One common form of fatty liver disease is caused by drinking too much alcohol. However, another form of fatty liver not caused by increased alcohol consumption is called nonalcoholic fatty liver. Liver fibrosis is a condition developed as a consequence of inflammation and build-up of scar tissue in the liver. This research study is designed to help us further understand if an investigational drug is safe and an effective 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 C-C Chemokine Receptor Type-5 (CCR5) antagonists.

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

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 II clinical trial. Phase II 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 to determine how safe and effective the study product, Leronlimab (PRO 140), is for treatment of NASH.

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 still 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 yet. The results of these studies will be used to design future studies to develop this investigational product for treatment of NASH.

About 90 participants [60 participants for the randomized phase of the study (Part 1); 30 participants for the non-randomized, open-label phase of the study (Part 2)] will enroll in the study across up to 20 centers within the USA.

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 typically in the blood generally react to foreign organisms or materials (bacteria, viruses, etc.). However, Leronlimab (PRO 140) binds to a protein (CCR5) that may be present on the surface of liver cells. When Leronlimab (PRO 140) binds to the CCR5 receptor on these cells, inflammation, and fibrosis of liver cells might decrease. This study is designed to help us further understand if and how Leronlimab (PRO 140) affects liver cells, thus improving NASH.

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.

Why have I been chosen?

You have been chosen for consideration for this study because you are diagnosed with NASH and your study doctor thinks that you might be a good candidate for this study. About 90 participants with NASH [60 participants for the randomized phase of the study (Part 1); 30 participants for the non-randomized, open-label phase of the study (Part 2)] will enroll at about 20 sites within the United States.

What other options are there?

Taking part in this research study is completely voluntary. You will always be free to withdraw from the study at any time. If you withdraw during the study, you will be asked to come in for a final visit for study evaluations. You do not have to give a reason for your withdrawal from the study. This will not affect the standard of care that you will receive, and it will not result in any penalty or loss of benefits to which you are entitled. The data collected up to that point will be kept with your medical records and will be kept confidential. Your identity will not be disclosed.

Instead of being in this research study, you have other options which may include the following:

- Other available treatments for your condition such as weight loss, taking vitamin E, etc. as recommended by your doctor
- Taking part in another research study
- Receiving no therapy specific to your condition

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

General Study Design and Duration of Study Involvement

The duration of your participation in this study will be approximately 22 weeks with the total of 16 study visits to the study site. The study will be conducted in 3 periods. After the initial screening period of the study (up to 4 weeks), you will enter the study treatment period (up to 14 weeks), concluded with the follow-up period [4 weeks after the End of Treatment Visit (or Early Termination Visit, if applicable)].

If you are enrolled in Part 1, you will either receive 700 mg of Leronlimab (PRO 140) or placebo. If you are enrolled in Part 2 (Non-Randomized, open-label), you will receive Leronlimab (PRO 140), 350mg.

Screening Period (before the research starts):

During this part of the study you will be evaluated to determine if you would be eligible to enter the study. The screening period will take up to 4 weeks.

Many of the tests and procedures are likely to be part of regular NASH care and may be done even if you do not take part in this research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

Screening Visit

After signing this consent form, the following procedures will be done at the screening visit:

- *Review of your demographics, medical condition and medications:* You will be asked a number of general questions about your age, race, ethnicity, alcohol use, your medical and surgical history, including any illnesses or health problems, and your prior or current medications.
- *Physical examination:* Your study doctor will give you a physical exam.
- *Vital Signs, height and weight measurements:* Your heart rate, body temperature, sitting blood pressure, and breathing rate will be assessed. These measurements will be taken in the sitting position after you have rested for at least 5 minutes. Your height and weight will also be measured.
- *Electrocardiogram:* Your study doctor will perform an ECG (electrocardiogram – a routine test that records the heart's electrical activity).
- *FibroScan:* Your study doctor will perform a FibroScan (a specialized ultrasound - to check your liver) or another equivalent imaging test (such as Shear Wave).
- *Liver MRI:* A liver MRI (an imaging exam – to check your liver) will be performed.
- *Laboratory assessments:*
  - 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, complete blood count, and some other tests for NASH.
    - A blood test for active Hepatitis B, C, A, and E (viruses that affect the liver) infection, and HIV (Human Immunodeficiency Virus), which can cause AIDS. If you test positive for HIV, hepatitis B or C, A or E you will be notified. It is required to notify state health authorities of positive results as required by state law. If you do not want to be tested, you should not take part in this research study.
    - If you are a female and able to become pregnant, a blood pregnancy test will be required at the Screening Visit. If the blood test is positive, you will not be able to be in the study.
  - A urine sample will be needed for lab tests.

<u>This visit will take about 2-4 hours of your time.</u>

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.

At the end of this 4-week period you will be informed if you are eligible to enter the study.

If the results from the "Screening Visit" procedures are acceptable to the study doctor, you will be scheduled for study treatment period.

Treatment Period

Treatment Visit 1 (T1):

The first visit of the treatment period (T1) will be conducted within 28 days from the Screening Visit. The treatment visits will occur every 7 days thereafter for a total of 14 weeks.

At T1, the study doctor will check to see if you continue to be eligible to participate in this study. If you are not eligible for the study, the study doctor will explain the reasons and arrange for the prescribed standard conventional therapy to continue. If you continue to be eligible for the study, you will continue your participation in the study.

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

- *Review of study eligibility:* the study doctor will evaluate you to determine if you are still eligible to take part in the study.
- *Review of any changes to your medical condition and medications:* you will be asked to report any changes in your medical status and medications, or new medications taken since the last visit.
- *Physical examination:* The study doctor will conduct a physical exam.
- *Vital Signs and weight measurements:* Your sitting blood pressure, heart rate, breathing rate and body temperature will be assessed. These measurements will be taken in the sitting position after you have rested for at least 5 minutes. Your weight will also be measured at this visit.
- *Electrocardiogram:* You will have an electrocardiogram (ECG) which is a routine test that records the heart's electrical activity.
- *Laboratory assessments:* You will have blood and urine tests for routine laboratory evaluations. The blood test will also include collecting samples for pharmacokinetics, immunogenicity and inflammatory biomarkers, monocyte/T cell CCR5 biomarker analysis and other assessment tests for NASH. The blood test will require taking approximately 30 mL (approximately one ounce) of blood from your arm.
- If you are a female of childbearing potential, a urine pregnancy test will also be performed. If found to be pregnant, your participation in the study will be terminated

- *Randomization:* If you are enrolled in Part 1 of the study (Randomized Phase), you will be randomly assigned (by chance) to one of the two study treatment groups. The study treatment assignment will be in a 1:1 ratio to one of the following:
  - Leronlimab (PRO 140), 700mg; Or
  - Placebo

  Neither you nor the study doctor will know which one you will receive. This information can be made available in case of an emergency. You will be asked to report any symptoms that you experienced.

  Randomization is not applicable if you are enrolled in Part 2 of the study and the study treatment will be leronlimab (PRO 140), 350 mg. You will be asked to report any symptoms that you experienced

Once all of the above assessments have been completed, you will receive your treatment injections of Leronlimab (PRO 140) or placebo. If you are enrolled in Part 1 (Randomized Phase), you will either receive 700 mg of Leronlimab (PRO 140) or placebo which will be given as two shots of 2 mL each, under your skin on opposite sides of the abdomen at the clinic. If you are enrolled in Part 2 (Non-Randomized, open-label), you will receive Leronlimab (PRO 140), 350mg which will be given as one shot of 2 mL, under your skin in your abdomen area.

Note: Subjects with low body fat may experience discomfort with 2 mL shots. In such cases, the study treatment (Leronlimab (PRO 140) or placebo) can be injected at different areas other than abdomen as per discretion of the study doctor.

After receiving the injection, the study doctor will perform the following procedures:

- *Review of any adverse events (bad side effects):* The study doctor will ask you for any unfavorable signs or symptoms.
- *Assess reaction to the study drug*: You will be observed at approximately 30 minutes after completing study drug administration and asked for any unfavorable signs or symptoms. Your doctor will assess the injection site for any pain, tenderness, etc.
- *Vital Signs:* Your sitting blood pressure, heart rate, breathing rate and body temperature will be assessed within 15 minutes after receiving the injection.

This visit will take about 4-5 hours of your time.

Treatment Visit 2 (T2) to Treatment Visit 13 (T13):

The following procedures will be performed every week at clinic at T2 to T13 and also at End of Treatment Visit, or Early Termination Visit (if applicable) (*Unless stated otherwise)*:

- *Review of any adverse events (bad side effects):* The study doctor will ask you for any unfavorable signs or symptoms.

- *Review of any changes to your medical condition and medications:* you will be asked to report any changes in your medical status and medications, or new medications taken since the last visit.
- *Vital Signs and weight measurement:* Your sitting blood pressure, heart rate, breathing rate and body temperature will be assessed before you receive your injection. Your weight will be measured at T2, T6, T10 and at End of Treatment Visit (or Early Termination Visit, if applicable).
- *Physical examination:* Your study doctor will conduct a physical exam based on any symptoms that you experienced, every 4 weeks at T2, T6, T10, and also at Early Termination Visit, if applicable. A complete physical exam will be performed at End of Treatment Visit.
- *Study drug administration:* If you are enrolled in Part 1 (Randomized Phase), you will receive your treatment injection of Leronlimab (PRO 140) 700 mg, or placebo every week from T2 to T13. If you are enrolled in Part 2 (Non-Randomized, open-label), you will receive Leronlimab (PRO 140), 350mg every week from T2 to T13.
- *Assess pain*: You will be asked to assess the pain at your injection site every week from T2 to T13 and also at End of Treatment Visit.
- *Assess reaction to the study drug:* You will be observed at approximately 30 minutes after completing study drug administration and asked for any unfavorable signs or symptoms. Your doctor will assess the injection site for any pain, tenderness, etc.
- *Laboratory assessments:* Urine and blood samples will be taken every 4 weeks at T2, T6, T10, and also at End of Treatment Visit (or Early Termination Visit, if applicable), *unless stated otherwise.* The blood sample will be collected for complete blood count, blood chemistry, pharmacokinetics, immunogenicity and inflammatory biomarkers, monocyte/T cell CCR5 biomarker analysis and other tests for NASH. The blood test will require taking approximately 30 mL (approximately one Ounce) of blood from your arm.
- If you are a female of childbearing potential, a urine pregnancy test will also be performed at T6, T10, and at End of Treatment Visit (or Early Termination Visit, if applicable). If found to be pregnant your participation in the study will be terminated.
- *Electrocardiogram:* You will have an electrocardiogram (ECG) which is a routine test that records the heart's electrical activity every 4 weeks at T2, T6, T10, and also at End of Treatment Visit (or Early Termination Visit, if applicable).
- Based on the tests on your liver function, you MAY be asked to come to clinic more than once a week for the following assessments per your study doctor's discretion:
  - Blood test for chemistry
  - Some other tests for assessment of possible other liver disease
  - Liver biopsy or consulting
  - Consultations from Gastroenterology or hepatology doctors
- *Liver MRI*: A liver MRI (an imaging exam – to check your liver) will be performed at End of Treatment Visit (or Early Termination Visit, if applicable).

Note: If you stop the study early for any reason, the investigator will ask you to perform the assessment of Early Termination Visit at clinic.

Treatment Visits 3, 4, 5, 7, 8, 9, 11, 12 and 13 will take about 1 hour of your time.

Treatment Visits 2, 6, 10 and End of Treatment Visit (or Early Termination Visit, if applicable) will each take about 3-4 hours of your time.

Follow-Up Period:

All participants will be followed up Twenty-eight (28) days after the End of Treatment Visit (or Early Termination Visit, if applicable), and will be asked at the clinic for performing the following procedures:

- *Review of any changes to your medical condition and medications:* you will be asked to report any changes in your medical status and medications, or new medications taken since the last visit.
- *Physical examination:* The study doctor will conduct a physical exam based on any symptoms that you experienced.
- *Vital Signs:* Your sitting blood pressure, heart rate, breathing rate and body temperature will be assessed within 15 minutes after receiving the injection.
- *Laboratory assessments:* You will have blood tests for routine laboratory evaluations. The blood test will also include collecting samples for blood chemistry, pharmacokinetics, immunogenicity and inflammatory biomarkers, monocyte/T cell CCR5 biomarker analysis and other tests for NASH. The blood test will require taking approximately 30 mL (approximately one ounce) of blood from your arm.
  Note: If you have already completed the EOT and follow-up visits, you will be asked to come to the clinic at a later time and a blood sample will be taken for monocyte/T cell CCR5 biomarker analysis during this unscheduled visit. This blood test will require taking approximately 10 mL of blood from your arm.
- *Review of any adverse events (bad side effects):* The study doctor will ask you for any unfavorable signs or symptoms you have experienced since last visit.

How long will I be in this research study?

You will be in this research study for around 22 weeks (including screening period, treatment period and follow-up period) if 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.
- A decision is made to close the study.
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

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. In a research study, all the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

You and your caregiver will be instructed by the study doctor to recognize the signs and symptoms of potential liver injury and report these symptoms immediately to the study center. Some of these symptoms include abdominal pain, nausea, vomiting, loss of appetite, dark yellow urine, yellow eyes or skin, or persistent fatigue.

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 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 Leronlimab:

- Reactions at the site of the injection such as:
  - Bruising
  - Redness of the skin
  - Fluid leakage
  - Itching
  - 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.
- Studies on Leronlimab (PRO 140) to determine its capability to cause harm to an unborn child have not been performed. Therefore, if you are pregnant or think you might be, you will not be allowed to participate in this study. If you are a woman of childbearing potential, you will be tested for pregnancy at the beginning and end 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.

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 two effective methods of birth control throughout the course of this study and for six (6) months after the last day of treatment. Let your doctor know immediately if you become pregnant.

If you 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.

ECG/EEG

You may have skin irritation from the contacts used.

Fibroscan

Risks include discomfort from gel or pressure from hand piece.

MRI

You may experience feelings of claustrophobia or anxiety. If you have metallic objects, there may be injury of tissue around the metallic objects and movement of the metallic object if not attached to bone.

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.

Will I be paid to take part in this research 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.

[You will not be paid for participating in this study].

OR

Patients will receive $[site specific details] 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.]

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 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 study that is 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 person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

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 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.

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 Amarex Clinical Research, 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) and other foreign regulatory bodies may review study results and subject records to check that the study is being conducted correctly. 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.

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 plan 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 late 2020. Once the study is 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.

The biological materials (e.g. blood, urine) collected during this research study, might be stored and used for future research studies without asking you to sign an additional informed consent form.

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.

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.

Early Termination:

Your participation in this study may be stopped at any time by the study doctor, the sponsor (CytoDyn, Inc), the FDA, and/or the IRB without your consent for any of the following reasons:

- If it is in your best interest;
- If you do not consent to continue in the study after being told of changes in the research that may affect you;
- If you do not follow research directions;
- If you experience any serious side effects to the study drug;
- If lost to follow-up;
- Administrative reasons;
- If you are found to be pregnant;
- Or other reason as per study plan.

Whom do I contact if I have questions about the research study?

If you have any questions, concerns, or complaints about the study or problems relating to your participation in this study, please contact:

[Site Specific – PI and CRC Contact Details]

If, at any time, you feel you have experienced a research-related injury or a reaction to the study drug, contact your study doctor:

[Site Specific – PI Contact Details] (24 hours)

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

WCG IRB at 855-818-2289 or researchquestions@wcgirb.com
IRB is a group of people who perform independent review of research.

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

Do not sign this consent form unless you have had a chance to ask questions and have 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 and date where indicated.

PARTICIPANT STATEMENT OF 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.

_____

Printed Name of Participant

_____ _____ _____

Participant's Signature *Date* *Time*

STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I, the undersigned, certify that to the best of my knowledge that subject named above 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 the study subject's satisfaction. I confirm that the study subject 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 and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. 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 because the subject 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. The subject freely consented to be in the research study.

_____ _____

Signature of Impartial Witness *Date*

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/her 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/she 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).

Under a United States federal law called the "Privacy Rule" or Health Insurance Portability and Accountability Act of 1996 (HIPAA), no one's PHI that is gathered and obtained during research can be used to conduct the research or be given to anyone for research purposes without one's permission. Because of this rule, you may not participate in this study unless you give your permission to use and disclose your PHI.

By signing and dating this consent form, you are giving permission for the study doctor and his/her study staff, along with the sponsor (CytoDyn, Inc.), Amarex Clinical Research (the Contract Research Organization) and the Regulatory authorities such as the U.S. Food and Drug Administration (FDA) and Institutional Review Boards (IRB) 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. 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 IRB may also have access to your PHI to meet its oversight responsibilities. These disclosures help to make sure that all information related to the research is available to those who need it.

IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
Jul 07, 2021

Your identity will remain confidential, except for the disclosures described above and detailed specifically in the consent page, and 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 those 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.

Your HIPAA Authorization will expire 50 years from the date you sign and date it unless you revoke (cancel or withdraw) it sooner. 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 (tests) and reports for this research.

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 for them to use or disclose your protected health information. If you cancel this authorization, you will not be allowed to continue in this study.

Subjects will receive a signed and dated copy of this document.

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.

_____

Printed Name of participant (Study Subject)

Participant' Signature	*Date*	*Time*