INFORMED CONSENT FORM

A Phase 3B, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants with Active Psoriatic Arthritis who had an Inadequate Response and/or Intolerance to One Prior Anti-Tumor Necrosis Factor α Agent

Study number: CNTO1959PSA3005

Study sponsor:

Janssen Research & Development, LLC

Represented by
[If appropriate, the Local Trial Manager (LTM) to insert name of local Sponsor/ regulatory Sponsor]
[Address of local legal entity]

Study doctor
[Insert Investigator name, address, and phone number]

You are kindly invited to be in a research study because you have psoriatic arthritis.

Here are a few things to know as you learn more:

1. Taking part in a research study is voluntary and is not part of your regular health care.
2. Before you decide, please read this form carefully so you know why the study is being done and what it involves.
3. Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your other doctors, family and friends.
4. Ask the study doctor/staff your questions.

Thank you for taking the time to consider taking part in this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you for the purpose of inviting you to make an informed decision about participating in the research study. We kindly ask you to consider this sensitive information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

STUDY OVERVIEW

Why is this study being done?

The purpose of this study is to see if guselkumab is safe and useful for treating participants with psoriatic arthritis.

All reference to the words “study drug” can mean guselkumab and/or placebo.

General Information about the study

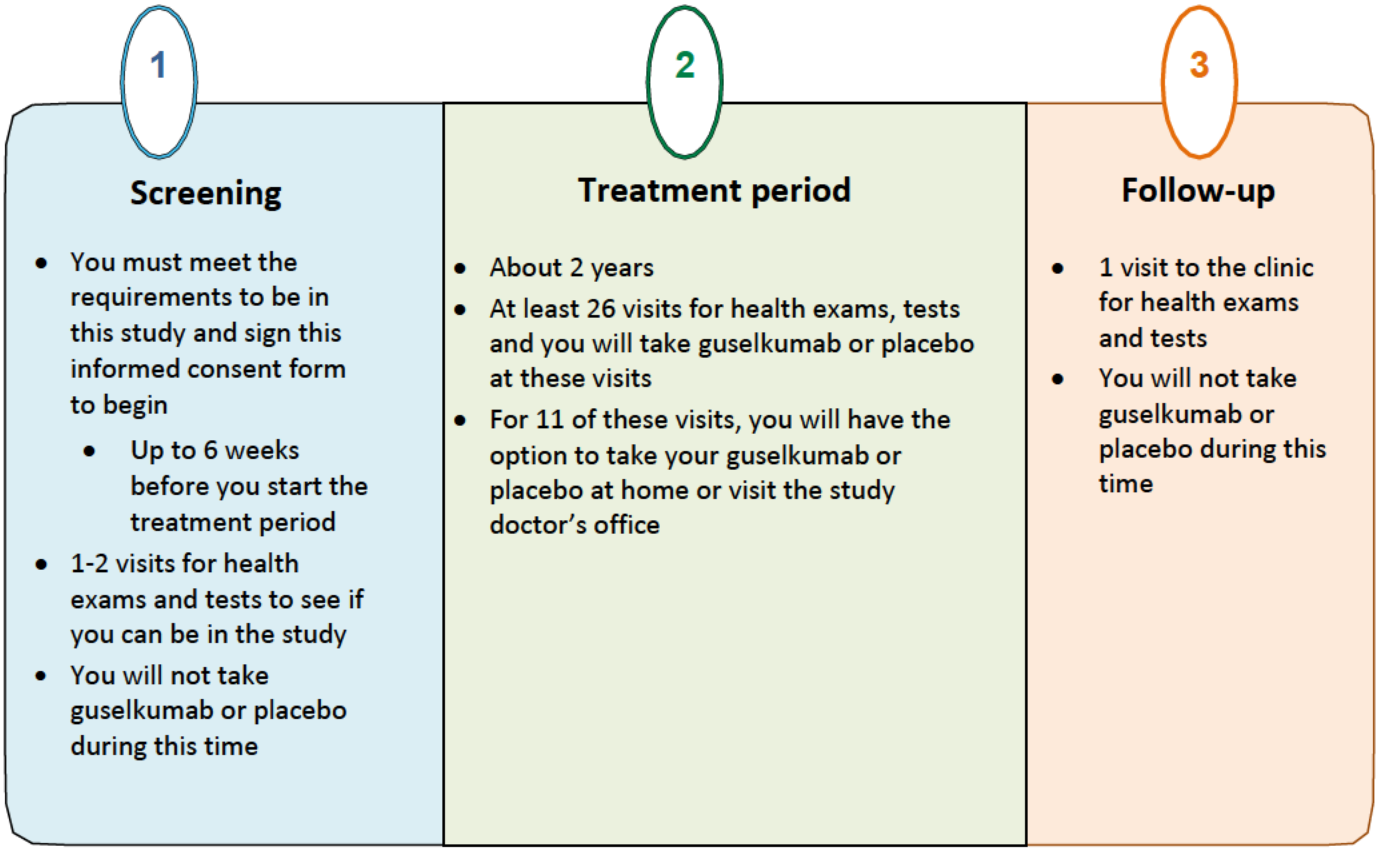
About 450 participants will take part in this study worldwide. If you join the study, you’ll be in it for about 2 years plus two months.

Sometimes during a study, the sponsor may learn new information about the study drug, the risks, or something else. Your doctor/staff will tell you in a timely manner if there is any new information that might make you change your mind about being in the study.

TABLE OF CONTENTS

WHAT HAPPENS DURING THE STUDY?

The study is divided into 3 parts.



WHAT IS DONE AT THE STUDY VISITS?

Study procedures and activities

This table describes all the procedures you can expect to have during the study. Not all procedures will be done at every visit. The study doctor/study staff will discuss this with you in more detail.

Procedure	What is it?	When is it done?

Informed Consent	The study doctor/staff will talk to you about the study and you will decide if you want to join.	Screening visit
Review medical history	You will discuss your current and past health with the study doctor/staff.	Screening visit, treatment, follow-up
Review of medications	You will talk with the study doctor/staff about any medicines you take.	Screening, treatment, and follow-up
Physical examination	The study doctor/staff will check your body for general health.	Screening, treatment, and follow-up
Vital signs	The study doctor/staff will take your blood pressure, heart rate, height, and weight	Screening, treatment, and follow-up
Review of side effects	At each visit, the study doctor/staff will ask about any side-effects. Side effects are any unexpected or unwanted reactions that may happen from taking a drug or having a procedure.	Screening, treatment, and follow-up
ECG (Electrocardiogram)	Sticky patches that are connected to a machine that shows the electrical activity of your heart, are placed on your chest.	Treatment (performed once prior to first dose), if not taken within three months prior to first dose)
Tuberculosis (TB) Test	A TB (tuberculosis) test will be given to you as well as a questionnaire on your potential exposure to TB in the past.	Screening
Doctor's assessment of disease related activities	The study doctor will examine you and rate your signs and symptoms, such as joint assessment, tendon pain assessment, and finger and toe inflammation.	Screening, treatment, and follow up
X-Ray	A picture of your chest will be taken. For some participants, a picture will	Screening

	also be taken of the inside of your pelvis. (if not taken within 3 months of screening). The amount of radiation in the x-rays in this study is small. There is no significant risk from this amount of radiation.	
Blood draw/tests	The study doctor/staff will draw blood from a vein in your arm. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint and, in rare cases, can get an infection. You must fast for at least 8 hours before the first treatment visit. Fast means you will not be allowed to eat or drink anything except for water. A total of about 2.5 cups (625 ml) will be drawn during the entire study. Sometimes you will need to repeat a blood test. Your blood will be used to check your eligibility to join the study and for ongoing participation: • Your general health • Hepatitis A, B, and C, and Human Immunodeficiency Virus (HIV-AIDS). The results of these tests will be kept confidential. [LTM TO INCLUDE THE FOLLOWING LANGUAGE IF APPLICABLE IN YOUR COUNTRY: Positive results for Hepatitis or HIV will be reported to health authorities as per the local requirements.] • Signs of tuberculosis & inflammation	Screening, treatment, and follow-up

	• How much study drug is in your blood • How your body handles the study drug • Pregnancy (if you are a female who could get pregnant.) • Samples collected for Scientific Research The study doctor/staff will discuss the test results with you.	
Sample collection for scientific research	Blood will be collected for scientific research as described in the "Samples Collected for Scientific Research" section below. You will be informed if testing on your samples for this study will change.	Treatment and follow-up
Sample collection for optional genetic research	For some participants, blood will be collected for scientific research as described in the separate informed consent form for "Optional Genetic Samples for Research". You will only have these samples collected if you signed a separate informed consent form. You will be informed if testing on your samples for this study will change.	Treatment (Only for some participants) Early Termination visit if applicable
Sample collection for optional sub study	For some participants, a small portion of skin (called a biopsy) will be taken to evaluate skin psoriasis changes. You will only have these samples collected if you signed a separate informed consent form.	Treatment (Only for participants at participating sites in the United States)

Diary	If you take study drug home, you will be given a diary and an explanation of how to use it. You will write in the diary on your day of injection. You will enter details about each injection (for example: the day and time, where the injection was given on your body). This will be in paper form. You must bring the diary with you to each visit.	Treatment
Patient questionnaires	You will be given several questionnaires to answer questions about your general health, your pain level, your symptoms and how your disease affects you. This will be done using an electronic device, like a tablet, OR paper form. These questions will give the study sponsor important information about how you are doing in the study, so it is important to complete these questions as your study doctor/staff, nurse, or coordinator instructs you.	Screening, treatment, and follow-up
Urine sample	Your urine will be used to check: • For pregnancy (if you are a female who could get pregnant)	Screening, treatment, and follow-up (before every study drug administration at the study clinic)
Study drug injections	The study drug is given as a subcutaneous (SC) injection. This is a process by which study drug is delivered to you through a small needed injected under the skin. The injection is given into your skin in areas such as your arm, lower	Treatment

	abdomen and thigh. Beginning at week 8, you will have the option to perform the injection yourself (self-inject) after training and under the supervision of a health care provider at the study site. At weeks 32, 40, 48, 56, 60, 64, 72, 80, 88, 92 and 96 you will have the option to self-inject at home.	

Sub-study (skin biopsy)

This study includes an optional skin biopsy sub-study that is being done in addition to the main study. Participants who choose to take part in the optional sub-study do all the things that a patient in the main study does, plus some extra tests. The reason for the sub-study is to look at the body's response to study treatment and to find out if there are certain marks in the tissue related to treatment or psoriatic arthritis. If you do not want to participate in the optional sub-study, you can still participate in the main study. There is a separate consent form for the optional skin biopsy sub-study which your study doctor will give you.

Study rules

To participate in the study, you must follow the below list of things to do and not do:

Overall study rules	
Do	**Do not**
• Give correct information about your health history and health condition • Tell the study doctor/staff about any health problems you have currently and during the study • Come to all study visit appointments • Carry your study participation card with you • Complete the diary and bring it with you to appointments	• Do not take part in any other medical research studies • Do not get pregnant or cause your partner to become pregnant • Do not use any other experimental treatments nor enroll in the same study at a different site.

• Complete the questionnaire information accurately during study visits	
Medicines	
Do	**Do not**
• Tell the study doctor/staff about any medicine or drug you are taking currently • Tell the study doctor/staff about any new medicine or drug you take during the study or any changes to your medicines or drugs If you take study drug home, you must: • Take the study drug as instructed • Dispose the study drug syringe properly in a Sharps or Biohazard container • Return unused study drug and all empty packages at each visit • Refrigerate the study drug as instructed • Keep study drug out of reach of children • Complete the diary card and bring it with you to all visits.	• Do not take any other drugs or remedies unless the study doctor/staff has approved them beforehand, including prescription and over-the-counter drugs such as vitamins and herbs • Do not receive a live virus or bacterial vaccination during the study and for 12 weeks after receiving the last injection. • Do not receive a BCG vaccination (vaccine primarily used against TB) during the study and for 12 weeks after the last injection. • Do not use medicated shampoos or topical medications on the day of a study visit. • Do not give your study drug to anyone else

STUDY DRUG/OTHER MEDICATIONS

What is the study drug?

The drug being studied is called “guselkumab”

Guselkumab has been approved in the United States, the European Union, and other countries to treat plaque psoriasis and psoriatic arthritis. It is sold as TREMFYA.

Guselkumab is also being studied to treat several other illnesses, including lupus nephritis and inflammatory bowel disease.

What treatment will I receive?

Not everyone in the study will receive guselkumab right away at the start of the study (Week 0). Everyone will receive guselkumab at Week 24 through the end of the study.

At the start of the study (Week 0), you will either receive guselkumab or placebo. You will be randomly (eg, by chance) put into 1 of 3 treatment groups. You will have approximately 1 in 3 chances of being put into each group:

- Group 1 (guselkumab every-8-weeks): Participants in this group will receive guselkumab 100 mg at Weeks 0, 4, then at Weeks 12, 20, 28, 36, 44, 52, 60, 68, 76, 84, 92 and 100. Participants will receive placebo at Weeks 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88 and 96 to maintain the blind.

- Group 2 (guselkumab every-4-weeks): Participants in this group will receive guselkumab 100 mg at Weeks 0, 4, then at Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96 and 100.

- Group 3 (Placebo and then guselkumab every-4-weeks): Participants in this group will receive placebo at Weeks 0, 4, 8, 12, 16 and 20, and will cross over at Week 24 to receive guselkumab 100 mg at Weeks 24, 28, then at Weeks 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96 and 100.

During the study, neither you nor the study staff will know which treatment group you are in. However, if needed for a medical emergency, the study doctor/staff can quickly find out which treatment group you are in.

How do I use the study drug?

The liquid study drug (guselkumab or placebo) is given in a shot. The needle is put just under the skin in your arm, lower abdomen, or thigh. This will be done approximately 1 time each month.

If you miss a dose of the study drug during the home self-injection period, you will be instructed to call your study doctor as soon as you realize that a dose was missed.

What other treatments are there outside of this study?

Do not remove this guidance box from the Master ICF.
ICF Author to add alternative treatments in consultation with SRP/SRS and other study representatives, as applicable.
<LTM to modify list based on locally available treatments.>

Instead of taking part in this study, you may choose to take other treatments that may be available, such as:

- Non-steroidal anti-inflammatory drugs (NSAIDs) and other pain relievers
- Conventional disease-modifying antirheumatic drugs (DMARDs), such as methotrexate, sulfasalazine, hydroxychloroquine, leflunomide
- Oral corticosteroids such as prednisone
- Other tumor necrosis factor (TNF) inhibitors (such as adalimumab, certolizumab,etanercept, golimumab, and infliximab)
- Other advanced therapies (such as apremilast, tofacinitib) or other biologic therapies (such as abatacept, ixekizumab, secukinumab, ustekinumab)

There may also be other clinical studies. The study doctor will explain to you the benefits and risks of these other treatments.

What about my current medicines?

You must tell the study doctor/staff about all prescription and over-the-counter drugs you take. This includes vitamins and herbs.

You may continue to take non-steroidal anti-inflammatory drugs (NSAIDS) and other analgesics, oral corticosteroids and ONE conventional disease-modifying antirheumatic drug (DMARD) such as methotrexate, sulfasalazine, hydroxychloroquine and leflunomide during the study if you take them now, however the dose may need to be adjusted prior to the start of study drug treatment.

Once in the study, you will be asked to keep the dosage of these medications the same through Week 112. If needed, your doctor may stop or change the dose, and your doctor may also start a new medication.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Risks

There may be risks to using guselkumab that we don't know yet. As stated above, the study doctor/staff will tell you in a timely manner if new information is discovered about the study drug or its side effects that could make you change your mind about being in the study.

All possible side effects and risks related to guselkumab are not known. Problems that are not expected may arise and they may be life threatening. If you have any side effects or problems during your participation in this study, you should let your study doctor know right away. This section describes how frequently side effects occurred in participants who were treated with guselkumab. In this section, the following terms are used:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000

Very Common:

- Infections of the nose, sinuses, airways or throat

Common:

- Increased level of liver enzymes in the blood (transaminases)
- Headache
- Joint pain
- Diarrhea
- Injection site reactions (redness, pain, bruising, swelling, itching, hardness, skin irritation, bleeding and/or rash at the place where the injection is given)

Uncommon:

- Herpes simplex infections, which may appear as blisters or sores on the lips (cold sores) or genitals (genital herpes)
- Fungal skin infections (for example athlete's foot)
- Gastroenteritis (an infection of the stomach and/or intestine)
- Rash

- Decreased number of a type of white blood cell (neutrophils)
- Hives
- Allergic reactions
- Serious allergic reactions (including anaphylaxis), which may appear as hives, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, low blood pressure or lightheadedness

Rare:

- None

Infections

Guselkumab is a drug that may change how your body fights infections. Serious infections requiring hospitalization have been seen in guselkumab studies. Life threatening infections may occur. It is unknown if guselkumab may stop you from developing a fever if you do have an infection, and therefore hide that you have one. Tell your study doctor if you have a new infection, if an infection keeps coming back, or if you have any signs of infection, such as fever, chills or cough.

Participants who receive guselkumab may also be at a greater risk for certain serious infections such as tuberculosis. Tell your study doctor if you have ever had tuberculosis or if you have come in contact with someone who has tuberculosis. Tell your study doctor if you develop symptoms such as night sweats, weight loss, and/or coughing up blood.

Cancer

It is unknown whether taking guselkumab increases your risk for developing cancer. Some drugs that suppress the immune system are associated with an increased risk of cancer. Because guselkumab may suppress your immune system, it is possible that it may increase your risk of developing cancer.

Allergic Reactions

Guselkumab may cause an allergic reaction in some people. Serious allergic reactions, including a type of reaction called anaphylaxis, have been reported with guselkumab and can be life threatening. Symptoms of an allergic reaction may include:

- hives
- rash
- nausea
- flushing
- lightheadedness
- shortness of breath

- wheezing
- swollen face, lips, mouth, tongue or throat
- difficulty swallowing or breathing
- low blood pressure
- anaphylaxis (life threatening allergic reaction)

Another type of allergic reaction (called serum sickness-like reaction) has occurred in some participants 1 to 14 days after receiving similar medications. The symptoms of this type of allergic reaction may include fever, rash, muscle aches and joint pain.

Tell your doctor or get medical help right away if you have symptoms of an allergic reaction so that appropriate treatment can be administered. If you experience a serious allergic reaction to guselkumab, you will not receive any more study treatments.

Antibodies to Guselkumab

Sometimes the body can make special antibodies that may increase the risk of an allergic reaction to either guselkumab or other antibody medicines. If you have an allergic reaction during this study, you may not be able to have these types of medications in the future. You should tell your doctors that you have been treated with human antibodies in this study.

Injection Site Reactions

Injection site reactions have been observed in participants receiving guselkumab and similar medications. The signs and symptoms seen at injection sites may include:

- swelling
- redness
- pain
- bruising
- itching
- skin irritation
- a burning sensation
- bleeding
- hardness
- rash

Vaccinations

Vaccines are made to help protect people from certain illnesses. Ask your study doctor about all vaccines you are thinking about getting. It is not known if guselkumab may interfere with your body's response to a vaccine.

Some vaccines are made from live bacteria or live viruses. You cannot receive live vaccines during the study. Some kinds of live vaccines may not be given to you for 3 months after your last dose of study drug. You could get sick from live vaccines while on guselkumab. If you do get a live vaccination during this study, you must tell your study doctor immediately.

Other Therapies

Tell your doctor if you are receiving medicines that weaken the immune system while you are enrolled in this study (For example, oral steroid medicines such as prednisone, prednisolone, methylprednisolone, or conventional DMARDs such as methotrexate, sulfasalazine hydrochloroquine, or leflunomide). It is unknown if taking these medicines with guselkumab increases your risk of diseases related to a weakened immune system.

Preventative Medicine for Tuberculosis Infection

Medicines used to prevent tuberculosis infection may have side effects. Side effects may include nausea, vomiting, abdominal pain, hepatitis and possibly other events. Your study doctor will provide you with more information on tuberculosis preventative treatment if you require this treatment in order to participate in the study.

Side Effects from Tests:
Blood draw: Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases infection, may occur.

X-Ray Risks: The radiation dose that is in the x-ray(s) taken for this study is small. There is no significant risk from this amount of radiation.

ECG Risk: There is generally no risk with having an ECG. The sticky patches may pull your skin or cause redness or itching.

Tuberculosis Skin Test: The skin test is given under the skin with a small needle. You may have mild pain, bleeding, a change in skin color or bruising, and/or an infection where you were tested. You will need to return to the study center or visit a qualified medical professional 48 to 72 hours after the injection for proper evaluation of the test site. If you have a positive skin test, you may have mild pain, itching, redness and slight swelling at the site of the skin test.

Other

During the study your condition may remain the same or get worse.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

Do not remove this guidance box from the Master ICF.

Any statements regarding compensation or reimbursement must be consistent with all study-related documents (e.g., the protocol, CTA, patient recruitment advertising materials or documents submitted by the investigational sites for review and approval). Any applicable company policies (e.g., Healthcare Compliance [HCC] policies) which cover these should be aligned.

You will not be paid for taking part in this study. You will be reimbursed for those expenses directly related to the study visits such as local travel, meals and parking.

Who pays for the study drug and tests?

Do not remove this guidance box from the Master or Country ICFs.

The following is a requirement per Declaration of Helsinki: A placeholder for information regarding potential conflicts of interest is included in this section to be completed by the site (investigator). Include financial relationships or interests associated with the study e.g., the source of funding and funding arrangements for the conduct and review of the study or information about a financial arrangement or interest of an institution or an investigator such as stock in the sponsor or patent on the investigational product. State if the investigator has no financial relationships or interests associated with the study.

The sponsor will pay [insert "the study doctor" and / or "the institution" depending on the agreement] for the study drug and tests that are part of the study.

The sponsor will not pay for doctor visits, treatments, or tests that are not part of this study. This means that you, your insurance company, or your government health plan are responsible for paying for these, if needed.

[LTM/SM TO INCLUDE A STATEMENT ABOUT FINANCIAL ARRANGEMENTS / CONFLICT OF INTEREST OR LACK THEREOF.]

Can the study staff remove me from the study?

Yes, the study doctor/staff and the study sponsor have the right to remove you from the study at any time, with or without your agreement. These decisions will be made if:

- It is in your best medical interest to stop
- You do not follow the study staff's instructions
- The study is canceled

- You no longer meet the eligibility criteria
- You become pregnant or plan to become pregnant within the study period

The study doctor/staff will discuss with you the reasons for removing you from the study, other treatment or research options, and plans to follow up with you for side effects, if needed.

Can I change my mind about participating?

Yes, you can agree to be in the study now and change your mind at any time and for any reason. You can withdraw from the study and your decision will not change your regular care from your doctors.

You can talk to the study doctor/staff first before making this decision.

What happens if I stop the study early?

If you stop the study early and are no longer taking guselkumab, you can still participate in the study by completing your planned study visits so the study doctor/staff can continue to perform study evaluations on you and continue to monitor your health until the study is officially completed. This is to make sure that information related to your disease activity and all possible side effects and risks related to guselkumab are recorded. This information will be added to your study record. If you do not want the study doctor to continue performing study evaluations or monitoring your health after you stop taking guselkumab, you will be asked to indicate this clearly.

If you stop taking the study drug early prior to the Week 24 visit, and you agree to continue study evaluations, you will be asked to return to the study doctor for all study visits until the Week 24 visit. You may also be asked to return for an additional final safety visit about 12 weeks after the last dose of study drug.

If you stop taking the study drug at or after the Week 24 visit, and you agree to continue study evaluations, you will be asked to return to the clinic for all study visits until the Week 100 visit. You may also be asked to return for an additional final safety visit about 12 weeks after the last dose of study drug. If you are unable to return for all visits through Week 100, you will be asked to return for two additional visits; one visit as soon as possible after stopping study medication and one visit about 12 weeks after your last dose of study drug.

The collection of information related to your disease activity and all possible side effects, even after you stop taking the study drug, are very important to the overall results of this research study. It is very important that you make every attempt to return to the study center for all required visits and that we do not lose contact with you during the study.

If you have side effects after you stop the study early, the study doctor/staff may contact your other doctors who you see regularly. By signing this consent form, you agree that this information can be obtained and added to your study record unless you indicate otherwise.

[LTM TO INCLUDE A STATEMENT OUTLINING MEASURES TAKEN TO IDENTIFY LOSS TO FOLLOW-UP PARTICIPANTS AS ALLOWED PER LOCAL REGULATIONS].

If you stop the study early and withdraw your consent at any time, you agree not to limit the use of information collected about you for the purpose of the study up to the point of your consent withdrawal. The sponsor will continue to collect information from you as described in other sections of this Informed Consent Form (see "Samples collected for Scientific Research," "Samples Used for Future Research," and "What happens if I stop the study early?"). The sponsor will not collect any new information from you for any parts of the study from which you have withdrawn your consent.

Can I take the study drug after the study is over?

This section must align with Post Trial Responsibilities (PTR) as outlined in the protocol. Adapt the text depending if PTR is provided via Extension trials or via Post Trial independent requests. **<LTM MUST ENSURE THAT THE PTR DECISION ALIGNS WITH LOCAL REGULATIONS>**

After you complete the trial, you will no longer receive guselkumab [LTM TO MODIFY BASED ON LOCAL REQUIREMENTS]. Your study doctor/staff will discuss your future medical care options with you.

What are the benefits of joining this study?

Taking part in this study may improve your psoriatic arthritis. This is not guaranteed to happen and there may not be any benefit to you by being in this study. During the study, your condition may stay the same or get worse and your study doctor will follow your condition closely. Your participation may help future participants.

What about my regular doctors?

The study doctor/staff will let your regular doctors know that you're in this study and may report any side effects. It is important for your other doctors to know that you are taking a study drug.

WHAT IF SOMETHING GOES WRONG?

PARTICIPANT INJURY: Do not remove this guidance box from the Master ICF.

The LTM will complete this section. It must include the country-specific injury language required by local/legal regulations. The text in this section of the site-specific ICF must be consistent with the clinical trial agreement.

CAUTIONS

Safe medicine storage

The study drug packaging is not child-resistant. The study drug may cause harm to a child. Keep the study drug out of reach of children, as they may be able to open the package and get to the study drug.

By signing this consent, you are saying that you understand that the study drug packaging is not child-resistant. You should not take part in this study if you feel that you can't keep your study drug in a safe place where children cannot get to it.

Birth control and pregnancy during the study

The effect of guselkumab on human sperm or unborn babies is not known.

Pregnant women and women who are breastfeeding cannot participate in this study. Female participants must have a blood test when beginning this study that shows they are not pregnant.

It is very important that women taking part in this study do not become pregnant while taking part in this study. It is very important that men taking part in this study do not get a woman pregnant or donate sperm while taking part in this study.

During this study and for 12 weeks after the last dose of study drug, women of childbearing potential and men must use proven birth control methods. Your study doctor will discuss effective birth control methods with you.

If you think that you have become pregnant or may have fathered a child while taking part in the study, tell your study doctor immediately. You should also notify your childbirth doctor that the mother/father received an experimental drug (guselkumab).

If you are a female participant and you become pregnant during your participation in this study, your treatment with study drug will be stopped and you may be withdrawn from some of the study procedures but not from follow-up by your study doctor. The study doctor will ask for your permission to stay in contact with you throughout the length of the pregnancy.

If you are a female participant, you must not donate eggs during the study and for 12 weeks after your last dose of study drug.

If you are a male participant, and you father a child during your participation in this study, the study doctor will ask for your partner's permission to stay in contact with her throughout the length of the pregnancy.

If you are a male participant, you must not donate sperm during the study and for 12 weeks after your last dose of study drug.

SAMPLES COLLECTED FOR SCIENTIFIC/GENETIC RESEARCH

What happens to the samples collected from me?

Biomarkers are measurable features that are derived from patient samples, including blood. In the future, these features may provide a better understanding of psoriatic arthritis and help to determine which participants may respond to this or other therapies. This research could also lead to the development of tests to predict development of psoriatic arthritis. Additionally, this research may help us better understand the effects of guselkumab in psoriatic arthritis and other diseases.

Radiographic images (eg, pelvic Xray) taken during this study could provide information that can improve our understanding of different subtypes of psoriatic arthritis and help the development of technologies for diagnosis or to monitor disease activity.

The sponsor may use any of your samples collected during this study for scientific research to help scientists understand:

- Psoriatic arthritis
- How guselkumab may work, or why it/they may cause side effects
- How to identify which people may respond differently to guselkumab
- Why people may respond differently to placebo
- How to develop tests for guselkumab and psoriatic arthritis

Your samples will be destroyed after they are no longer needed for the study or once the retention period of 15 years had been reached.

The research may begin at any time during the study or the post-study storage period.

Scientific research is done to help improve the development of drugs and understand the disease better. The sponsor may use any of your samples collected during this study for scientific research to help scientists understand:

- Psoriatic Arthritis

- How guselkumab may work, or why it/they may cause side effects
- How to identify which people may respond differently to guselkumab
- Why people may respond differently to placebo
- How to develop tests for guselkumab and psoriatic arthritis

No genetic research will be done on your samples unless you provide separate consent. This study has a separate informed consent form for an Optional Genetic Sample for Research. If you sign this optional informed consent form, a sample will be taken from you for genetic research. [LTM TO MODIFY BASED ON LOCAL REQUIREMENTS – ESCALATE TO BIOMARKER REPRESENTATIVE IF THERE ARE CHANGES:]

The results of tests done on these samples are only for scientific research. They will not be used for your medical care. They will not be used to make a diagnosis about your health. Therefore, these results will not be given to you or the study doctor/staff.

Your collected samples will continue to be analyzed as described in this form unless you specifically ask for your samples to be destroyed. This is to protect the quality of the study.

Samples Used for Future Research

Future Research Testing: Any samples leftover after they are used for the main study will be stored for future use (up to 15 years or as defined by local regulations). Testing will depend on the available technology at the time of testing.

You have the option to opt out of future use of your samples and can withdraw your consent at any time during or after the study by notifying your study doctor. If you withdraw consent for future use of your samples, your samples will be destroyed after they are no longer required for the main study. This will not affect your access to the care, medicine, and equipment you would otherwise be getting. This can be done at any time and for any reason. You will need to do this before [#] years since the study doctor/staff will discard the medical records that link your name to your study number in [insert # based on local regulations] years.

The sponsor plans to keep the samples securely in a biorepository facility in CCI [redacted] The samples may be re-located at any time by the sponsor.

How are my samples kept private?

To protect your privacy, your samples will be labeled with the study number and your participant number. No personal identifiers (such as name, initials, social security number) are used. The scientists doing the research will not know your identity.

Your samples may be sent to other members of the Johnson & Johnson group of companies, to contractors working for them and to regulatory authorities.

Your samples may also be shared with research partners for scientific research purposes. Your samples will not be sold, loaned or given to any other independent groups for their own use. Research partners working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor. The sponsor will manage what is done with your samples.

You will not be paid for any use of your samples, results, or inventions made from research on them. You are providing your samples, for use by the sponsor. The sponsor (and research partners, where applicable) plan(s) to own the use of the results, treatments, or inventions that can be made from this research.

HOW IS MY PRIVACY PROTECTED?

Privacy Language: Do not remove this guidance box from Master ICF.

This section includes boilerplate privacy language only for Global Master Clinical ICF.

<LTM MUST INSERT THE LEGAL AND PRIVACY WORDING THAT IS THE APPROVED COUNTRY-SPECIFIC TEXT REQUIRED BY LOCAL REGULATIONS **THROUGHOUT** THIS SECTION OF THE ICF. SAMPLE LANGUAGE AND KEY ELEMENTS ARE PROVIDED IN THE COUNTRY ICF LANGUAGE SUMMARY.>

<LTM/SM: THE LANGUAGE IN THE SITE-SPECIFIC ICF MUST BE CONSISTENT WITH THE SPECIFIC CLINICAL TRIAL AGREEMENT.>

NOTE: THE TEXT IN THIS SECTON DOES NOT COVER ALL INFORMATION EXPECTED TO ADDRESS DATA PROTECTION AND PRIVACY. For example:

- The statement that the Clinical Trial will be available on https://www.clinicaltrials.gov is included in another section of the ICF).
- Information about withdrawal, including the requirement (if applicable) to consult public records to find out the health status of the patient is including in section "What happens if I stop the study early?"

Refer to Job Aid: Escalation of Requested ICF Changes in case of requested changes to privacy language.

The Study Staff and the sponsor will manage your personal data (information about you) in compliance with [insert reference to applicable law on data protection and privacy] as described in this consent form.

What personal data will the study staff collect?

If you join this study, the study doctor/staff will collect and use your personal data to do the research. This personal data may include, among other items, your name, address, date of birth, and health data (information about your health). Health data includes past medical records and data collected during this study, including data collected when analyzing your biological samples as described in "What is Done at the Study Visits?"

Sensitive data such as racial or ethnic origin will also be collected, as it is necessary for the evaluation of the study results.

Who will have access to your personal data?

Your personal data may be stored in paper files and electronic databases which have limited access. The study doctor/staff will have access to these paper files and databases. Other people may also need direct access to this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements.

Monitor(s), auditor(s), IRB/IEC, and regulatory authorities will be granted direct access to your original medical records for verification of clinical study procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this informed consent form, you authorize such access.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your identity will remain confidential.

Remote access to your records at the study site

Representatives of the sponsor (i.e., auditors) may use an electronic tool to access your personal data remotely. This electronic tool provides a secure electronic gateway between the study doctor and staff's computer system and the computer of the representatives of the sponsor, who may be located outside of your country of residence. This minimizes the risk that anyone else might be able to access the information.

How will your personal data be protected?

Your personal data will be labeled with the study number and your participant number ("Your Coded Data") before it is reported to the sponsor. No direct personal identifiers such as your name, initials, date of birth, or social security number are included in Your Coded Data.

How will Your Coded Data be used?

Your Coded Data is needed for the sponsor to learn about guselkumab, get permission to introduce and keep it on the market, monitor its safety and get it covered by health insurances and health service providers. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how guselkumab and similar medicines work in the body;
- better understand psoriatic arthritis and associated health problems;
- develop diagnostic tests;
- learn from past studies to plan new studies or improve scientific analysis methods;
- publish research results in scientific journals or use them for educational purposes.

How will Your Coded Data be shared and transferred?

The sponsor may share Your Coded Data with its affiliates, regulatory authorities, authorized service providers and, with select investigators and scientists conducting scientific research, which is compatible with research related to this study including statistical purposes. Your Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your identity will not be revealed in any of these cases.

The sponsor will protect Your Coded Data as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

Sharing of your anonymized data

The sponsor believes that access to study data advances clinical science and medical knowledge and is in the best interest of participants and public health, provided that the patient's privacy is protected. Therefore, the sponsor may generate and share with some researchers, contractual partners or institutions an anonymized set of your study data. This means Your Coded Data will be stripped of your participant number as well as of any other information that could indirectly identify you such as your exact height or weight or exact dates of treatment. This anonymized study data set may be shared only for scientific research as allowed by applicable law.

How long will my personal data be stored?

Records containing your personal data will be retained at the study site for a period of [insert retention period as per local requirements]. In addition, the sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

What rights do I have concerning my personal data?

If you would like to review, correct, delete personal data, or make other requests concerning your personal data in accordance with the laws in your country, you should contact your Study Doctor at [insert contact details].

Please note that you may not be able to review some of the data until after the end of the study, and a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained.

You can request your study doctor to forward any questions, concerns or complaints you may have to the sponsor or its representative.

WHAT HAPPENS AFTER THE STUDY?

PLS Language: Do not remove this guidance box from Master ICF.

Plain Language Summary (or "PLS") language is to be included verbatim if study qualifies per EU Clinical Trial Regulation and/or voluntary adoption.

<LTM MUST NOTIFY CTM IN THE EVENT OF ANY LOCAL REQUESTED CHANGES (INCLUDING REMOVAL) TO THE PLS LANGUAGE>

At your last visit or after completing the study, you may be contacted by a third party of the sponsor and asked to provide feedback about your participation in the study.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have any questions about the study, please contact:

[Insert appropriate study site personnel name, phone number, and title]

If you feel that this study has caused you harm, please contact:

[Insert Investigator name, phone number, and title]

If you have any questions about your rights as a research participant, please contact the study doctor/staff or:

[Insert IRB or IEC name and phone number]

Study information

Protocol title: A Phase 3B, Multicenter, Randomized, Double-blind,Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants with Active Psoriatic Arthritis who had an Inadequate Response and/or Intolerance to One Prior Anti-Tumor Necrosis Factor α Agent

Protocol number: CNTO1959PSA3005

[WHERE APPLICABLE BASED ON COUNTRY REQUIREMENTS, INCLUDE THE FOLLOWING STATEMENTS VERBATIM:]
A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. In addition, it will also be available on www.clinicaltrialsregister.eu and [LTM to insert other local registries as applicable]. These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

[INCLUDE IF REQUIRED BY LOCAL IRB/IEC:] An independent ethics committee or institutional review board has approved this study.

YOUR AGREEMENT TO PARTICIPATE

If you consent, please read and then sign below

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the guselkumab, and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or laboratories to release information to [institution/clinic (name) /clinical investigator (name)] about my disease and treatment for the purposes of this study. I understand this information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.

Based on this information, I volunteer to take part in this study.

- I have been informed that the study doctor/staff may inform my other doctors about my participation in this study, and I agree to this (You may still be in this study even if you do not agree to this.)

  Check Yes, No, or Not applicable:

  Yes ☐ No ☐ Not applicable, I have no other doctors ☐

- I agree to be contacted by a third party of the sponsor to provide feedback about my participation in the study. My feedback results will be shared anonymously with the sponsor. (You may still be in this study even if you do not agree to this.)

  Check Yes or No:

  Yes ☐ No ☐

- I agree to the use of my blood samples for future scientific research as described in section "Samples Collected for Scientific Research," in addition to the testing required for this study.

  Check Yes or No:

  Yes ☐ No ☐

You will receive a copy of this signed Informed Consent Form.

[NOTE: THE USE OF ELECTRONIC, INCLUDING DIGITAL, SIGNATURES MUST BE IN COMPLIANCE WITH THE APPLICABLE LOCAL REGULATIONS]

Printed name of participant in full

Signature of participant Date (dd/MON/yyyy)

Printed name of person obtaining consent

Signature of person obtaining consent Date (dd/MON/yyyy)

[THE FOLLOWING INVESTIGATOR SIGNATURE MAY BE DELETED, IF NOT APPLICABLE:]

Printed name of investigator if different from the person obtaining consent	

Signature of investigator if different from the person obtaining consent	Date (dd/MON/yyyy)

[INCLUDE THE FOLLOWING OPTIONAL SIGNATURES AS REQUIRED BY NATIONAL/LOCAL REGULATIONS FOR THE CONSENT OF MINORS, ADOLESCENTS, OR PARTICIPANTS WHO CANNOT CONSENT FOR THEMSELVES (E.G., REQUIRE A LEGALLY ACCEPTABLE REPRESENTATIVE:]

Legally Designated Representative Signature, if applicable:

Printed name of Legally Designated Representative, in full	

Signature of Legally Designated Representative	Date (dd/MON/yyyy)

Relationship of Legally Designated Representative to the patient

Impartial Witness Statement

At least one **impartial** witness is mandatory when the patient or patient's legally acceptable representative is unable to read or write. An **impartial** witness must be present during the entire informed consent discussion.

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the patient and/or the patient's legally acceptable representative, and that consent was freely given by the patient and/or the patient's legally acceptable representative.

Printed name of Impartial Witness, in full

Signature of Impartial Witness Date (dd/MON/yyyy)