INFORMED CONSENT FORM ADDENDUM

This is an addendum to the Master Clinical Informed Consent Form version dated 17January2023.

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 ID: CNTO1959PSA3005 SOLSTICE

You have already read and signed an Informed Consent Form (ICF) to participate in the SOLSTICE study. We said we would let you know of any new information during the course of the study that could make you want to change your mind about continuing. The purpose of this form is to tell you about these updates so you can decide if you want to continue participating in this study.

- Take your time to read this ICF Addendum carefully to understand what the changes are.
- Ask questions and request any additional information from the clinical staff at the study site.
- You are free to decide to continue in this study or not and if you agree now, you can change your mind any time. Whatever choice you make, you will not lose access to the medical care you already receive, gain any penalty, or give up any of your existing rights or benefits.

The sponsor may share sensitive Company information with you to help you decide about your continuation in this study. We kindly ask you to consider this when discussing details about the study with people other than your healthcare provider(s), family, and friends or when using social media.

YOUR CONTACTS

Study sponsor	**Represented by** [LTM to insert local legal entity]
Janssen Research & Development, LLC	

[Add Principal Investigator contact details (name, address, phone number including 24-hour telephone if applicable)]
Independent Ethics Committee/Institutional Review Board (IEC/IRB) contact: An independent ethics committee (IEC) or institutional review board (IRB) has approved this study.

SUMMARY OF UPDATES

The sections listed in the tables below have been updated. For the risks section, no new risks have been found, but for some of the known risks, how often they may occur has changed. For vaccinations once the study has been completed, we have updated the timing from months to weeks. All other text in the original ICF you signed remains the same.

Original Language	Updated Language
Risks 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	**Risks** Common: • Increased level of liver enzymes in the blood (transaminases) • Headache • Joint pain • Diarrhea • Rash ***(change from Uncommon to common)*** 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) • Decreased number of a type of white blood cell (neutrophils)

• 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	• Hives • Injection site reactions (redness, pain, bruising, swelling, itching, hardness, skin irritation, bleeding and/or rash at the place where the injection is given) ***(change from Common to Uncommon)*** Rare: • Allergic reactions ***(change from Uncommon to Rare)*** • 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. ***(change from Uncommon to Rare)***
Original Language	**Updated Language**
Vaccinations 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.	**Vaccinations** Some vaccines are made from live bacteria or live viruses. You cannot receive live vaccines during the study and for 12 weeks 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.

HOW IS MY PRIVACY PROTECTED?

Clinical staff and the sponsor will look after your personal data (information collected from you and collected during this study) as required by [LTM to insert reference to applicable local law on data protection and privacy]. The "Privacy Appendix" in the main ICF document describes your rights about the use and protection of your personal data and also refers to data collected for the ICF Addendum.

YOUR AGREEMENT TO REMAIN IN THE STUDY

The updates to the study ICF Addendum have important information to help you decide if you want to continue in this study. **If you agree to all the following statements and choose to continue in the study, please sign below. You will receive a copy of the signed Informed Consent Form.**

- **I have read the whole Consent Addendum document and I understand the information provided and voluntarily consent to participate.**
- The clinical staff and I discussed the updates to the study and my responsibilities in detail. I understand what is expected of me as a research participant.
- I am satisfied with the answers to all my questions about the study, guselkumab, and possible risks and side effects.
- I agree to the processing and transfer of my data as described in this consent form.
- I understand my rights and that I can withdraw at any time.

Printed Name of participant:	
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 above:	
Signature of Investigator, if different from above:	Date (dd/MON/yyyy):

[LTM TO INCLUDE THE FOLLOWING OPTIONAL SIGNATURES AS REQUIRED BY NATIONAL/LOCAL REGULATIONS FOR PARTICIPANTS WHO CANNOT CONSENT FOR THEMSELVES (E.G., MINORS) OR REQUIRE A LEGALLY DESIGNATED REPRESENTATIVE. ENSURE PROTOCOL ALLOWS LEGALLY DESIGNATED REPRESENTATIVE. IF NOT, DELETE THE FOLLOWING:]

Legally Designated Representative Signature, if applicable:

By signing this consent, I confirm I understand I am legally representing the participant and that I understand the study requirements on their behalf.

Printed Name of legally designated representative:	
Relationship of representative to participant:	
Signature of legally designated representative:	Date (dd/MON/yyyy):

Impartial Witness Statement [DELETE IF THE PROTOCOL REQUIRES PARTICIPANTS TO BE ABLE TO READ AND WRITE.] If the participant or their legally designated representative is unable to read or write, one mandatory **impartial** witness must be present during the entire informed consent discussion.

I confirm that the consent form information was accurately explained to, and apparently understood by, the participant and/or their legally designated representative, and that consent was freely given.

Printed Name of impartial witness:	
Signature of impartial witness:	Date (dd/MON/yyyy):