

INFORMED CONSENT FORM

A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide (TRIllogy-5)

Study ID: Protocol 79635322MMY3002

If you are eligible, you are invited to participate in a research study, sponsored by Janssen Research & Development, LLC, a pharmaceutical company. Here are a few things to know:

- Taking part in a research study is completely voluntary and is not part of your regular health care.
- Take enough time to read this Informed Consent Form (ICF) carefully so that you clearly understand what this study is, why it is being done, and what it involves.
- Discuss taking part in this study with your doctor, medical professionals, family members, and friends.
- Ask questions and request any additional information from the clinical staff at the study site.
- You are free to decide to join this study or not and, if you agree now, you can change your mind any time. Whether or not you take part is up to you. 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.

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

To help you decide whether or not to participate in this study, the study sponsor may share some sensitive company information with you. 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

Sponsors of the study: Janssen Research & Development, LLC	Represented by JOHNSON & JOHNSON PRIVATE LIMITED HIGI house, LBS Marg, Mulund (West), Mumbai – 400080
Name of Principal Investigator: Dr. Jeevan Kumar Site Name and address: Tata Medical Center, 14, MAR (E-W), New-town, Rajarhat, Kolkata - 700160 Contact number of Principal Investigator: +91-9007016755 24-hour telephone (if applicable): NA	
Contact of Independent Ethics Committee/Institutional Review Board (IEC/IRB): Name of the Institutional Ethics committee: TATA MEDICAL CENTER, INSTITUTIONAL REVIEW BOARD (TMC-IRB) Address of the Institutional Ethics committee: TATA MEDICAL CENTER, 14, Major Arterial Road (EW), New Town, Rajarhat, Kolkata - 700160 Name and details of the contact person of the Institutional Ethics committee: Dr. Indranil Mallick Contact: +91-9831171235 The study has been approved by an Independent Ethics committee (IEC) or Institutional Review Board (IRB).	

A description of this clinical study will be available on www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you, but will include a summary of the results. You can search this website at any time.

<http://ctri.nic.in/Clinicaltrials/login.php> In addition, it will also be available on <https://www.clinicaltrialsregister.eu/>

In addition, it will also be available on <https://euclinicaltrials.eu>

STUDY OVERVIEW AND GENERAL INFORMATION

The purpose of this study is to compare the effects of JNJ-79635322 against teclistamab. Teclistamab is already being used to treat adults with multiple myeloma.

All reference to the words “**study drug**” means JNJ-79635322 or teclistamab.

All reference to “**clinical staff**” includes the site doctor(s) and other site staff specifically involved in the study (for example, nurses, scientists, healthcare professionals).

“**Site**” can refer to an institution or hospital depending on where the study is being conducted.

You can ask the clinical staff to forward any questions, concerns, or complaints you may have to the IEC/IRB (The Independent Ethics Committee/Institutional Review Board), the sponsor, or the sponsor’s authorized representatives. IEC/IRB are independent committees who review research studies to protect the rights and welfare of research participants.

We expect about **700** participants will take part in this study worldwide at approximately **230** sites. You will be in the study for about 5 and a half years (including treatment and follow-up phase).

Research have shown that certain diseases, treatments, and medications have different effects on humans based on differences in age, sex, race, ethnicity, access, and genetic background. You may be asked questions which may help ensure various groups are included in the study. Your personal information will be included in your study record, but this information will not change the treatment and care you receive during the study or in the future. In order to ensure that the clinical trials are available to everyone, you may be asked about where you live and how easy it is to come to the clinical trial site. This ensures people are made aware of available trials and how to access them.

WHAT HAPPENS DURING THE STUDY?

The clinical staff will check if you meet the requirements to be in this study. If you are eligible and agree, you will sign this informed consent form when you have read and understood the study requirements. **You should come to all your study visit appointments. If you have any health problems or concerns during the study, including side effects, please inform the clinical staff.**

The procedures you can expect during this study are described in the table below. Not all procedures happen at all visits. The clinical staff will discuss this with you in more detail.

Visits	Examinations, Tests and Procedures
Screening (≤28 days before randomization)	After the study doctor or site staff explains the study and answers your questions, you can decide whether to participate. If you decide to join the study, you will be asked to sign the Informed Consent Form. The following will be reviewed/conducted by the clinical staff: Your medical history (including disease diagnosis), previous treatments or procedures, and all medications. Clinical staff will discuss if you need to stop

	taking any of your current treatments before starting the study. • Standard physical exam • Neurologic examination is a check of your nervous system • General health status • Your blood and urine samples will be collected to check if you are eligible to participate in this study. In addition, blood tests will also be done to check the status of your previous or current hepatitis. The amount of blood collected will be approximately 2 to 3 tablespoons (about 35.5 mL). The clinical staff will discuss all tests and risks with you. • You will be asked to collect urine samples over 24 hours to measure the amount of multiple myeloma-related protein in your urine. • If you are likely to become pregnant, a pregnancy test will be performed using your blood or urine sample. • ECG (Electrocardiogram): Sticky patches are placed on your chest (and limbs) and are connected to a machine that shows the electrical activity of your heart. • Imaging: To evaluate bone cancer lesions and abnormal growths near or outside the bones, images of the inside of your body will be taken using a whole-body PET/CT scan (Positron Emission Tomography/Computed Tomography) or a Whole Body DWI/MRI scan (Diffusion-Weighted Imaging/Magnetic Resonance Imaging). The PET/CT scan uses a very small amount of radiation, while MRI uses a strong magnet (it contains no radiation). If none of these scans are available, an alternative whole-body low-dose CT scan may be used, which also involves a small amount of radiation.. • Bone Marrow Aspirate: A procedure that involves inserting a needle into a large bone and removing a portion of the bone marrow fluid to determine your disease status and for scientific research as described in the “Information on Study Samples” section below. If you have had a bone marrow test as part of your regular treatment within 42 days before enrollment, we may ask for the results of that sample. The study also requires a fresh bone marrow aspirate to be collected and sent to a central laboratory for scientific research. The bone marrow procedure is performed under a local anesthetic which numbs the area of bone.
Duration of Study Treatment	• The study drug (JNJ-79635322 or teclistamab) is given with a short needle just under the skin (in the belly (preferred), in upper arm(s) or thigh(s)). You will receive some pre-treatment and post treatment medications to reduce the risk of certain side effects. Some of those treatment medications may be taken by mouth, and others may be given through your vein. • Diary: A staff member will give you a diary and explain how to use it. You will record your oral temperature at least twice a day (at least 8 hours apart) after your SUD(s) and first treatment dose. If you have a fever (body temperature is 38°C or 100.4°F or higher), you should report it to your study doctor immediately. Regardless of the treatment you receive, these rules apply to all participants. ○ If you receive JNJ-79635322, you will also record every dose of any post-study treatment medication you take during the 48 hours after your first SUD injection and for 48 hours after your first full dose of JNJ-79635322. Please bring your diary with you when the study clinical staff asks for it.

	• Monitoring for Dose Administration: ○ JNJ-79635322: Hospitalization is not required for administration of JNJ-79635322 (SUD and treatment dose) unless your doctor thinks it is necessary or according to local regulations and institutional guidelines. You should remain in company of a competent adult for 2 days after the SUD and first treatment dose. During this time, you and your companion will need to stay within 30 minutes travel time from the clinic. ○ Teclistamab: Hospitalization is not required for administration of teclistamab. However, your doctor may decide to admit you to the hospital for monitoring during the SUDs and the first treatment dose, if needed and if you agree. Otherwise, you may receive these doses as an outpatient. After each SUD and the first treatment dose, you need to stay within a 30-minute distance of the clinic and be in the company of a competent adult for at least 2 days. Your condition will be monitored throughout your participation on this study. The number of clinic visits per cycle will vary depending on which treatment arm you are assigned to. Clinical staff will evaluate your physical condition by: • Reviewing your health status, extent of your disease, any side effects and how you are feeling including the following: ○ Physical exam. ○ General health status. ○ A neurological exam is a check of your nervous system • Pregnancy tests (urine or blood sample) will be performed if you are able to become pregnant. • At each visit, blood samples will be collected to evaluate your disease status and for scientific research. At some visits, blood samples may be collected for scientific studies as described in the ‘Information on Study Samples’ section below. The estimated total amount of blood collected for the duration of the treatment phase will be about 4 cups (approximately 1049.5 mL). • A 24h urine sample will be collected before the start of every cycle. This is to help better understand your cancer status. • Bone marrow samples: If your disease responds well, there will be an additional sample collected at that time. Additional samples to look for low levels of disease in your bone marrow will be taken at 12 months, 36 months and 60 months after Cycle 1 Day 1. If your disease worsens, another sample will also be collected. Find more information in the “Information on Study Samples” section below. • Your imaging may be tested every 3 to 6 months. • You will be asked to complete questionnaires via an electronic device at SUD, on Day 1 of Cycle 1 and every 4 weeks for the first 6 months; followed by every 8 weeks until 24 months; followed by every 16 weeks. It will take you approximately 20 minutes to complete this questionnaire.
End of treatment	• After you discontinue the treatment, you will visit the site 30 days after the last dose of study drug received and before starting another treatment for your myeloma. You will be asked to answer a series of questionnaires. A physical exam including vital signs and weight, and general status of your health will be assessed.

	• Blood samples will be collected to evaluate your general health and for scientific research: about 1 teaspoon to 2 tablespoons (approximately 5 to 28.5 mL) of blood will be taken. Find more information in “Information on study samples” section.
After Study treatment completion or discontinuation	After you discontinue the study treatment, you will enter the Follow-up period. Depending on your cancer condition, you will need to visit the site every 4 weeks or every 4 months and different tests will be performed. <u>Follow up before worsening of the multiple myeloma (every 4 weeks):</u> If you have stopped receiving the study treatment before worsening the disease, you will be asked to visit the site every 4 weeks to evaluate your disease status: • Blood samples may be collected. About 1 teaspoon (approximately 11 mL) of blood will be used for testing and for scientific research. Find more information in “Information on study samples” section. • A 24-hour urine sample will be collected before each visit. This is to help the study team better understand your cancer status. • An additional sample of bone marrow will be collected if your disease condition worsens, to help the study team better understand your cancer status and for scientific research as described in the “Information on Study Samples” section below. • There will be imaging at the time your disease gets worse (using the same method as mentioned during screening) performed to monitor cancer in your body. • You will be asked to complete questionnaires via an electronic device for every 4 weeks for the first 6 months; followed by every 8 weeks through 24 months; followed by every 16 weeks. It will take you approximately 20 minutes to complete this questionnaire. <u>Follow up after worsening of the multiple myeloma (every 4 months):</u> If you have a worsening of your disease, you will be asked to visit the site or be contacted by phone every 4 months: • Depending on which treatment arm you belong to, your blood sample may be collected. About 1.5 teaspoons (approximately 13 mL) of blood will be used for testing and scientific research. Find more information in “Information on study samples” section. • To check on your general status. • You will be asked to complete questionnaires via an electronic device for every 4 weeks for the first 6 months; followed by every 8 weeks through 24 months; followed by every 16 weeks. It will take you approximately 20 minutes to complete this questionnaire.
During the study period (from screening to the end of the study)	If it is assumed that you will be involved in this study for about 5 and a half years, your total amount of blood drawn on study would be about 4 to 5 cups (approximately 1019 to 1299.5 mL). During the study you should: • Always carry a wallet study card with you containing study information.

	• Agree to monitor and report (yourself and/or caregiver) signs and symptoms to the clinical staff for certain side effects that are explained later in this document (such as fever, cytokine release syndrome (CRS) and ICANS) (*See below section “What are the possible risks and side effects of the study?”) and to seek immediate medical attention. • Inform the clinical staff about any other drugs or treatments BEFORE taking them. • Not use any other experimental treatments nor enroll in the same study at a different site. • Not donate blood until 90 days after the last study treatment dose. During the study, your doctor might ask to: • To take photographs or videos, if applicable. During the study, photographs or videos may be taken of side effects (e.g., rash, nail findings, neurotoxicities) and may be shared with the sponsor. Photographs and videos will be anonymized, meaning that they can no longer be linked to you, before being included in presentations and publications related to the study. You agree or disagree to include your photographs/videos in presentations and publications by ticking the appropriate checkbox at the end of this document. • Take tissue biopsy as part of standard of care (SOC) workup of a side effect (e.g. rash) at your hospital, if applicable. A biopsy is a surgical procedure to remove a tissue sample by making an incision to remove a piece of tissue. You may be given local anesthesia. The sponsor may request to receive additional material from that biopsy sample. Your personal identifying information which can directly identify you will be removed from your sample.
	Optional Other Services, See the “Privacy Appendix” for additional details about how your information is collected and shared.

WHAT IS THE INVESTIGATIONAL STUDY TREATMENT?

The sponsor provides the investigational study treatment, called “JNJ-79635322”, which is a type of treatment called a trispecific antibody. Antibodies that normally occur in the body attach to proteins that are foreign to your body, such as those found on viruses or bacteria, to help stop an infection. Trispecific antibodies are a type of antibodies that can attach to 3 different proteins. The study drug can attach to 2 different parts of cancer cell proteins while the third part attaches to T cells. T-cells are a type of white blood cells that help protect the body from infections and fight cancer. By attaching to proteins and T cells, the study drug may help your body fight cancer cells.

JNJ-79635322 is not approved for use in any country by Regulatory Authorities who are responsible to approve medications. Therefore, it can only be used in a research study like this, and the results may be used to gain approvals.

Teclistamab sold as TECVAYLI is approved by US FDA, and the EMA to treat patients with Multiple Myeloma who received more than 3 prior lines of therapy. Based on recently available clinical trial data, teclistamab shows improved response compared to standard of care for patients with multiple myeloma who received 1-3 prior lines of therapy, similar to your current stage of disease.

What treatment will I receive?

Not everyone taking part in this study will receive JNJ-79635322. You will by chance (like rolling dice) be put into a treatment group. There are 2 treatment groups in this study which means each person will have the same chance of being put into each group. Importantly, your study doctor will not have the authority to decide which group you will get in to.

You will receive the study drug for the first time as a low step-up dose(s) (SUD). The SUDs are lower doses than the full treatment dose to allow your body to adjust and manage any possible side effects (See Risks section below). The full dose of the study drug will then be administered. Each treatment **cycle lasts 28 days**, starting after the SUD(s).

- **Treatment Group 1:** will receive JNJ-79635322

You will receive 1 step-up dose 2-8 days before the full treatment dose of the study drug is given treatment dose will be every 4 weeks until your 6th treatment dose, then every 8 weeks. As long as you can tolerate the drug and your disease responds to treatment, you will receive the study drug but for a maximum duration of 36 months. You will receive some post-treatment medications to try to reduce the risk of certain side effects.

- **Treatment Group 2:** will receive teclistamab

You will take 2 step-up doses, the first on the first day of treatment and the second about 2-4 days after that. For the first cycle, you will receive one dose per week for 3 weeks. In the second cycle, you will receive one dose per week for 4 weeks. Starting with the third cycle, you will receive two doses every two weeks (biweekly), twice per cycle, until cycle 6. Starting from the 7th cycle, you will receive one dose on the first day of each cycle. You will continue to receive the study drug as long as you tolerate the medication and your disease responds to the treatment.

Both you and the clinical staff will know the treatment you are receiving. This is an open-label study.

If you cannot make it to the site to take a scheduled dose, please discuss this with the site clinical staff treating you.

WHAT ARE THE POSSIBLE RISKS AND SIDE EFFECTS OF THE STUDY?

There may be some risks associated with the procedures described under "What Happens During the Study". If you have any concerns or questions, please discuss with the clinical staff.

- **ECG:** There is generally no risk with having an ECG. Sticky patches may pull your skin or cause redness or itching.
- **MRI:** You need to stay in a small enclosed space, which can be noisy; so, this may cause some anxiety. If a contrast material is used, your study doctor will tell you about possible side effects or allergic reactions.
- **CT Scan/PET:** Bruising from injection of contrast material; possible reaction to the injection but you will be closely monitored. Low doses of radiation (which is equivalent to 1 to 5 years background radiation) are used in CT scans, which has a small potential to cause cancer and other defects.
- **Bone Marrow aspirate:** You may experience pain and discomfort during and after this procedure and there is also a risk of infection or bleeding. You may have an allergic reaction to the numbing medication. If you have a prior history of drug allergies, you should inform your study doctor.
- **Blood draw/tests:** You may get a bruise or irritation at the place where the needle goes into your skin to collect your blood sample. Some participants may faint and, in rare cases, can get an infection.

- **Tissue biopsy:** [As part of standard of care (SOC) workup of a side effect (e.g. rash) at your hospital, if applicable] You may experience some soreness on or near the biopsied site for a few days. You may develop bleeding, bruising, scarring, or infection. If you are prescribed an antibiotic after a biopsy, there's a possibility of an allergic reaction to that antibiotic. If anesthesia is used, there is a small risk of problems, such as an allergic reaction or breathing difficulties.

Risks

Any drug has risks and side effects, which may vary from person to person. Side effects can range from mild to very serious, even fatal. Most of the side effects go away after stopping treatment, but some may be long-lasting. Side effects observed in the research study may be due to patient's disease, the study drug, other drugs, other diseases, or a combination of these.

Pre-dose (applicable for all study drugs) and post-dose (applicable only to participants on JNJ-79635322) medications

Acetaminophen, diphenhydramine, corticosteroids, tocilizumab (only applicable for participants on JNJ-79635322), or potentially other medications given by IV or by mouth may have risks and benefits depending on characteristics related to your health and other medications. Please consult your doctor for information regarding these medications.

Not all possible discomforts, side effects, and risks associated with the study drug are known. New side effects may occur. Your study doctor will monitor, and you will receive appropriate care if side effects happen. If you experience any of the side effects described below or any other side effects not listed here, please inform your study doctor immediately. You will be informed of any new information or findings that become available which could influence your decision to continue participating in this study. Your study doctor will monitor and treat you for side effects during study treatment.

Risks Associated with JNJ-79635322

As of September 28, 2025, 263 clinical study patients have been treated with JNJ-79635322. This section gives you the information known so far about possible side effects of JNJ-79635322 based on clinical experience with JNJ-79635322 and other therapies that work in a similar way.

Cytokine Release Syndrome (CRS)

- CRS may occur as a result of using the study drug. It can be mild or moderate in severity; however, in very rare cases, it may become severe or even lead to death. Most patients who have CRS have a fever, but some may also have abnormal blood pressure, chills, elevated heart rate, trouble breathing, tiredness or weakness, headache, nausea, vomiting, or wheezing. CRS occurred in approximately 50% of patients treated with JNJ-79635322. Most occurred within the first few doses, and most have been mild; all patients recovered with supportive treatments.
- If you experience CRS during this study, you may be given a drug called Tocilizumab, corticosteroids, or any other treatment to relieve the symptoms of CRS; your study doctor will explain to you in detail the possible side effects of this treatment.
- Before taking the full dose of the treatment, you will be given a relatively lower dose of the study drug (known as a step-up dose).
- Your study doctor will check and monitor you for symptoms of CRS during further treatment. Hospitalization may be needed for monitoring or treatment. If CRS is severe, treatment with the study drug may be interrupted or discontinued.

Neurological Side Effects

- Neurological side effects may occur, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The severity of ICANS may be mild or moderate; however, in rare cases, it can become severe and may even lead to the patient's death. Side effects of neurological side effects include—but are not limited to— sleepiness, confusion, slurred speech or difficulty speaking, difficulty writing, delirium, numbness or tingling in the hands, feet, or limbs, slowed thinking, difficulty remembering things, and changes in mental status. ICANS has been observed in three patients so far (representing approximately 1% of all patients treated with JNJ-79635322); these cases were mild in nature and resolved rapidly with appropriate treatment.

Infections

- Compared to periods when the study drug is not being taken, taking the medication may increase the risk of developing an infection or of an existing infection becoming more severe. This may be due to a deficiency in antibodies (hypogammaglobulinemia) or a deficiency in white blood cells (neutropenia)—conditions that can arise either during the course of treatment or as a result of the underlying disease itself. Infections have occurred in up to 75% of patients; however, most of these infections were mild in nature and resolved with treatment. Serious infections, including life-threatening and fatal infections, have been observed very rarely among patients treated with JNJ-79635322.
- Infections may occur in any part of the body. Examples include:
 - Upper respiratory tract infections, which affect your nose, sinuses, and throat. Examples of these include viral infections such as the common cold and the flu.
 - Lower respiratory tract infections, which affect the lungs—such as pneumonia.
 - Other infections, which may cause various symptoms in organs such as your gut, liver, or bladder.
- If you currently have any infection, have a history of frequent infections, or if you feel sick, you should tell your study doctor right away. Signs of an infection may include fatigue, headache, fever, chills, aches and pains, coughing, congestion, chest tightness, or shortness of breath. Severe infections such as pneumonia and sepsis (a life-threatening condition that occurs when the body's response to an infection damages its own tissues and organs)—have also been observed.
- Your study doctor may test for infection, and may administer medication(s) to prevent and/or treat infections.

Hypogammaglobulinemia (low antibodies)

- Treatment with the study drug may result in low antibodies, which can affect your immune system and increase the risk of infections. Hypogammaglobulinemia has been reported in about 20% of patients who received study drug.
- You should not receive live attenuated vaccinations against viruses as there is a chance of an infection due to the vaccine itself if your immune system is weakened. Vaccines may not work as well when taking the study drug.
- Your study doctor may recommend immunoglobulin replacement, which provides replacement antibodies, which may help in fighting off infections.

Immune-related effects

- Immune system-related side effects can happen when the immune system is stimulated by drugs that bind immune cells. Side effects may include rash, abnormal liver function tests, thyroid and/or adrenal dysfunction, inflammation in the colon, and neuropathy (for example: sensations of pain, tingling, numbness in hands and feet).

Bone Pain

- Bone pain can happen when the study drug targets cancer cells in the bone, and has been reported in about 15% of patients.
- Your study doctor may administer supportive care, such as corticosteroids, as part of pain management

Oral side effects

- Oral side effects may include dry mouth, altered taste, loss of taste, and difficulty swallowing. Approximately 50% of patients have experienced altered taste. Over time, notable weight loss may occur. Weight change will be monitored regularly during the study.
- Your study doctor may administer supportive care, such as saliva stimulating agents, steroid mouth wash, or they may suggest a consultation with a nutritionist, or both.

Skin and Nail Problems

- Skin and nail changes may occur. Skin changes may include dryness, peeling or shedding of the skin, itching, and rashes. Palmar-plantar erythrodysaesthesia (PPE), also called “hand foot syndrome,” can cause redness, swelling, and blistering of hands and feet. Nail changes may include nail loss, peeling, ridging, discoloration, breaking, loosening, and shedding of the nails, and nail separation from the skin. Rashes may be local, at the site of a subcutaneous administration, or may be widespread. About 30% of patients so far experienced dry skin and about 25% of patients have experienced nail changes, and all have been mild.
- Your study doctor may prescribe lotions, corticosteroid creams or corticosteroid pills, and may also consult a dermatologist.

Systemic Administration Related Reactions (sARR)

- sARRs (Systemic Administration Related Reactions) may occur during, or immediately following, the administration of the study drug. If you feel dizzy, weak, nauseated, light-headed, itchy, or if you feel like you have a fever, chills, cough, throat tightening, flu-like symptoms, runny nose, sneezing, sore throat, trouble breathing, nausea, vomiting, or pain (in your chest, back, abdomen, muscle, or joints). Get emergency medical help if you have any of the following: hives, wheezing, difficulty breathing, swelling of your face, lips, tongue, or throat, or pain in your chest.
- Medications may be given before and after at least the first doses of the study drug to help managing systemic administration related reactions. Your doctor will explain the side effects of these medications.
- If you experience any sARR, your study doctor will continue to monitor you and may make changes to the administration of the study drug, or to the medications given before and/or after administration of study drug. If the reaction is severe, treatment with the study drug may be interrupted or discontinued.

Reaction at the site of injection

- When the study drug is administered via subcutaneous injection (under the skin), certain reactions may occur at the injection site.
- Symptoms of these reactions may include: mild pain, bruising, swelling, a burning or stinging sensation, itching, redness, or hardening of the skin at the injection site. Redness at the injection site was observed in approximately 25% of patients; the majority of these instances were mild or minor in nature. Severe or serious reactions at the injection site occurred in fewer than 1% of patients.
- Your doctor will decide whether an injection site reaction requires treatment and the best way to treat it.

Tumor Lysis Syndrome (TLS)

- TLS is a potentially life-threatening condition caused when cancer cells are destroyed rapidly. Signs of TLS are abnormal blood test results for potassium, phosphate, calcium, and uric acid levels. TLS can result in kidney damage, heart problems (such as abnormal heartbeat), and seizures. TLS has occurred in two patients (less than 1% of patients), and both resolved with appropriate treatment.
- Your study doctor will monitor you for signs of TLS during treatment with the study drug and will treat you if that is necessary.

Effects on Blood Cells

- During treatment with the study drug, the following effects on blood cells may occur:
- Low neutrophil counts (neutropenia). Neutrophils are a type of white blood cell that fights against infections as part of the body's immune system. If the neutrophil count drops too low, you are at risk of developing a serious infection. If you experience both fever and neutropenia at the same time, you will require special monitoring or treatment by your study doctor. Neutropenia was observed in approximately 45% of patients.
 - Low lymphocyte counts (lymphopenia). Lymphocytes are a type of white blood cell that fights against infections as part of the body's immune system. If the lymphocyte count drops too low, you are at risk of developing an infection. Lymphopenia was observed in approximately 30% of patients.
 - Low Hemoglobin (Anemia). Hemoglobin is the component of red blood cells that carries oxygen through your blood. Low hemoglobin may make you feel tired, weak, or short of breath. About 20% of patients have experienced anemia.
 - Low Platelets (Thrombocytopenia). Platelets help to clot your blood and stop or prevent bleeding. If they are very low, you are at risk for bruising or bleeding. About 15% of patients have experienced thrombocytopenia.
- Your study doctor will monitor your blood counts during treatment and provide transfusions or supportive care as needed.

Other

- During the study your condition may remain the same or get worse.
- Unanticipated side effects not listed here may occur as the study drug is given to more people. Please tell your doctor about any side effect you experience right away.

Risks Associated with Teclistamab

This section provides information regarding side effects associated with the study drug, Teclistamab, based on clinical studies conducted to date.

As of August 22, 2024, approximately 1,815 clinical study patients with Multiple Myeloma have been treated with Teclistamab; of these, approximately 797 patients received Teclistamab alone, while 1,018 patients received Teclistamab in combination with other therapies.

The following side effects have been identified in association with Teclistamab:

Body system	Very Common (May affect 1 in 10 patients or more)	Common (May affect fewer than 1 in 10 patients)
Immune System	• Cytokine Release Syndrome (see separate section below for details) • Hypogammaglobulinemia (see separate section below for details)	
Infections (see separate section below for details)	• Upper respiratory tract infection • Infection of the lung (pneumonia) • COVID-19 • Urinary tract infection	• Sepsis (a life-threatening condition that occurs when the body's own response to an infection damages its own tissues and organs) • Cellulitis (a bacterial infection of the skin, causing redness, swelling, and pain in the infected area of the skin)
Effects on Blood Cells	• Low white blood cell count (including neutropenia, lymphopenia, leukopenia) • Low platelet count (thrombocytopenia) • Low red blood cell count (Anemia or blood deficiency)	• Fever associated with a low white blood cell count (Febrile Neutropenia)
Metabolism and Nutrition	• Low blood phosphate levels (Hypophosphatemia) • Low blood magnesium levels (Hypomagnesemia) • Low blood potassium levels (Hypokalemia) • High blood calcium levels (Hypercalcemia) • Decreased appetite	• Low blood calcium levels (Hypocalcemia) • Low blood sodium levels (Hyponatremia) • Low blood albumin levels (Hypoalbuminemia) • High blood potassium levels (Hyperkalemia) • Low blood sugar levels (Hypoglycemia)
Nervous system	• Headache • Abnormal sensations, including numbness, tingling, or pain in the hands, feet, or limbs (Peripheral Neuropathy)	• Brain disorders (Encephalopathy) • Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (See the “Neurological Side Effects” section below for details)
Vascular	• High blood pressure • Low blood pressure • Bleeding	

Body system	Very Common (May affect 1 in 10 patients or more)	Common (May affect fewer than 1 in 10 patients)
Lungs	• Cough • Shortness of breath (Dyspnea)	• Low oxygen levels (Hypoxia)
Gastrointestinal	• Nausea • Diarrhea • Constipation • Vomiting • Abdominal pain	• Abnormal levels (elevated) in pancreatic blood test (Increased Amylase and Lipase levels)
Muscles, bones, and connective tissues	• Muscle or bone pain (Musculoskeletal pain) • Sudden muscle movements (Muscle spasm)	
General disorders and administration site conditions	• Injection site reactions (see separate section below for details) • Tiredness (Fatigue) • Pain • Fever • Swelling of the face, hands, feet, or limbs (edema)	
Liver	• Abnormal (elevated) levels in liver blood tests	
Kidney		• Abnormal results in kidney blood tests

Cytokine Release Syndrome (CRS)

For definition, signs and symptoms and management of CRS see section ‘Risks JNJ-79635322-CRS’. The signs and symptoms of CRS with teclistamab are fever and may also include chills, abnormal blood pressure, trouble breathing, elevated heart rate, headache and abnormal liver function tests.

CRS has occurred in approximately 72% of patients treated with Teclistamab. Most cases occurred within the first few doses and most have been mild or moderate.

Neurological Side Effects

For definition, signs and symptoms and management of Neurological side effects see section ‘Risks JNJ-79635322 Neurological Side effects. ICANS has occurred in approximately 3% of patients receiving any dose of Teclistamab. Most cases of ICANS were mild or moderate in severity; however, serious, life-threatening, or fatal (resulting in death) cases of ICANS have also occurred following treatment with Teclistamab.

Reaction at the site of injection

For definition, signs and symptoms and management of Injection site reactions see section ‘Risks JNJ-79635322 Injection Site Reactions’. Injection-site reactions may occur following the subcutaneous

administration of medication; such reactions have been observed in approximately 38% of patients who received teclistamab as a subcutaneous injection.

Hypogammaglobulinemia

For definition, signs and symptoms and management of Hypogammaglobulinemia see section ‘Risks JNJ-79635322 Hypogammaglobulinemia’s. Hypogammaglobulinemia has been observed in approximately 75% of patients treated with teclistamab.

Infections

- Due to the risks of hypogammaglobulinemia and decreased white blood cell counts, the risk of developing an infection—or a more severe infection—may be increased. Among patients treated with teclistamab, the most commonly observed infections included upper respiratory tract infections (37%), pneumonia (28%), and COVID-19 (18%).
- If you currently have an infection, have a history of recurrent infections, or if you feel sick or think you may have fever, you should tell your study doctor immediately.
- Reactivations of viruses have been observed with teclistamab including Hepatitis B and JC virus
 - Reactivation of the Hepatitis B virus can lead to severe liver infection or death. Before initiating treatment under this study, your doctor will test you to determine the presence of the Hepatitis B virus. If you test positive for the virus, you will be closely monitored for signs of infection. Tell your doctor if you get worsening tiredness or yellowing of your skin or white part of your eyes.
 - Progressive Multifocal Leukoencephalopathy (PML) is a condition primarily caused by the reactivation of a virus (the JC virus) and can be fatal. Your doctor will monitor you for any signs of PML; if there is any suspicion of PML, the administration of Teclistamab will be discontinued. Tell your doctor if you develop changes in vision, difficulty speaking, weakness in an arm or leg, a change in the way you walk, problems with your balance, changes in sensation, or memory loss or confusion. PML has been reported in <1% of patients receiving teclistamab.

Additional Conditions Observed with Teclistamab

Immune-related effects is an additional condition that has been observed when teclistamab was given to patients. However, it is unclear if teclistamab caused it or if it was due to other factors.

Immune system-related side effects may occur when the body's immune system becomes stimulated by the influence of a study drug that interacts with immune cells. Side effects may include rashes, abnormal liver function test results, thyroid and/or adrenal gland dysfunction, inflammation in the colon, inflammation in the lung and neuropathy.

Driving and Using Machines

Neurological side effects may impair your ability to drive or operate machinery. Since these side effects are more likely to occur early in the course of treatment, you should not drive or operate machinery from the time you receive the first dose of the step-up dosing regimen of teclistamab until 48 hours after receiving the first dose of the full treatment regimen. If you experience any neurological side effects at any other time during the course of treatment, you should refrain from driving or operating machinery unless advised otherwise by your study doctor.

WHAT ARE THE BENEFITS OF JOINING THE STUDY?

Participating in this study may lead to an improvement in your physical condition; however, there is no guarantee that this will occur. During the course of the study, your physical condition may remain unchanged or could worsen; furthermore, you may experience various side effects or require hospitalization. Your participation may benefit other patients in the future, as it will enable researchers to gain more detailed insights into the potential efficacy and safety of JNJ-79635322 in the treatment of Multiple Myeloma.

There is a possibility of failure of investigational product to provide intended therapeutic effect.

WHAT ELSE DO I NEED TO KNOW?

What other treatment options are available outside of this study?

Instead of participating in this study, you may decide to receive other available treatments.

Other treatments available for relapsed or refractory multiple myeloma may include the following classes of medications; these medications may be used alone or in combination with other drugs:

Proteasome Inhibitors: Carfilzomib, Bortezomib

Immunomodulatory Drugs (IMiDs): Lenalidomide, Pomalidomide

Monoclonal Antibodies (Anti-CD38): Daratumumab

Bispecific Antibodies: Teclistamab

Chemotherapy Medications: Cyclophosphamide, Melphalan

The clinical staff will explain to you in detail the benefits and risks associated with these other treatments or studies and discuss which would be best for you.

Birth Control and Pregnancy During the Study

No information is available about the risks of pregnancy and effects on an unborn child during treatment with JNJ-79635322 or Teclistamab. The effect of the study drug on eggs, sperm and reproductive organs is unknown. It is unknown whether the study drug can reduce the effectiveness of hormonal contraceptives.

For participants of childbearing potential:

- If you are pregnant or are currently breastfeeding, you **cannot** participate in this study, as the study drug may harm your unborn child or nursing infant.
- If you can become pregnant, you must agree not to become pregnant or donate eggs (ova, oocytes) while in this study and for 6 months after the last study drug is given.
- If you can become pregnant and are sexually active, you must agree to use effective methods of contraception until 6 months after the last study drug is given. The type of contraception you use must be discussed with, and approved by, the study doctor before you begin the study.
- If you become pregnant during the course of the study, you must inform the study doctor immediately and discontinue taking the study drug at once. The study doctor will advise you about your medical care and will ask your permission to collect information about your pregnancy and the health of your baby.
- If your childbearing potential changes after the start of the study or the risk of pregnancy changes, you must begin to use effective methods of contraception and discuss this immediately with your study doctor.

For participants capable of producing sperm:

- You must agree not to donate sperm or father a child during the course of this study, or within 6 months after receiving the last dose of the study drug.
- If you are sexually active with a partner who is capable of becoming pregnant, you must agree to use effective methods of contraception throughout the duration of the study and for 6 months following the last dose of the study drug.
- The type of contraception you (and your partner who could become pregnant, if applicable) use must be discussed with, and approved by, the study doctor before you begin the study.
- If your partner becomes pregnant at any time between the commencement of your study drug and 6 months following the last dose of the study drug, you must immediately inform the study doctor. The study sponsor may ask for your and your partner's permission to collect information about your partner's pregnancy and baby's health.
- Condom usage when transmission of sperm/ejaculate can occur

The study may pose risks to your embryo or fetus that are currently unforeseen. If you become pregnant during the course of the study, you must notify the clinic staff immediately. They will advise you about continuing the study treatment, medical care, and collecting information about the pregnancy and the baby. By signing this consent, you agree to share relevant medical information about your pregnancy. You are free to change your mind at any time.

If your partner becomes pregnant by you during the study, they will be asked to sign a separate consent to collect information about the pregnancy and the health of the baby. This is optional for your pregnant partner, and they can change their mind at any time. When you sign this main consent as the study participant, you agree to this information being collected.

Will I be paid?

You will not be paid for participating in this study. You and your caregiver will be reimbursed for reasonable expenses directly related to the study visits, such as local travel, meals, and / or stays if any. Caregiver costs may be reimbursed for expenses directly related to those study visits where you may need to be accompanied and reviewed on a case-by-case basis.

You will get upto **Rs. 2000** per visit to help cover your expenses for attending study visits, e.g., travel.

Your caregiver may get upto **Rs. 2000** per visit to help cover your expenses for attending study visits as applicable for you, per study, e.g., travel.

Please discuss with the clinical staff about the reimbursement allowed by sponsor for you and caregiver.

Who will pay for the study-related tests and procedures?

The sponsor will provide all investigational treatments for the study and will cover the costs of visits, tests, and procedures conducted as part of the study.

The sponsor will not cover the costs of doctor visits, tests, or procedures that are not part of this study. These costs will be borne by you, your insurance company, or a government health plan. If you have any concerns, please discuss them with the clinical staff.

The investigator has no financial relationships or interests associated with the study.

Can I change my mind about participating?

You may change your decision at any time, for any reason; however, we encourage you to speak with the clinical staff before making this decision. You may be asked to confirm your decision in writing, but this is not mandatory. Please refer to the "Withdrawal of Consent" section.

Can I be removed from the study?

Yes, but this will be fully discussed with you, along with alternative treatments or research options. Reasons can include:

- It is in your best medical interest to stop.
- You do not follow the instructions of the clinical staff.
- The study is cancelled or stops accepting new participants, before you enroll.
- You no longer meet the eligibility criteria.

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 take the study drug after the study is over?

After the study is ended you may continue to receive the study drug(s) upon receiving approval of the independent ethics committee / institutional review board as determined by treating Physician and the Sponsor. Your study doctor/staff will discuss your future medical treatment options with you.

FINANCIAL COMPENSATION AND MEDICAL MANAGEMENT

Regulations governing the conduct of clinical trials in India require that medical management be provided to you and financial compensation be paid in case of study-related injury or death.

(a) In the event of any injury or harm during this study, you will be provided with free medical care for as long as it is required, or until it is established that said injury is unrelated to this clinical trial—whichever occurs first.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, shall provide financial compensation for the injury or death in accordance with Rule 39 of New Drugs and Clinical Trial Rules, 2019.

The above statement does not limit your legal rights.

HOW WILL MY PRIVACY BE PROTECTED?

Clinical staff and the sponsor will look after your personal data (information collected from you and collected during this study) as required by The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with applicable Indian data protection and privacy laws and in the manner described in this consent form. The "Privacy Appendix" in this document describes your rights about the use and protection of your personal data.

INFORMATION ON STUDY SAMPLES

Clinical staff will collect biological samples (blood, urine, bone marrow) from you for the purpose of the study and provide them to the sponsor or an authorized representative, as described in this consent form. Clinical staff will tell you if there are any changes to testing on your samples during the study.

How are my samples kept confidential?

To protect your privacy, clinical staff will label your samples and test results with a study number and a unique participant code assigned specifically to you. In this process, no information that directly identifies you will be used; only the clinical staff will be able to match your samples to your name.

How long will my samples be stored?

Your samples will be stored for a maximum of 15 years—or until you request their destruction or disposal. The Sponsor of this study plans to securely store these samples in a long-term repository located in the United States. The samples may be transferred by the Sponsor at any time.

Will genetic testing be performed on my samples?

Genetic testing may be performed on your biological samples and involves examining genes, which are the instructions for our cells. Genes are composed of molecules called DNA. Cells can create copies of DNA and convert them into another molecule called RNA. RNA provides instructions to the cells for producing proteins.

The tests conducted as part of this study may include a test known as Fluorescence in Situ Hybridization (FISH) of targeted pieces of DNA. FISH looks for changes in the structure of your DNA without revealing the details of your genetic sequence.

As part of this study, whole-genome sequencing and/or single-cell sequencing tests may be performed; these tests involve examining the complete set of DNA or RNA obtained from your bone marrow.

What are the risks associated with Genetic Analysis?

Since your genetic information is entirely personal and unique to you, there remains a possibility that someone could use your genetic information to identify you or a close biological relative. The risk of this occurring is currently very low; however, as technology advances, there is a possibility that this risk could increase in the future. In the unlikely event that your genetic information is released to other companies, applicable country laws may not fully protect you or your family from judgements based on genetic information.

Will I receive the results of the Genetic Analysis?

The results of the genetic tests conducted on these samples will be used solely for the purposes of scientific study. These results will not be used for your medical care or for diagnosing any health conditions you may have. Therefore, these test results will not be provided to you or the clinical staff.

USE OF STUDY RECORD AND SAMPLES

This section describes how your Study Record and samples may be used, shared and the measures in place to protect participant privacy.

Coded Data and Samples

To advance clinical science and medical knowledge, study sponsors and other authorized parties may use and share your coded study records and samples (without personally identifiable information) for the purposes described below:

- To evaluate and understand JNJ-79635322 and multiple myeloma. This may include genomic analysis of biological samples.

- To support the development and approval of JNJ-79635322 and diagnostic tests for multiple myeloma
- To apply learnings from past studies to new ones or improve scientific analysis methods
- To ensure the sponsor complies with decisions and/or approvals from the Regulatory authorities for study drug availability and reimbursement (where applicable)
- To meet legal and regulatory obligations, in relation to clinical studies and product safety requirements
- To publish the results of the research described above in scientific journals or use them for educational purposes

Anonymous Data and Samples

The sponsor may generate anonymous data or samples for the purposes of scientific research. Research using anonymous data or samples may have a scientific purpose beyond the compatible research described above. During the process of creating anonymized data or samples, the code-linked number assigned to you as a study participant—along with other information that could indirectly reveal your identity (such as specific dates of your medical treatment)—will be removed from your data and samples. Within the limits permitted by applicable law, the sponsor may share these anonymized data or samples with others for the purpose of scientific study.

For any scientific research that might be conducted that is not part of the study, you will not receive details nor results of the research and that research is not expected to provide any financial or direct benefit to you.

WITHDRAWAL OF CONSENT

You may withdraw your consent or change your decision about participating in this study at any time. This means that you can either stop taking JNJ-79635322 or teclistamab, but you can continue with the study assessments or you can stop taking JNJ-79635322 or teclistamab and stop coming to any further study visits. If you withdraw from the study, the data, tests or test results and samples, videos, or photographs of physical findings related to adverse events have already been collected will continue to be shared and used for the study purposes to protect the scientific validity and integrity of the study. If you stop coming to study visits, no further study-related tests will be done. The clinical staff will discuss with you how your health will be managed if you do not want to come to further study visits. The clinical staff may also discuss how they will follow up on your health status, as described in the table below.

You can also withdraw consent for your samples to be used for compatible uses as described above in the “Use of Study Record and Samples” section, once the study is completed.

Clinical staff may request that you complete a Withdrawal of Consent form. The Withdrawal of Consent form is optional but can help you understand the different withdrawal options and how your follow-up may be managed. You don’t have to sign this form and can just tell the clinical staff that you want to stop JNJ-79635322 or teclistamab and attending further visits.

It is very important to collect long-term results of JNJ-79635322 or teclistamab. These results can assist regulatory or health authorities in evaluating how beneficial a new medication or treatment might be for other patients. Therefore, it is important to monitor your health condition until the end of the study; and this can be done in accordance with the procedures outlined below. Please discuss these options with the clinical staff and ask any questions. You don’t have to do this and can just let the clinical staff know you want to stop study participation.

Please review the health status follow-up options below if you stop coming to study visits:

Clinical staff can contact you directly through the methods described below.	If you do not wish to be contacted directly, clinical staff may use the following sources or methods:	If you don't agree to direct or indirect contact as described previously, if allowed in your country, the clinical staff can use the following:
[Telephone/Video Calls, Text/Email Messages, Standard mail]	[Family members; other doctors/medical professionals involved in your standard care; Medical records (including standard care results); Insurance data]	<u>Publicly available</u> registries/sources

If this is not successful, the clinical staff may use an independent locator company, who reviews publicly available sources to identify your health status. This is described above in this ICF under “What Happens During the Study - Other Optional Services”. You will not be contacted directly, and you can refuse this if you stop participating in the study.

WHAT HAPPENS AFTER THE STUDY?

Johnson & Johnson Private Limited will use the information collected about you for the purposes of the study and for scientific research, such as study of your disease and genetic research [if applicable]. Johnson & Johnson Private Limited may also use this information to apply for permission to sell the drug in some countries. The information will be stored both on paper and on computer. To protect your privacy, the information will be labeled in a way that will not identify you. To protect your privacy, the information will be labeled in such a way that it cannot identify you. If the results of the study are published, your identity will be kept confidential. By signing this form, you grant permission for the use of your information.

Your study doctor will keep your personal medical records and a list that links each participant's name to his or her code number for at least 15 years.

Regulatory authorities, members of the ethics committee/institutional review board, employees at the study site and representatives of Johnson & Johnson Private Limited will have access to this list and be able to compare and check the study information collected about you with information in your medical records. As far as the law allows, your medical records will not be made public. By signing this form, you are allowing direct access to your medical records by those who have legitimate reason to look at them.

The information collected may be sent to other members of the Johnson & Johnson Group of Companies, other contractors working on their behalf, and regulatory authorities.

You can arrange with your study doctor to see the information collected about you, and you can ask for any mistakes to be corrected. Johnson & Johnson Private Limited may postpone your access to your information if it would interfere with the study itself. If you decide to leave the study at any time, Johnson & Johnson Private Limited may still use your information collected up to that point, if the law allows.

A summary of study results written in plain language will be made available to you sometime after all study participants have completed the study. Please ask the clinical staff if such a summary will be made available to you. By signing this consent, you agree that you may be contacted by clinical staff after you have finished the study to be offered the results summary.

A market research company employed by the sponsor may contact you after you finish the study to discuss your clinical trial experiences and your disease/condition. This is very important and could help improve future clinical trials for both participants and clinical site teams. Please indicate your choice at the end of this consent to allow your contact details to be provided to a supplier. This feedback is optional; you can agree now but

you may decline when contacted later. If you withdraw early, you can change your mind and let the clinical staff know not to share your contacts.

PRIVACY APPENDIX TO MAIN INFORMED CONSENT

Medical Record – information and data, including personal details, recorded by the clinical staff; stays on-site Study Record – Medical Record data (without personal details) documented by the clinical staff and shared with the sponsor
1. What kind of personal data will clinical staff collect? If you participate in the study, clinical staff will collect and share your personal information for the purposes of the study. Personal data may include: - Health-related information about you that is found in current or past medical records, or is collected during the course of this study. This may include medical images, written descriptions (including records of phone calls, visits, and examinations), and other formats like health questionnaires. - Information collected through the analysis of your biological samples. - Information related to any adverse reactions or side effects. - Information collected directly from you using a device. - Direct personal identifiers, such as your name, initials, date of birth, and address. - Other sensitive information—such as [racial or ethnic origin, sex assigned at birth]—which is collected only if it is necessary for evaluating the results of the study.
2. Who will have access to my Medical Records? Your personal information will be recorded in your Medical Record; these records may be stored in paper files and electronic databases—including databases that can be accessed remotely (if permitted in your country). The clinical staff will have access to your Medical Record. Furthermore, to ensure that the study is being conducted properly, the individuals listed below may have direct access to your medical records. - Monitors and auditors from the sponsor or the sponsor’s representatives. - The Institutional Review Board (IRB) or Independent Ethics committee (IEC) (a group of people who review research studies to protect the rights and welfare of people participating in research). - Regulatory authorities—local and outside your country. - Other persons or groups required by law, whose location may be outside of your country. The level of protection for your information may vary in accordance with the laws of other countries.
3. How will my personal information be protected? Clinical staff will extract information from your medical records and record it in your Study Record. This data is provided to the sponsor for the purpose of the study. This will only be identified by the study number and your coded participant number. Direct personal identifiers such as your name, initials, date of birth will not be included in your Study Record. The clinical staff can match the Study Record to your name, but this information will be kept confidential and not be shared with the sponsor or anyone else, except where required by law.

4. How will my study records be used and shared?

The sponsors and other authorized parties mentioned in this consent form will use and share your coded **Study Record** for the purposes of scientific study—and as required for other compatible studies described and authorized in this consent form. . See the section on “Use of Study Record and Samples”. Authorized parties may include organizations providing services for the sponsor (such as laboratories), researchers, collaborators, and companies who may share an interest in the study drug or the disease. The sponsor, other authorized parties and Regulatory Authorities may be located outside your country, where laws may provide a different protection level.

5. Transfer of data

In accordance with applicable laws, appropriate security measures have been implemented to safeguard your personal information when it is transferred outside your country. This provision also applies to individuals who access your information remotely, and remains in effect when your information is shared as described above.

6. Will my personal identifying information be shared with service providers?

Clinical staff may share some personal identifiers such as your name, home, email address or phone number with a service provider for applicable service, e.g., locator agency . Clinical staff will discuss the details with you. These identifiers will not be part of your Study Record and will not be used or retained by the service provider except for the purposes of this service for the study.

7. How long will my personal information be retained?

Clinical staff will retain your **Medical Record** at the site according to local laws and requirements. The Sponsor may retain your **Study Record** for as long as required OR 15 Years in accordance with applicable laws.

8. What rights do I have regarding my personal information?

If you would like to review, correct, delete personal data, or make other requests in accordance with the laws in your country, you should contact the clinical staff +91-9007016755. You may not be able to review your data until after the end of the study. A request to delete your personal data may not be allowed, depending on regulations and laws that require clinical research and personal data to be retained.

YOUR CONSENT TO PARTICIPATE

If you consent to all of the statements below and decide to participate in this study, please sign below. You will receive a copy of the signed Informed Consent Form.

- The clinical staff and I have discussed the study and my responsibilities in detail. I understand what is expected of me as a study participant.
- I agree that the clinical staff may inform my other doctors that I am participating in this study, as well as notify them if any side effects occur.
- I agree that my doctors, other healthcare professionals, institutions and hospitals, or laboratories may disclose my medical and treatment-related information to the clinical staff for the purposes of this study.
- I understand that I shall be required to keep confidential (a) “Confidential Information” as defined in the above Information Sheet and (b) the information I gain during the study and to return all the study products (used or unused, even empty tubes or boxes as the case may be) and diary sheets (used and unused) to the Principal Investigator.
- It is written in a language that I can read and understand
- I understand that a copy of signed ICF will be provided to me

AUDIO VIDEO CONSENTING:

You are requested to sign the audio – video consent form. Audio video recording of Informed Consent process is a requirement by India Regulations. This consent form is required if the study drug is not approved for use for the disease or condition in India and in case you are from a group that represents prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions, patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or other incapable of personally giving consent. Only audio recording of the informed consent process will be done if you have certain conditions like Leprosy or HIV.

I understand that audio – video consent is required by Indian regulations and have agreed to sign the audio – video consenting form, as applicable.

Please tick Yes or No:

Yes ☐ No ☐ Not Applicable ☐

HIV (Human Immunodeficiency Virus) Test:

I understand that to determine my eligibility to participate in the study, the HIV status will be checked either via history or a blood test. The significance, relevant information and pre-test counselling has been provided to me by the study doctor. All details pertaining to HIV, its transmission, prevention, testing procedures, its limitations and interpretation of results have been explained to me by the study doctor, in the language best understood by me.

Based on the information provided, I provide my consent to provide any history or conduct an HIV test.

Please tick Yes or No:

Yes ☐ No ☐

I understand that if I do not provide consent for providing history or HIV test or if I test positive then I will not be eligible to participate in the study. Please tick Yes or No:

Yes ☐ No ☐

I understand that my HIV test results will be kept confidential. Please tick Yes or No:

Yes ☐ No ☐

I understand that if I test positive for HIV, Post-test counselling shall be done by the study doctor or a qualified person assigned by him/her or the study site. Please tick Yes or No:

Yes ☐ No ☐

Please indicate if you agree to your contact details to be shared with a market research company:

☐ I agree ☐ I don't agree

Please indicate if you agree to include anonymized photographs and videos that can be shared with Sponsor and used in presentations and publications related to the study. If you do not agree, it will not affect your participation in the study.

☐ I agree ☐ I don't agree

Consent to Participate in the Study

Study Title: A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide (TRIlogy-5)

Study ID: 79635322MMY3002

Participant's Initials: _____

Participant's Name: _____

Participant's Date of Birth / Age: _____

Participant's Address: _____

Qualification of the Participant: _____

Participant's Occupation: Student / Self-employed / Service / Housewife / Others

(Please tick as appropriate)

Participant's Annual Income: Rs. _____

Name and address of the nominee(s) and relation to the Participant (for the purpose of compensation in case of trial related death): _____

Serial Number	Declaration	Place initial box (Participant)
(i)	I confirm that I have read and understood the Information Sheet Version 1.1.0 dated 08 Apr 2026 for the above study and have had the opportunity to ask questions and have received satisfactory answers and information.	[]
(ii)	I understand that my participation in this study is voluntary, and that I may withdraw my participation at any time, without providing a reason, and without affecting my medical care or legal rights.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[]
(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[]
(v)	I agree to participate in the above study on the terms set out in the above Information Sheet.	[]

Signature (or Thumb impression) of
the Participant/ Legally Acceptable
Representative: _____

Date: ____/ ____/ ____
dd-MON-YYYY

Name of the Signatory: _____

Signature of the Investigator _____

Date: ____/ ____/ ____
dd-MON-YYYY

Name of the Study Investigator: _____

Impartial Witness Statement 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.

Signature of the Witness _____

Date: ____/ ____/ ____
dd-MON-YYYY

Name of the Witness: _____

(Copy of the Patient Information Sheet and duly filled Clinical Informed Consent Form shall be handed over to the Participant or his / her attendant)