

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 (TRIlogy-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 that are essential to know:

- Participating in a research study is voluntary and is not part of your regular health care.
- Take your time to carefully read this Informed Consent Form (ICF) so that you can understand this study, why it is being conducted and what it involves.
- Discuss participating in this with your doctors, medical professionals, family, and friends.
- Ask questions and request any additional information from the clinical staff at the study site.
- You are free to decide whether or not to participate in this study, and if you agree now, you may change your mind at any time. Whether or not you participate in this depends entirely on you. Whatever decision you make, you will not lose access to the medical care you are already receiving, incur any penalties, or give up any of your existing rights or benefits.

Thank you for taking the time to consider joining this study.

To assist you in making a decision about participating in this study, the sponsor may share sensitive company information with you. We humbly request that you please keep this in mind when discussing the details of this study with people other than your healthcare provider(s), family, and friends, or when using social media.

YOUR CONTACTS

Study Sponsor Janssen Research & Development, LLC	Represented by: JOHNSON & JOHNSON PRIVATE LIMITED HIGI House, LBS Marg, Mulund (West), Mumbai – 400080
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Independent Ethics Committee / Institutional Review Board (IEC/IRB) Contact: Institutional Ethics Committee Name: TATA MEDICAL CENTER, INSTITUTIONAL REVIEW BOARD (TMC-IRB)	

Institutional Ethics Committee Address: **TATA MEDICAL CENTER, 14, Major Arterial Road (EW), New Town, Rajarhat, Kolkata - 700160**

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An Independent Ethics Committee (IEC) or Institutional Review Board (IRB) has approved this study.

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

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

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

STUDY OVERVIEW AND GENERAL INFORMATION

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

All reference to the terms "**study drug**" refers to JNJ-79635322 or Teclistamab.

All references to "**clinical staff**" include the site doctor(s) and other site staff specifically involved in the study (e.g., nurses, scientists, healthcare professionals).

"**Site**" may refer to an institution or a hospital, depending on where the study is being conducted.

You may ask the clinical staff to convey any of your questions, concerns, or complaints to the IEC/IRB (Independent Ethics Committee/Institutional Review Board), the sponsor, or the sponsor's authorized representatives. IEC/IRB are independent committees that 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 this study for about 5 and a half years (this includes the treatment and follow-up phases).

Research has shown that certain diseases, treatments, and medications affect people differently based on their age, gender, race, ethnicity, access, and genetic background. You may be asked questions that may help ensure various groups are included in this study. Your information will be included in your study records, but does not change the care and treatments you receive during the study or in the future. To ensure that clinical trials are available to everyone, you may be asked where you live and how easy it is for you to reach a clinical trials site. This ensures that people receive information about the available trials and how to access them.

WHAT HAPPENS DURING THE STUDY?

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

The table below describes the procedures you can expect during this research study. Not all procedures will be performed at every visit. The clinical staff will discuss this with you in more detail.

Visit	Examinations, Tests and Procedures
Screening (≤ 28 days prior randomization)	After the study doctor or site staff has explained the study and answers your questions, you may decide whether or not to participate. If you decide to join, you will be asked to sign the informed consent form. The following will be reviewed/performed by the clinical staff: • Your medical history (including 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 examination • A neurological examination is a check of your nervous system. • General health status • To determine whether you are eligible to participate in this study, blood and urine samples will be collected. In addition, blood tests to check your past or current hepatitis status. The volume of the sample taken will be approximately 2 to 3 tablespoons (approximately 35.5 mL). The clinical staff will discuss all tests and risks with you. • You will be asked to collect urine samples over a 24-hour so that the amount of multiple myeloma-related proteins in your urine can be measured. • If you can become pregnant, a pregnancy test will be performed on your blood or urine sample. • ECG (Electrocardiogram): Adhesive patches are placed on your chest (and limbs), which are connected to a machine that displays your heart's electrical activity. • Imaging: To assess bone cancer lesions and abnormal growths occurring near or outside the bones, images of the inside of your body will be captured using whole-body PET/CT scans (Positron Emission Tomography/Computed Tomography) or Whole-Body DWI/MRI scan (Diffusion-Weighted Imaging/Magnetic Resonance Imaging). A PET/CT scan uses a small amount of radiation, while an MRI uses a strong magnet (it involves no radiation). If none of these scans is

	available, a low-dose whole-body CT scan may be performed instead; however, this too involves a small amount of radiation. • Bone Marrow Aspiration: A procedure in which a small amount of bone marrow fluid is removed by inserting a needle into a large bone to determine your disease status and for scientific research as described in the "Information on Study Samples" section below. If you had a bone marrow test as part of routine care within 42 days before enrolment, we may request the results from that sample. The study also requires to collect a fresh bone marrow aspirate and send it to a central laboratory for scientific research. The bone marrow procedure is performed under a local anesthesia which numbs the bone area.
Study treatment period	• The study drug (JNJ-79635322 or Teclistamab) is administered just under the skin using a small needle (in the belly (preferred), upper arm(s), or thigh(s)). To reduce the risk of certain side effects, you will receive some pre-treatment and post-treatment medications. Some of these treatment medications can be taken orally, while others can be administered intravenously. • Diary: A member of the study staff 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 (a temperature of 38 °C or 100.4 °F or higher), you will need to report it to your study doctor immediately. This applies to all participants, regardless of which treatment you receive. ○ If you receive JNJ-79635322, you will also record every dose of any post-study treatment medication you take during the 48 hours following your first SUD injection, and during the 48 hours following your first full dose of JNJ-79635322. Please bring the diary with you when asked by the study's clinical staff. • Monitoring for Dose Administration: ○ JNJ-79635322: Hospitalization is not required for the administration of JNJ-79635322 (SUD and treatment doses), unless your doctor thinks it is necessary or it is required as per local regulation 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 partner will need to stay within 30 minute travel distance from the clinic. ○ Teclistamab: Hospitalization is not required to administer Teclistamab. However, if necessary and if you agree, your doctor may decide to admit you to the hospital for monitoring during the SUDs and the first treatment dose. Otherwise, you may receive these doses as an outpatient. For every SUD and the first dose of treatment, you should stay within a 30-minute distance of the clinic and stay with 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 group you have been assigned to. Your condition will be assessed by the clinical staff as follows: • By reviewing your health status, the extent of the disease, any side effects, and how you are feeling, including the following: ○ Physical examination ○ General health status ○ A neurological examination is a check of your nervous system. • If you are able to become pregnant, pregnancy tests (urine or blood samples) will be performed. • At every visit, blood samples will be collected to assess your disease and for scientific research. At some visits, blood samples may be collected for scientific research, as described in the ‘Information on Study Samples’ section below. The total estimated amount of blood to be drawn during the treatment phase will be about 4 cups (approximately 1049.5 mL). • Before each cycle begins, a 24-hour urine sample will be collected. This is to help better understand your cancer status. • Bone marrow samples: If your disease responds well, an additional sample will be collected at that time. Additional samples will be collected at 12, 36, and 60 months following Cycle 1, Day 1, to check for low levels of disease in your bone marrow. If your disease worsens, another sample will also be collected. For more information in the “Information on Study Samples” section below. • You may have imaging performed 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, thereafter every 8 weeks for 24 months, and then every 16 weeks. It will take you around 20 minutes to complete these questionnaires.
End of treatment	• After you discontinue the treatment, you will visit the site 30 days after receiving the last dose of the study drug and before starting another treatment for your myeloma. You will be asked to complete 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 assess your general health and for scientific research: about 1 teaspoon to 2 tablespoons (about 5 to 28.5 mL) of blood will be drawn. Find more information in "Information on study samples."

After completion or discontinuation of study treatment	After discontinuing the study treatment, you will enter the Follow-up period. Depending on your cancer status, you will need to visit the site every 4 weeks or every 4 months, and various tests will be performed. <u>Follow-up before the worsening of 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 can be collected. About 1 teaspoon (approximately 11 mL) of blood will be used for testing and scientific research. Find more information in "Information on study samples." • 24-hour urine sample will be collected before every visit. This will help the study team better understand your cancer status. • If your disease begins to worsen, an additional bone marrow sample will be collected at that time to assist the study team in better understanding the status of your cancer, as well as for scientific research, as described in the "Information on Study Samples" section below. • As your disease worsens, imaging will be performed to monitor the cancer in your body (using the same method mentioned during screening). • You will be asked to complete questionnaires via an electronic device for every 4 weeks for the first 6 months, thereafter every 8 weeks for 24 months, and thereafter every 16 weeks thereafter. It will take you around 20 minutes to complete these questionnaires. <u>Follow-up in case of worsening 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 group you are in, blood samples may be collected. Approximately 1.5 teaspoons (about 13 mL) of blood will be used for testing and for scientific research. Find more information in "Information on Study Samples." • 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, thereafter every 8 weeks for 24 months, and thereafter every 16 weeks thereafter. It will take you around 20 minutes to complete these questionnaires.
During the study (from screening to End of Study)	Assuming you are on the 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: • Carry a wallet-sized study card containing information about the study. • 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. • Tell the clinical staff about any other drugs or treatments BEFORE you take them. • Not use any other experimental treatment, nor enroll in this same study at any other site. • Not donate blood until 90 days after the last study treatment dose. During the study, your doctor might ask you to: • To take a photograph or video, 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. These photographs and videos will be anonymized, meaning they can no longer be linked back 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 in which an incision is made to remove a portion of tissue, and a tissue sample is obtained. You may be given local anesthesia. The sponsor may request to obtain additional material from that biopsy sample. Your personally identifiable information that could directly identify you will be removed from your sample.
	Optional Other Services: For more information on how your information is collected and shared, please see the “Privacy Appendix.”

WHAT IS THE INVESTIGATIONAL STUDY TREATMENT?

The sponsor provides the investigational study treatment, called “JNJ-79635322,” which is a type of treatment known as a trispecific antibody. Naturally occurring antibodies in the body attach to proteins that are foreign to your body, such as those found on viruses or bacteria, thereby helping to prevent infection. Trispecific antibodies are antibodies that attach to 3 different proteins. The study drug can attach to 2 different parts of a cancer cell's protein, while its third part attaches to T-cells. T-cells are a type of white blood cell that helps protect the body from infections and may help 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, has been approved by the US FDA and the EMA for the treatment of patients with Multiple Myeloma who received more than 3 prior lines of therapy. Based on recently available clinical trial data, teclistamab has demonstrated improved response compared to standard of care in patients with multiple myeloma who have previously received 1–3 prior lines of therapy, similar to your current stage of disease.

What treatment will I receive?

Not every person in this study will receive JNJ-79635322. You will be assigned to one of the treatment groups by chance (much like rolling a dice). This study involves 2 treatment groups, which means that every individual will have an equal opportunity to be placed in either group. Importantly, your study doctor will not have any power to decide which group you get into.

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). Subsequently, the full dose of the study drug is administered. Each treatment **cycle lasts 28 days**, beginning 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. You will receive the study drug as long as you can tolerate it and your disease responds to the treatment; however, you will receive it for a maximum of 36 months. To reduce the risk of certain side effects, you will receive some post-treatment medications.

- **Treatment Group 2:** Teclistamab will be administered.

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

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

If you are unable to come to the site to take your scheduled dose, please discuss with the clinical staff treating you at the site.

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

There may be risks associated with the procedures described under “What Happens During the Study.” If you have any concerns, please speak to the clinical staff.

- **ECG:** There is generally no risk with having an ECG. The sticky patches can pull your skin or cause redness or itching.
- **MRI:** You will be in a small enclosure which can be noisy, so this may cause some anxiety. If a contrast agent is used, your study doctor will inform you about possible side effects or allergic reactions.

- **CT Scan/PET:** Injecting contrast material may cause bruising; possible reaction to the injection, but you will be closely monitored. CT scans do use low levels of radiation (equivalent to 1-5 years background radiation), which has a small potential to cause cancer and other defects.
- **Bone marrow aspiration:** You may experience pain and discomfort during and after the procedure, and there is a risk of infection and 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:** The site where a needle is inserted into your skin to collect a blood sample may get a bruise or become irritated. Some participants may faint and, in rare cases, can get an infection.
- **Tissue biopsy:** [as part of the Standard of Care (SOC) action for side effects (such as rashes) at your hospital, if applicable] You may experience slight pain at or around the biopsy site for a few days. You may experience bleeding, bruising, scarring, or infection. If you are prescribed antibiotics after the biopsy, there may be a possibility of an allergic reaction to the antibiotics. If anesthesia is used, there is a small risk of problems, such as an allergic reaction or difficulty breathing.

Risks

Any drug has risks and side effects, which may vary from person to person. These side effects can be mild to very severe, and even life-threatening. Most side effects will go away after treatment is stopped, but some may be long lasting. Side effects seen in research studies can result from a 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 (applicable only to participants taking JNJ-79635322), or potentially other medications administered by IV or by mouth, may have risks and benefits, depending on characteristics related to your health and other medications. Please consult your study doctor for information regarding these medications.

Not all potential discomforts, side effects, and risks associated with the study drug are known. New side effects may occur. Your study doctor will monitor you, and if any side effects occur, you will receive appropriate treatment. If you experience any of the side effects listed below, or any side effect not included in this list, please inform your study doctor immediately. You will be informed of any new information that may affect your decision to continue participating in this study. During the study treatment, your study doctor will monitor you for side effects and provide treatment.

Risks Associated with JNJ-79635322

As of September 28, 2025, 263 clinical study patients have been treated with JNJ-79635322. This section provides you with the information currently known regarding the potential side effects of JNJ-79635322, based on clinical experience with JNJ-79635322 and other treatments that work in a similar way.

Cytokine Release Syndrome (CRS)

- CRS may occur upon taking the study drug. It may be mild or moderate, and rarely, it may be severe or even lead to death. Most patients who develop CRS experience a fever; however, some

may also experience abnormal blood pressure, chills, rapid heartbeat, difficulty breathing, fatigue or weakness, headache, nausea, vomiting, or wheezing. CRS has occurred in approximately 50% of patients treated with JNJ-79635322. Most cases occurred after just the first few doses and mostly have been mild; all patients recovered with supportive care.

- If you develop CRS during this study, you may receive a medication called tocilizumab, corticosteroids, or other treatments for CRS symptoms; your study doctor will explain the potential side effects to you.
- You will be given a lower dose of the study drug (known as a step-up dose) before receiving the full therapeutic dose.
- Your study doctor will examine and monitor you for symptoms of CRS throughout the course of your treatment. Hospitalization may be required for monitoring or treatment. If CRS is severe, treatment with the study drug may be paused or discontinued.

Neurological Side Effects

- Neurological side effects, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), may occur. ICANS can be mild or moderate, but in rare cases, it can be severe or even fatal. Neurological side effects may include, but are not limited to: sleepiness, confusion, speech disorders, difficulty writing, delirium, numbness/tingling in the hands, feet, or limbs, slowed thinking, difficulty remembering things, and changes in mental status. To date, ICANS has occurred in three patients (approximately 1% of patients treated with JNJ-79635322); these cases were mild and resolved quickly with appropriate treatment.

Infections

- Taking this medication may increase your risk of developing an infection or a more severe infection compared to when you are not taking the study drug. This may occur due to low antibodies (hypogammaglobulinemia) or a decrease in the number of white blood cells (neutropenia), which may result from the treatment or because of the disease itself. Infections have occurred in up to 75% of patients; most of these infections were mild and resolved with treatment. Serious infections including life-threatening and fatal infections have been observed rarely in patients treated with JNJ-79635322.
- Infections can occur in any part of the body. Examples include:
 - Upper respiratory tract infections, which affect your nose, sinuses, and throat. Examples include viral infections, such as the common cold and the flu.
 - Lower respiratory tract infections, which affect the lungs, such as pneumonia.
 - Other infections that may cause symptoms in organs such as your intestines, liver, or bladder.
- If you currently have an infection, have a history of recurrent infections, or are feeling unwell, you should inform your study doctor immediately. Signs of an infection may include fatigue, headache, fever, chills, aches and pains, cough, congestion, chest tightness, or difficulty breathing. Serious 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 reported.
- Your study doctor can check for infections and may prescribe medication(s) to prevent and/or treat them.

Hypogammaglobulinemia (low antibody levels)

- Treatment with the study drug may result in reduced antibody levels, which can affect your immune system and increase the risk of infection. Hypogammaglobulinemia has been reported in approximately 20% of patients taking the study drug.
- You should not receive live attenuated vaccines against viruses, as there is a possibility that the vaccine itself could cause an infection if your immune system is compromised. While you are taking the study drug, vaccines may not work as effectively.
- Your study doctor may recommend immunoglobulin replacement therapy, which provides replacement antibodies that can help fight infections.

Immune-related Effects

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

Bone Pain

- Bone pain may occur when the study medication targets cancer cells present in the bone, and this has been reported in approximately 15% of patients.
- Your study doctor may administer supportive care, such as corticosteroids, to manage the pain.

Oral Side Effects

- Oral side effects may include dry mouth, changes in taste, loss of taste, and difficulty swallowing. Approximately 50% of patients have experienced changes in taste. Over time, significant weight loss may occur. Changes in weight will be monitored regularly throughout 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

- Changes to the skin and nails may occur. Skin changes may include dryness, skin peeling, itching, and rashes. Palmar-plantar erythrodysesthesia (PPE) also called as "hand-foot syndrome", may cause redness, swelling, and blistering of the hands and feet. Changes in the nails may include nail loss, peeling, ridging, discoloration, breaking, loosening, and shedding of the nails, and nail separation from the skin. Rashes may be localized, occurring at the site of subcutaneous medication administration, or may be widespread. To date, approximately 30% of patients have experienced dry skin, and about 25% have experienced changes in their nails; all of these changes were mild.
- Your study doctor may prescribe lotions, corticosteroid creams, or corticosteroid tablets, and they may also consult with a dermatologist.

Systemic Administration-Related Reactions (sARR)

- sARR may occur during or immediately after study drug administration. This applies if you experience dizziness, weakness, nausea, lightheadedness, itching; or if you feel that you are

developing a fever, chills, a cough, throat tightness, flu-like symptoms, a runny nose, sneezing, a sore throat, difficulty breathing, nausea, vomiting, or pain (in the chest, back, abdomen, muscles, or joints). If you experience any of the following, seek emergency medical assistance: hives, wheezing, difficulty breathing, swelling of the face, lips, tongue, or throat, or chest pain.

- To help control reactions associated with systemic administration, medications may be administered before and after at least the first dose of the study drug. Your doctor will explain the side effects of these medications to you.
- If you experience a sARR, your study doctor will continue to monitor you and may make changes to the method of administering the study drug, or to the medications given before and/or after the study drug. If the reaction is severe, treatment with the study drug may be paused or discontinued.

Injection Site Reactions

- Injection site reactions may occur when the study drug is injected under the skin.
- Symptoms may include mild pain, bruising, swelling, a burning sensation, itching, redness, or hardening of the skin at the injection site. Approximately 25% of patients have experienced redness at the injection site, and most cases were mild. Severe injection site reactions have occurred in less than 1% of patients.
- Your doctor will determine whether treatment is required for an injection site reaction and what the best method of treatment is.

Tumor Lysis Syndrome (TLS)

- TLS is a potentially life-threatening condition that occurs when cancer cells are destroyed rapidly. Signs of TLS include: abnormal results on blood tests for levels of potassium, phosphate, calcium, and uric acid levels. TLS can lead to kidney damage, heart problems (such as an irregular heartbeat), and seizures. TLS has occurred in two patients (less than 1% of patients), and in both cases, the condition was 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 necessary.

Effects on Blood Cells

- During treatment with the study drug, the following effects on blood cells may occur:
 - Decrease in neutrophil count (neutropenia). Neutrophils are a type of white blood cell that forms part of the body's immune system and fights against infections. If their count drops too low, you are at risk of developing a serious infections. If you experience both fever and neutropenia at the same time, this will require additional monitoring or treatment by your study doctor. Approximately 45% of patients have experienced neutropenia.
 - Decrease in lymphocyte count (lymphopenia). Lymphocytes are a type of white blood cell that forms part of the body's immune system and fights against infections. If their count drops too low, you are at risk of developing an infection. Approximately 30% of patients have experienced lymphopenia.
 - Decrease in hemoglobin (anemia). Hemoglobin is the component of red blood cells that carries oxygen in your blood. If your hemoglobin levels are low, you may experience

fatigue, weakness, or difficulty breathing. Approximately 20% of patients have experienced anemia.

- Decrease in platelet count (thrombocytopenia). Platelets help your blood clot and stop bleeding, or prevent it from occurring. If their count drops too low, you are at risk of bruising or bleeding. Approximately 15% of patients have developed thrombocytopenia.
- Your study doctor will monitor your blood during treatment and will administer blood transfusions or provide supportive care if necessary.

Other

- During the study, your condition may remain unchanged or it may worsen.
- As this study medication is administered to more people, unexpected side effects may occur that have not been described here. If you experience any side effects, please inform your doctor immediately.

Risks Associated with Teclistamab

This section provides information regarding the side effects observed 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 received Teclistamab alone, and 1,018 patients received Teclistamab in combination with other therapies.

The following side effects have been identified for 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 • Lung infection (Pneumonia) • COVID-19 • Urinary tract infection	• Sepsis (a life-threatening condition that occurs when the body responds to an infection in a way that damages its own tissues and organs) • Cellulitis (a bacterial infection of the skin causing redness, swelling, and pain in the infected

Body System	Very Common (may affect 1 in 10 patients or more)	Common (may affect fewer than 1 in 10 patients)
		area)
Effects on Blood Cells	• Low white blood cells (including neutropenia, lymphopenia, leukopenia) • Low platelets (thrombocytopenia) • Low red blood cells (anemia)	• Fever with 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 disorder (encephalopathy) • Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (see “Neurologic Side Effects” below for details)
Vascular	• High blood pressure • Low blood pressure • Hemorrhage	
Pulmonary	• Cough • Shortness of breath (Dyspnea)	• Low oxygen levels (hypoxia)
Gastrointestinal	• Nausea • Diarrhea	• Elevated pancreatic blood test (increased amylase and lipase)

Body System	Very Common (may affect 1 in 10 patients or more)	Common (may affect fewer than 1 in 10 patients)
	• Constipation • Vomiting • Abdominal pain	
Muscles, Bones, and Connective Tissues	• Pain in muscles or bones (musculoskeletal pain) • Sudden muscle movements (muscle spasms)	
General Disorders and Administration Site Conditions	• Injection site reactions (See separate section below for details) • Fatigue (Weakness) • Pain • Fever • Swelling of the face, hands, feet, or limbs (Edema)	
Hepatic	• Elevated liver blood test	
Renal		• Abnormal kidney blood test

Cytokine Release Syndrome (CRS)

For the definition, signs and symptoms, and management of CRS, see the 'Risk JNJ-79635322-CRS' section. Signs and symptoms of CRS with Teclistamab include fever, and may include chills, abnormal blood pressure, difficulty breathing, rapid heartbeat, headache, and abnormal liver function test results.

CRS has occurred in approximately 72% of patients treated with Teclistamab. Most cases occurred within the first few doses, and the majority of these cases were mild or moderate.

Neurological Side Effects

For the definition, signs and symptoms, and management of neurological adverse reactions, refer to the 'Risks: JNJ-79635322 Neurological Side effects' section. ICANS has occurred in approximately 3% of patients who received any dose of teclistamab. Most cases of ICANS were mild or moderate; however, severe, life-threatening, or fatal (potentially resulting in death) cases of ICANS have also occurred following treatment with teclistamab.

Injection Site Reactions

For the definition, signs and symptoms, and management of injection site reactions, please refer to the 'Risks: JNJ-79635322 Injection Site Reactions' section. Injection site reactions can occur when medications are administered via subcutaneous injection; these reactions have been observed in approximately 38% of patients who received subcutaneous injections of teclistamab.

Hypogammaglobulinemia

For the definition, signs and symptoms, and management of hypogammaglobulinemia, please refer to the 'Risks: JNJ-79635322 Hypogammaglobulinemia' section. Hypogammaglobulinemia has occurred in approximately 75% of patients treated with teclistamab.

Infections

- Due to the risks of hypogammaglobulinemia and a low white blood cell count, the risk of developing an infection or a more severe infection may increase. The most common infections observed in patients treated with teclistamab 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 are feeling unwell or suspect you may have a fever, you must inform your study doctor immediately.
- Teclistamab has been associated with reactivation of viruses, including hepatitis B and JC virus is included.
 - Reactivation of hepatitis B can lead to severe liver infection or death. Before starting treatment in this study, your doctor will test you for the Hepatitis B virus. If you test positive for the virus, you will be closely monitored for signs of infection. If you experience worsening fatigue, or if your skin or the white part of your eyes begin to turn yellow, inform your doctor.
 - Progressive multifocal leukoencephalopathy (PML) is caused by the reactivation of a virus (the JC virus) and can be life-threatening. Your doctor will monitor you for symptoms of PML and will discontinue the administration of Teclistamab if PML is suspected. Inform your doctor if you experience changes in vision, difficulty speaking, weakness in your arms or legs, changes in your gait, difficulty with 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 are an additional condition that has been observed in patients treated with Teclistamab. However, it is unclear whether this was caused by Teclistamab or if it occurred due to other factors.

Immune-related side effects may occur when the immune system is stimulated by medications that bind to immune cells. Side effects may include rashes, abnormal liver function tests, thyroid and/or adrenal dysfunction, inflammation of the large intestine, inflammation of the lungs, and neuropathy.

Driving and Operating Machinery

Nervous system-related side effects may affect your ability to drive or operate machinery. Because these side effects are more likely to occur at the beginning of treatment, you should not drive a car

or operate machinery from the time you receive the first step-up dose of teclistamab until 48 hours after receiving the first full treatment dose. If you experience any other nervous system-related side effects at any other time during treatment, you should also refrain from driving a car or operating machinery until your study doctor advises otherwise.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participating in this study may improve your condition, but there is no guarantee that this will happen. During the study, your condition may remain unchanged or may worsen, and you may experience side effects or require hospitalization. Your participation may help future patients, as researchers will gain a better understanding of the potential efficacy and safety of JNJ-79635322 in the treatment of multiple myeloma.

There is a possibility that the investigational product may fail to provide the expected therapeutic benefit.

WHAT ELSE DO I NEED TO KNOW?

What other treatments are available besides this study?

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

Other treatments available for Relapsed or Refractory Multiple Myeloma may include medications from the categories listed below, which may be used alone or in combination:

Proteasome Inhibitors: Carfilzomib, Bortezomib

Immunomodulatory Drugs (IMiDs): Lenalidomide, Pomalidomide

Monoclonal Antibodies (Anti-CD38): Daratumumab

Bispecific Antibody: Teclistamab

Chemotherapy agents: Cyclophosphamide, Melphalan

Clinical staff will explain the benefits and risks of these other treatments or studies and discuss what will be best for you.

Birth control and pregnancy during the study

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

For participants with childbearing potential:

- If you are pregnant or are actively breastfeeding, you **cannot** participate in this study, as the study medication could 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 receiving the final dose of the study medication.
- If you can become pregnant and are sexually active, you must agree to use effective methods of contraception until 6 months after receiving the final dose of the study medication. It is mandatory

to discuss the type of contraception you intend to use with the study doctor and obtain their approval before beginning the study.

- If you become pregnant during the study, you must inform the study doctor and immediately stop taking the study medication. The study doctor will advise you regarding your medical care and will request your permission to collect information about your pregnancy and the health of your child.
- If your childbearing potential changes, or if your risk of becoming pregnant changes after the study has begun, you should start using effective methods of contraception and immediately discuss this with your study doctor.

For participants capable of producing sperm:

- You must agree not to donate sperm or father a child while participating in this study, or within 6 months after receiving the final dose of the study medication.
- When you are sexually active with a partner who could become pregnant, you must agree to use effective methods of birth control during the study and for 6 months after receiving the last dose of the study medication.
- The type of contraception you (and your partner, if she could become pregnant and if applicable) intend to use must be discussed with, and approved by, the study doctor before you begin the study.
- If your partner becomes pregnant at any time from the start of your taking the study medication until 6 months after your last dose of the study medication, you must immediately inform the study doctor. The Sponsor may request your and your partner's permission to collect information regarding the pregnancy and the health of the child.
- Use condoms whenever there is a possibility of transmission of sperm/ejaculate.

This study may involve risks to your embryo or fetus that are currently unforeseen. If you become pregnant during the study, you must immediately inform the clinical staff. They will advise you regarding the study treatment, continued medical care, and the collection of information about the pregnancy and the child. By signing this consent, you agree to share necessary medical information regarding your pregnancy. You may change your mind at any time.

If your partner becomes pregnant by you during the study, she will be asked to sign a separate consent form to allow for the collection of information regarding the pregnancy and the health of the child. This is optional for your pregnant partner, and she may change her mind at any time. By signing this main consent form as a study participant, you agree to the collection of this information.

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 study visits, such as local travel, meals, and/or accommodation costs, if any. Caregiver expenses may be reimbursed for costs directly associated with study visits where you require an accompanying person, and this will be reviewed on a case-by-case basis.

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

Your caregiver may receive up to **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 regarding reimbursements permitted by the sponsor for you and your caregiver.

Who pays for study tests and procedures?

The sponsor will provide all investigational study treatments and will pay for the visits, tests, and procedures that are part of the study.

The sponsor will not pay for doctor visits, tests, and procedures that are not part of this study. These will be covered by you, your insurance company, or a government health plan. If you have any concerns, please speak 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 mind 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; however, this will be fully discussed with you, along with alternative treatments or research options. Reasons for removal may include:

- It is in your best medical interest to discontinue participation.
- You do not follow the instructions of the clinical staff.
- The study is cancelled or the recruitment of new participants is stopped before you are enrolled.
- You no longer meet the eligibility requirements.

The study doctor/staff will discuss with you the reasons for your removal from the study, other treatment or research options, and if necessary, will plan for follow-up regarding any side effects.

Can I continue taking the study medication after the study has concluded?

After the study concludes, you may continue taking the study medication(s) provided that approval is obtained from the treating physician and the Independent Ethics Committee/Institutional Review Board as designated by the Sponsor. Your study doctor/staff will discuss your options regarding your future medical care with you.

FINANCIAL COMPENSATION AND MEDICAL MANAGEMENT

The regulations governing the conduct of clinical trials in India require that, in the event of a study-related injury or death, you be provided with medical management and paid financial compensation.

(a) In the event that you sustain an injury during the study, you will be provided with free medical treatment for as long as it is required, or until it is proven that the injury is not related to the clinical trial, whichever occurs first.

(b) In the event of a trial-related injury or death, the Sponsor or its representative, or the Investigator or the Center, as the case may be, shall provide financial compensation for the injury or death in accordance with Rule 39 of the New Drugs and Clinical Trials Rules, 2019.

The above statement does not limit your legal rights.

HOW IS MY PRIVACY PROTECTED?

The clinical staff and the Sponsor will safeguard your personal data (information collected from you and during this study) as required. The study staff and the Sponsor will manage your personal data (information about you) in accordance with applicable Indian data protection and privacy laws, and in the manner described in this consent form. The “Privacy Appendix” provided in this document describes your rights about the use and protection of your personal data.

INFORMATION ON STUDY SAMPLES

The clinical staff will collect biological samples (blood, urine, bone marrow) from you for the purposes of this study and will provide them to the Sponsor or an authorized representative, as described in this consent form. If there are any changes to the testing of your samples during the study, the clinical staff will inform you of such changes.

How are my samples kept confidential?

To protect your privacy, clinical staff will label your samples and any test results with a study number and your coded participant number. No direct personal identifiers are used, and only clinical staff will be able to link the samples to your name.

How long will my samples be stored?

Your samples will be stored for up to 15 years, or until you request that they be destroyed. The sponsor plans to securely store the samples in a long-term storage facility in the USA. The samples may be moved to a different location by the Sponsor at any time.

Will genetic testing be performed on my samples?

Genetic testing may be performed on your biological samples. This involves examining genes, which serve as instructions for our cells. Genes are composed of molecules called DNA. The DNA can be copied by cells into a molecule called RNA. RNA provides instructions to the cells for making proteins.

Testing conducted as part of this study may include a test called 'Fluorescence In Situ Hybridization' (FISH) on specific regions of your DNA. FISH detects changes in the structure of your DNA, but it does not reveal the complete details of your genetic sequence.

Testing conducted as part of this study may include whole genome sequencing and/or single-cell sequencing, which involves examining the entire set of DNA or RNA obtained from your bone marrow.

What are the risks associated with Genetic Analysis?

Because your genetic information is unique to you, there is a possibility that someone could identify you or your close biological relatives using your genetic information. The risk of this occurring is

low; however, as technology advances, this risk may increase in the future. In the rare event that your genetic information is disclosed to other companies, applicable national laws may not fully protect you or your family from decisions made based on that genetic information.

Will I receive the results of the Genetic Analysis?

The results of the genetic testing performed on these samples are solely for scientific research purposes and will not be used for your medical care or to provide any diagnosis regarding your health. Therefore, these results will not be provided to you or to the clinical staff.

USE OF STUDY RECORDS AND SAMPLES

This section explains how your study records and samples may be used and shared, and what measures have been taken to protect the privacy of participants.

Coded Data and Samples

For the purposes of this study and related research, the Sponsor and other authorized parties may use and share your coded Study Records and samples (without personal identifiers) to advance clinical science and medical knowledge, as 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 previous studies to new studies, or to improve methods of scientific analysis.
- To ensure that the sponsor complies with decisions and/or approvals from regulatory authorities regarding the availability and reimbursement (where applicable) of the study drug.
- To fulfill legal and regulatory obligations related to clinical studies and product safety requirements.
- To publish the results of the research described above in scientific journals or to use them for educational purposes.

Anonymized Data and Samples

The Sponsor may generate anonymized data or samples for scientific research purposes. Research using anonymous data or samples may have a scientific purpose beyond the compatible research described above. To prepare anonymized data or samples, your coded participant number and other information that could indirectly identify you, such as the exact dates of your treatment, will be removed from your data and samples. The Sponsor may share anonymized data or samples with others for scientific research purposes, as permitted by applicable laws.

For any such scientific research that may be conducted and which is not part of this study, you will not receive details or results of that research, and it is not expected that such research will provide you with any financial or direct benefit.

WITHDRAWAL OF CONSENT

You may withdraw your consent or change your mind about participating in the study at any time. This means that you may either stop taking JNJ-79635322 or Teclistamab but continue with the study assessments; or you may stop taking JNJ-79635322 or Teclistamab and stop attending any further study visits. If you withdraw from this study, in order to maintain the scientific validity and integrity of the study, data already collected, including test or test results, samples, videos, or images of physical findings related to adverse events, will continue to be shared and used for the purposes of the study. If you stop attending study visits, no further tests related to the study will be conducted. The clinical staff will discuss with you how your health will be managed if you choose not to attend further study visits. The clinical staff may also discuss how they will follow up on your health status, as described in the table below.

Upon completion of the study, you may also withdraw your consent for your samples to be used for the corresponding purposes described in the "Use of Study Records and Samples" section above.

The clinical staff may ask you to fill out a Withdrawal of Consent form. The Withdrawal Of Consent form is optional, but it can help you understand the different withdrawal options and how your follow-up can be managed. You do not need to sign this form; you can simply tell the clinical staff that you want to stop taking JNJ-79635322 or teclistamab and stop coming to further appointments.

It is necessary to collect long-term outcomes for JNJ-79635322 or Teclistamab. These results may help regulatory or health authorities determine how a new drug/treatment may benefit other patients. Therefore, it is important to follow-up on your health status until the end of the study, and this can be done as described below. Please discuss these options with the clinical staff and ask any questions you may have. You do not need to do this; you can simply tell the clinical staff that you want to stop participating in the study.

If you stop coming to study visits, please review the health status follow-up options below:

The clinical staff may contact you directly in the ways described below.	If you do not wish to be contacted directly, clinical staff may use the sources listed below:	If you do not consent to the previously mentioned direct or indirect contact, if it is permitted in your country, the clinical staff may 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 unsuccessful, the clinical staff may seek the assistance of an independent locator company, which reviews publicly available sources to locate you based on your health status. This is described above in this ICF, under the section "What Happens During the Study – Other Optional Services." You will not be contacted directly; however, if you decide to discontinue your participation in this study, you may opt out of this process.

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 studying your disease and conducting genetic research [if applicable]. Johnson & Johnson Private Limited may also use this information to apply for permission to market the medication in certain countries. The information will be stored on both paper and computer. To protect your privacy, information will be marked in such a way that you cannot be identified. If the results of the study are published, your identity will be kept confidential. By signing this form, you are granting permission for this use of your information.

Your study doctor will retain your personal medical records, as well as a list linking each participant's name to their code number, for a period of at least 15 years.

Regulatory authorities, members of the Ethics Committee/Institutional Review Board, staff at the study site, and representatives of Johnson & Johnson Private Limited have access to this list and will be able to compare and verify the information collected about you against the information contained in your medical records. To the extent permitted by law, your medical records will not be made public. By signing this form, you are granting direct access to your medical records to those individuals who have a valid reason to view them.

The collected information may be shared with other members of the Johnson & Johnson group of companies, contractors working on their behalf, and regulatory authorities.

You can arrange to view the information collected about you with your study doctor, and you may request to correct any errors. Johnson & Johnson Private Limited may suspend your access to your information if it interferes with the study itself. If you decide to withdraw from the study at any time, Johnson & Johnson Private Limited may still use the information collected about you up to that point, if permitted by law.

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 form, you agree that, after the study is completed, the clinical staff may contact you to provide a summary of the results.

A market research company appointed by the Sponsor may contact you after the study is completed to discuss your clinical trial experiences and your illness/condition. This is very important, as it can help improve future clinical trials for both participants and for the clinical site teams. Please indicate your preference at the end of this consent form so that your contact information may be shared to a supplier. Providing this feedback is optional; you may agree now, but you may decline later when you are contacted. If you withdraw from the study prematurely, you may change your mind and inform the clinical staff not to share your contact information.

PRIVACY ADDENDUM TO THE MAIN INFORMED CONSENT FORM

Medical Record - information and data, including personal details, recorded by the clinical staff; stays on-site.

Study Records – Medical record data (excluding personal details) documented by the clinical staff and shared with the Sponsor.

1. What personal data will clinical staff collect?

If you participate in this study, clinical staff will collect and share your personal data for research purposes. **Personal data** may include:

- Information about your health obtained from existing or past medical records, or 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 such as 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 data such as [racial or ethnic origin, sex assigned at birth] which is collected only when necessary to evaluate the results of the study.

2. Who will have access to my medical records?

Your personal data will be recorded in your **Medical Records**, which may be stored in paper files and electronic databases, including databases that can be accessed remotely (if permitted in your country). Clinical staff will have access to your **Medical Records**. Additionally, the individuals listed below may also have direct access to your medical records to ensure that the research study is being conducted properly.

- 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 individuals participating in the research).
- Regulatory Authorities: local and outside your country.
- Other persons or groups, as required by law, who may be located outside your country. In other countries, the level of security for your information may vary.

3. How will my personal data be protected?

Clinical staff will extract information from your medical records and also enter it into your **Study Records**. These data are provided to the sponsor for study purposes. You will be identified solely by the study number and your coded participant number. Direct personal identifiers such as your name, initials, or date of birth will not be included in your **Study Records**. Clinical staff may link the Study Records to your name; however, this information will be kept confidential and will not be shared with the sponsor or any other party, except where required by law.

4. How will my Study Record be used and shared?

The sponsor and other authorized parties specified in this consent form will use and share your coded **Study Records** for scientific research purposes, as well as for relevant research described and authorized within this consent form. Refer to the section titled “Use of Study Records and Samples.” Authorized parties may include organisations providing services for the sponsor (such as laboratories), researchers, collaborators, and companies that may have a common interest in the study drug or disease. The sponsor, other authorized parties and Regulatory Authorities may be located outside of your country, where laws may provide a different level of protection.

5. Data transfer

As required by applicable laws, when your personal data is transferred outside of your country, safeguards are in place to ensure its protection. This also applies to individuals who access your data remotely, as well as when such data is shared in the manner described above.

6. Will my personal identifiers be shared with service providers?

Clinical staff may share certain personal identifiers such as your name, home address, email address, or phone number with a service provider relevant to the applicable service, for instance, a locator agency. The clinical staff will discuss this with you in detail. These identifiers will not form part of your study records; furthermore, the service provider will neither use nor retain them for any purpose other than fulfilling the objectives of this specific service for the study.

7. How long will my personal data be retained?

In accordance with local laws and requirements, the clinical staff will retain your **Medical Records** at the study site. The Sponsor may retain your **Study Records** in compliance with applicable laws for as long as necessary, OR for a period of 15 years.

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

If you wish to review, correct, or delete your personal information, or make any other request in accordance with the laws of your country, you should contact the clinical staff at **+91-9007016755**. You may not be able to review your data until the study ends. Your request to delete your personal data may not be granted, depending on the rules and laws that require the retention of clinical research data and personal information.

YOUR CONSENT TO PARTICIPATE

If you agree with all the statements below and wish 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 research participant.
- I agree that the clinical staff may inform my other doctors that I am participating in this study and may disclose any side effects.
- I agree that my doctors, other healthcare professionals, institutions and hospitals, or laboratories may provide information regarding my disease and treatment to the clinical staff for the purposes of this study.
- I understand that I must keep confidential (a) "Confidential Information" described in the Information Sheet provided above, and (b) the information I receive during the study; furthermore, I must return all study supplies (whether used or unused, including even empty tubes or boxes, as applicable) and diary sheets (both used and unused) to the Principal Investigator.
- This document is written in a language that I can read and understand.
- I understand that I will be provided with a copy of the signed ICF.

AUDIO-VIDEO CONSENTING:

You are requested to sign the Audio-Video Consent Form. Audio-video recording of the Informed Consent process is a requirement under Indian Regulations. This consent form is required if the study drug is not approved for use in India for the specific disease or condition, and if you belong to a group representing prisoners, armed forces personnel, staff and students of medical, nursing, and pharmacy academic institutions, patients with incurable diseases, unemployed or impoverished individuals, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, or other individuals unable to provide personal consent. If you have certain conditions such as Leprosy or HIV, only an audio recording of the informed consent process will be made.

I understand that audio-video consent is required under Indian regulations, and I agree to sign the audio-video consent form, as applicable.

Check Yes or No:

Yes ☐ No ☐ NA ☐

HIV (Human Immunodeficiency Virus) Testing:

I understand that, to determine my eligibility to participate in this study, my HIV status will be assessed either through a medical history review or via a blood test. The study doctor has explained to me the importance of this assessment, provided the necessary information associated with it, and conducted pre-test counseling. 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 hereby give my consent to provide my medical history or to undergo HIV testing.

Check Yes or No:

Yes ☐ No ☐

I understand that if I do not consent to provide my medical history or undergo HIV testing, or if my test result is positive, I will not be eligible to participate in this study. Check Yes or No:

Yes ☐ No ☐

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

Yes ☐ No ☐

I understand that if my HIV test result is positive, post-test counseling will be conducted by the study doctor, or by a qualified person appointed by them or by the study site. Check Yes or No:

Yes ☐ No ☐

Please indicate whether you consent to your contact information being shared with a market research company:

☐ I agree ☐ I do not agree

Please indicate whether you consent to the inclusion of anonymized photographs and videos, which may be shared with the sponsor and used in presentations and publications related to this study. If you do not agree, this will not affect your participation in the study.

☐ I agree ☐ I do not 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: _____

Participant's Qualification: _____

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

(Please tick the appropriate option)

Participant's Annual Income: Rs. _____

Name and Address of Nominee(s), and Relationship to Participant (for the purpose of compensation in the event of death related to the trial): _____

Sr. No.	Declaration	Initial in the 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; that I have had the opportunity to ask questions; and that I have received satisfactory answers and information.	[]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on behalf of the Sponsor, the Ethics Committee, and regulatory authorities will not require my permission to view my health records in relation to both the current study and any further research that may be conducted in connection with it, even if I withdraw from the trial. I consent to this access. However, I understand that my identity will not be disclosed in any information released or published to third parties.	[]
(iv)	I agree not to restrict the use of any data or results arising from this study, provided that such use is solely for scientific purpose(s).	[]
(v)	I agree to participate in the above-mentioned study, subject to the conditions set forth in the above Information Sheet.	[]

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

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

Name of Signatory: _____

Signature of the Investigator: _____

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

Name of Study Investigator: _____

Statement of Impartial Witness: I confirm that the information provided in the consent form was accurately explained to the patient and/or the patient's legally acceptable representative and was clearly understood by them, and that consent was given voluntarily by the patient and/or their legally acceptable representative.

Signature of the Witness: _____

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

Name of the Witness: _____

(A copy of the Patient Information Sheet and the duly filled Clinical Informed Consent Form shall be provided to the Participant or his/her attendant)