

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

|                       |                                                                                                                                                                                                                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study Protocol:       | TAK-226-3001                                                                                                                                                                                                                                                                                                |
| Study Title:          | A Phase 3, Multicenter, Open Label, Randomized Trial to Compare the Efficacy and Safety of Elritercept versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in+ ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions |
| Study Drug:           | Elritercept (TAK-226), mentioned throughout the document as the “study drug”                                                                                                                                                                                                                                |
| Sponsor of the study: | Takeda Development Center Americas, Inc.<br>500 Kendall Street<br>Cambridge, MA 02142 USA                                                                                                                                                                                                                   |
| Phase of the study:   | III                                                                                                                                                                                                                                                                                                         |

|                                   |                                                                                                           |
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| Investigator:                     | Dr. Arijit Nag                                                                                            |
| Site Number (in case applicable): | 24003                                                                                                     |
| Site Name & Address:              | Tata Medical Center, 14 Major Arterial Road (EW) New Town, Rajarhat, Kolkata- 700160, West Bengal, India. |
| Country:                          | India                                                                                                     |

# PARTICIPANT INFORMATION SHEET AND CONSENT FORM

## Introduction

You are requested by us to participate in a clinical research study for Study drug (the “Takeda Study Medication(s)”) since you have anemia because of diagnosis of lower-risk myelodysplastic syndrome (MDS) needing blood transfusions. The study is being paid by the company Takeda (“Sponsor”).

Participating in the study is completely voluntary. At any time, you might deny to take part or leave the study, without penalty or loss of benefits to which you are else entitled. It is up to you whether you want to participate or not.

Kindly take time to carefully read this form.

This form tells you vital information regarding the research study. It is vital for you to know why the research is being performed, the possible risks and benefits included, and what you have to do prior to you make a decision in case you want to participate in this research study. Kindly take time to carefully read and discuss the information on this form.

You are encouraged to discuss the information with friends, family, and your doctors in case you wish.

The study to you will be explained by your study doctor or a study team member. Kindly ask your study doctor or a study team member if there is anything that is unclear. Additional information can also be given by them if you require it.

The medical care you get from your doctors at present or in the future will not be changed by your decision.

In case you make a decision to participate, you should put a signature and date on the consent at the end of this form. Even after putting a signature on the consent, you are at liberty to leave the study at any time without providing a reason. This form will tell you how to withdraw and what that means to you.

In case anything regarding the research study changes, you will be informed and you will be asked to put a signature again in case you consent to the changes.

## Why is this study being performed?

We are asking you to participate in a research study for an investigational treatment of anemia because of lower-risk myelodysplastic syndrome (LR-MDS). Your bone marrow is impacted by LR-MDS causing it to not produce enough mature red blood cells resulting in low hemoglobin levels and anemia symptoms. This research study is being offered to you as you require red-blood cell (RBC) transfusions for treating your symptoms of anemia and you have not received other therapies (with some exceptions that your study physician will review) to treat your symptoms of anemia or LR-MDS. ‘Investigational’ in this study means that regulatory authorities has not yet permitted the drug for treatment of anemia because of LR-MDS. In patients with LR-MDS, previous studies showed the study drug could be administered at a safe dose with manageable side effects. In LR-MDS patients, the earlier studies also showed few improvements in hemoglobin and decreased requirement for blood transfusions. This study will assess the study treatment’s use compared to a commonly used treatment.

This study is being performed to help answer the given below queries(s):

- How safe is Study drug and what are the side effects that might be associated with it compared to epoetin alfa?
- How much does Study drug improve symptoms of anemia compared to epoetin alfa which is a commonly used therapy?
- How much does Study drug improve requirement for RBC transfusions compared to epoetin alfa?
- How much does Study drug improve quality of life compared to epoetin alfa?

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Protocol Number: TAK-226-3001

Based on FORM-269793, Version 5

Sponsor Name: Takeda Development Center (TDC) Americas, Inc.

TAK-226-3001 Master ICF Version 2.0 24Sep2025

Back Translation of TAK-226-3001 Master India Participant Information Sheet and Consent Form Version 1.0(bn) 20Jan2026

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This research might permit study doctors to better understand the study drug effects on the body and to recognize future patients who might benefit.

### What is the Takeda study drug?

The Takeda study drug utilized in this study is elritercept (TAK-226).

Elritercept (TAK-226) is a manufactured protein (called a recombinant fusion protein) designed to block other proteins in your body that interfere with blood cell production in the bone marrow. This permits the bone marrow to generate more cells that become mature red blood cells that might improve hemoglobin levels.

This study drug is provided by injection into the fat beneath the skin known as a subcutaneous injection. It is provided one time every 28 days (one time per month). The study drug's dose will not be provided in case your hemoglobin level is raising rapidly or is at a high level, or if the study drug is leading to significant side effects.

### What is the other study drug(s)?

The other drug utilized in this study is epoetin alfa to compare to the Takeda study drug.

Epoetin alfa is a manufactured protein called an erythropoiesis-stimulating agent (ESA) designed to act like a hormone (specialized protein known as erythropoietin) which stimulates the bone marrow to generate more red blood cells. Epoetin alfa was selected as the comparator drug because it is commonly utilized for initial treatment of anemia because of LR-MDS. International clinical practice guidelines has suggested Epoetin alfa.

Epoetin alfa is provided by injection into the fat beneath the skin known as a subcutaneous injection. It is provided one time every 7 days (one time a week). The study drug's dose will not be provided in case your hemoglobin level is raising rapidly or is at a high level, or if the study drug is leading to significant side effects.

In case you are allotted to epoetin alfa treatment, your study physician might permit you to get few of the weekly injections at home or at another permitted location. In case permitted, these injections can be provided by a home healthcare provider or, in case training has been given to you appropriately, by yourself. In case you are permitted to self-administer the epoetin alfa, then you will be asked to fill out a medication diary card and at your next study visit return it to the site.

### How is the study set up?

Patients eligible for the study are randomized study into one of two treatment groups.

You will be chosen randomly to get one of the given below two study treatments:

- Study drug: You have a 1 in 2 (50%) likelihood of getting this treatment. This study drug will be provided as a subcutaneous injection one time every 28 days (once a month).
- Epoetin alfa: You have a 1 in 2 (50%) likelihood of getting this treatment. This study drug will be provided as a subcutaneous injection one time every 7 days (one time a week).

When you are allotted randomly a treatment, this means you are put into a treatment group by chance (such as tossing a coin).

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### How many individuals are in the study and how long will you be in the study?

There will be 210 to 300 patients who will be taking part in this study. Patients should be adults aged 18 years or older with anemia needing blood transfusions because of LR-MDS who have not received other treatment. The study will occur in 28 countries at around 150 clinical sites all over the world. You will be in the study around 5-8 years based on how many patients are enrolled prior to you.

### What will occur at the time of the study visits and what do you have to do?

In case you make a choice to take part in this study, certain personal information will be gathered by the study doctor and study personnel. This section explains what methods will be performed to gather this information.

To take part in the study, you might also be requested to stop certain medicines you are taking presently. The medications you take at present will be discussed by the study doctor prior to you begin the study and tell you whether you are required to stop taking any of them prior to you take the study drug.

As part of this study, this study will collect blood, urine and bone marrow samples from you. To monitor your health status the samples will be used at the time of the study.

Additionally, few of these samples might be used for additional research on MDS looking at “markers” of the disease that can be found in the blood and bone marrow. The Sponsor, its agents and its affiliated companies might use these sample(s) and test data:

- To help develop new ways for monitoring and treating anemia because of LR-MDS diagnosis.
- To generate information required for additional research and diagnostic tests associated with diseases or conditions that might be treated by the Study drug.
- To help acquire country health authority approvals for Study drug.
- To develop a better understanding of how disease-associated gene mutations (from your diseased tissue samples) correlate with safety and efficacy of Study drug and MDS disease states.

This study includes 4 time periods:

1. **Screening Period:** This period begins at the time you provide consent to take part in the study and ends when your study doctor has affirmed whether you are eligible for the study or not and can be randomized to the study treatment. During this time several evaluations and tests will be performed and the study doctor will review your medical history information. This period might take up to 6 weeks and can be raised by an extra 6 weeks (for a total of 12 weeks) in case required for your doctor to affirm whether you are eligible for the study treatment.
  - Rescreening: In case at the time of the screening period it is determined by your study doctor you have the applicable diagnosis of LR-MDS however you are not eligible for the study for other reasons you will not be permitted to begin the study. However in case these reasons are conditions that might change or improve over time, your study doctor might offer to you to repeat the screening for the study. You would have to start from the beginning with providing your consent and repeat the evaluations and tests, however you might not have to repeat the bone marrow test.
  - Randomization: In case you are eligible for the study, then your information will be entered by your study doctor into an electronic system that is programmed to automatically allot you to either Study drug or epoetin alfa treatment. Your study treatment will be started within 3 days of randomization.

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2. **Treatment Period:** This is the time period from beginning of study treatment until your study doctor and you make a decision to permanently discontinue the study treatment. During this time you will be seen at the site or, in case permitted, by a home healthcare provider every other week and at times weekly. At the time of these visits there will be regularly repeated evaluations and tests carried out, any side effects or blood transfusions you have will be recorded by the study personnel and you will fill out questionnaires regarding how you feel. You will be given the study drug during this time on a monthly basis if you are allotted to Study drug treatment or on a weekly basis if you are allotted to epoetin alfa treatment.
  - In case your study treatment discontinues prior to 6 months: You will be asked to still fill out the questionnaires and information regarding blood transfusions up to 6 months.
  - End of Treatment Visit: When your study doctor and you make a decision to discontinue the study treatment you will be asked to return for a study visit to complete few evaluations and tests to evaluate any effects from the treatment.
3. **Safety Follow-Up Period:** This time period will last around 60 days beginning from the day post your End of Treatment Visit. You will be asked to visit the site at 1 month and 2 months following you complete the End of Treatment Visit for few evaluations and tests to evaluate any continuing effects from the treatment.
4. **Survival Follow-Up Period:** This time period will begin on the day after your last safety follow-up visit and will carry on until you have been on the study around 5-8 years or the study is discontinued. During this time you will be reached out every 3 months to check on your disease status, to report any other treatment you are getting and to answer few queries regarding your health status.

Kindly go through **Table 1** on the next page for the schedule of all tests and evaluations to be carried out at the time of the study. An explanation for each test and evaluation is given in **Table 2**.

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**Table 1: Activities Schedule**

|                                                              | <b>Screening Period</b><br>Up to 6 Weeks<br>Before<br>Randomization | <b>Treatment Period</b><br>Day 1 to End of<br>Treatment Visit | <b>Safety Period</b><br>Through 60 Days<br>Following Last Dose | <b>Follow-Up</b><br>Survival<br>Period<br>~5 to 8 Years Post<br>Randomization |
|--------------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------|
| <b>Informed Consent</b>                                      | X                                                                   |                                                               |                                                                |                                                                               |
| <b>Medical History</b>                                       | X                                                                   |                                                               |                                                                |                                                                               |
| <b>MDS Disease and Transfusion History</b>                   | X                                                                   |                                                               |                                                                |                                                                               |
| <b>Physical Exam</b>                                         | X                                                                   | X                                                             | X                                                              |                                                                               |
| <b>Vital Signs</b>                                           | X                                                                   | X                                                             | X                                                              |                                                                               |
| <b>Height</b>                                                | X                                                                   |                                                               |                                                                |                                                                               |
| <b>Weight</b>                                                |                                                                     | X                                                             |                                                                |                                                                               |
| <b>Electrocardiogram</b>                                     | X                                                                   | X                                                             |                                                                |                                                                               |
| <b>Echocardiogram</b>                                        | X                                                                   | X                                                             |                                                                |                                                                               |
| <b>Coagulation</b>                                           | X                                                                   |                                                               |                                                                |                                                                               |
| <b>Hematology</b>                                            | X                                                                   | X                                                             | X                                                              |                                                                               |
| <b>Chemistry</b>                                             | X                                                                   | X                                                             | X                                                              |                                                                               |
| <b>Urinalysis</b>                                            | X                                                                   | X                                                             | X                                                              |                                                                               |
| <b>Pregnancy Testing</b>                                     | X                                                                   | X                                                             | X                                                              |                                                                               |
| <b>Checking of HBV, HCV and HIV Status</b>                   | X                                                                   |                                                               |                                                                |                                                                               |
| <b>Serum Erythropoietin (EPO)</b>                            | X                                                                   | X                                                             |                                                                |                                                                               |
| <b>Collection of Peripheral Blood and Bone Marrow Sample</b> | X                                                                   | X                                                             |                                                                |                                                                               |
| <b>Evaluation of MDS Disease</b>                             | X                                                                   | X                                                             |                                                                |                                                                               |
| <b>Randomization</b>                                         |                                                                     | X                                                             |                                                                |                                                                               |
| <b>Study drug vs. Epoetin Alfa Dosing</b>                    |                                                                     | X                                                             |                                                                |                                                                               |
| <b>Verification of Transfusion</b>                           |                                                                     | X                                                             |                                                                |                                                                               |
| <b>Pharmacokinetic (PK) Assessment</b>                       |                                                                     | X                                                             |                                                                |                                                                               |
| <b>Evaluation of Anti-Drug Antibody (ADA)</b>                |                                                                     | X                                                             | X                                                              |                                                                               |
| <b>Biomarker Assessments</b>                                 | X                                                                   | X                                                             | X                                                              |                                                                               |

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|--------------------------------------------------------------|---|---|---|---|
| <b>Evaluation of Patient Reported Outcome</b>                | X | X | X | X |
| <b>Healthcare Resource Utilization Assessment</b>            |   | X |   |   |
| <b>Evaluation of Adverse Event and Concomitant Treatment</b> | X | X | X |   |
| <b>Survival and Disease Status</b>                           |   |   |   | X |
| <b>Subsequent Treatment</b>                                  |   |   |   | X |

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Tests and evaluations details are given in Table 2.

**Table 2: Details of Activity**

|                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Informed Consent                    | Prior to you can start the study, the study personnel will speak to you regarding the study and you will have to put a signature on a consent form in case you wish to take part.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Medical History                     | You will be asked how you are feeling, regarding your medical history, demographics (like year of birth, age, gender, race, and ethnicity), and regarding any medicines you are taking. Any prescription or non-prescription medications will be included in this. This helps us understand your overall health and whether this study is appropriate for you.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| MDS Disease and Transfusion History | Your study doctor will gather information regarding your diagnosis of MDS, which includes when you were diagnosed, the type of MDS you have, and how it has been treated.<br>Tests to affirm your MDS disease status will be carried out at the time of the screening period which includes bone marrow and blood tests.<br>Your study doctor will also gather information about your earlier treatments with red blood cell or platelet transfusions, which includes the results of any blood work acquired beforehand to see how much hemoglobin was in your blood prior to each transfusion. In earlier 2 months the number of transfusions provided to you when your hemoglobin was low will be counted.<br>All of this information assists your study doctor in understanding your disease status and whether this study might be an option for treatment. |
| Physical Exam                       | To check your overall physical health a physical examination is a routine evaluation by your study doctor. It normally consist of: looking at the body, feeling and tapping areas of the body, like your belly, and listening to sounds, like your lungs. After the first complete physical examination later repeat evaluations might be limited to a few areas of your body depending on your symptoms or physical complaints.                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Vital Signs                         | Vital signs are your blood pressure, heart rate, respiratory rate (number of breaths per minute), and temperature measurements.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Height and Weight                   | Measuring of your height will be done once at the starting of the study. Your weight will be checked every month to ensure the study drug's correct dose is provided. To measure your weight, you will be asked to take out your shoes and any heavy clothing as well as empty your pockets.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Electrocardiogram (ECG)             | An electrocardiogram (ECG) is a test that tells how the heart is functioning. You will have small, soft pads placed on the chest, wrists and ankles temporarily and connected to a monitor that will show your heart's electrical activity.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Echocardiogram (ECHO)               | An echocardiogram (ECHO) is a test that utilizes sound waves (ultrasound) to make your heart's pictures to show how well the heart muscle and the heart's structure is functioning. A probe known as a transducer is passed over your chest (transthoracic) or in your throat (transesophageal) to take your heart's pictures shown on a video monitor. This exam might take up to 30 minutes to 1 hour to complete.<br>In case a transesophageal ECHO (TEE) is carried out, a thin, flexible tube with a small probe will be placed down your throat into your food pipe                                                                                                                                                                                                                                                                                       |

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|                                                                                                             | (esophagus) gently, which sits behind your heart, to take clear pictures using sound waves. Medication will be given to you to relax and numb your throat beforehand.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Coagulation                                                                                                 | A blood sample will be taken by needle stick (or an intravenous (IV) line in case you have one) to check how well your blood clots.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Hematology                                                                                                  | A blood sample will be taken by needle stick (or an intravenous (IV) line in case you have one) to measure the number and types of cells in your blood, like red blood cells, white blood cells, and platelets. The total amount of blood needed each time this test is carried out is around 4 mL or approximately 1 teaspoon. This test will be repeated a minimum of every 2 weeks or more frequently in case required. The hemoglobin results from this test will be used to monitor your response to the study drug and to evaluate whether you might require blood transfusions.                                                                                                                                                                                                  |
| Chemistry                                                                                                   | A blood sample will be taken by needle stick (or an intravenous (IV) line in case you have one) to check your general health and to measure your blood components to see how well your liver and kidneys are functioning. The total amount of blood needed each time this test is carried out is around 6 mL or approximately 1½ teaspoons.                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Urinalysis                                                                                                  | A cup will be provided to you to take to the bathroom. You will be asked to urinate into this cup. The urine collected will be utilized to perform few tests. Some of the urine will also be transferred to a clinical laboratory for testing.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Pregnancy Testing                                                                                           | In case you are a woman who can bear children, a urine sample is needed to test in case you are pregnant. In case the test is positive, then a blood test (around 5 mL or 1 teaspoon) will be needed to affirm. In case you are pregnant, you will be unable to begin the study or will have to discontinue the study treatment in case you have started already.                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Checking of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV) Status | You will be asked regarding your history of HBV, HCV and HIV infection. You will be unable to take part in the study, in case you have any of these viruses. In case you have never been tested or are not sure of your status, then your study doctor might require a blood sample taken by needle stick (or an intravenous (IV) line in case you have one) to test your blood for HBV, HCV and/or HIV. In case the results show that you have hepatitis B, hepatitis C, and human immunodeficiency virus, you will be told this in confidence and be provided information regarding medical follow-up. Positive results for certain viruses leading to these infectious diseases might require to be reported to the local health authorities in your country, in case needed by law. |
| Serum Erythropoietin (EPO)                                                                                  | A blood sample will be taken by needle stick (or an intravenous (IV) line in case you have one) to evaluate how much of the hormone erythropoietin (serum EPO) is present in your blood. This hormone assist in balancing the red blood cells amount produced in the bone marrow. In case the level is too high this study treatment might not be a good option and you would not be eligible.                                                                                                                                                                                                                                                                                                                                                                                          |
| Collection of Peripheral Blood (for Blood Smear) and Bone Marrow Sample                                     | Collection of bone marrow sample consist of bone marrow aspirate and bone marrow biopsy. These methods are performed to collect and examine bone marrow, a spongy tissue inside some of your larger bones. For the bone marrow aspirate, a special thin needle is inserted into the hip bone to withdraw around 5 mL (1 teaspoon) of bone marrow fluid. A special hollow needle is inserted into the hip bone for the bone marrow                                                                                                                                                                                                                                                                                                                                                       |

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|                                 | <p>biopsy to withdraw a small piece (around 1.5 cm or 0.5 inches long) of the solid part of the bone and bone marrow. This is regarding the lead pencil thickness. You might be provided some sedation or local anesthesia to numb your skin to minimize any pain related to these methods, however there might still be discomfort and bone pain for some time post these methods. Your study doctor might give you with medication, in case required for the discomfort.</p> <p>Additionally, the bone marrow evaluation, a few drops of blood will be taken by needle stick (or an intravenous (IV) line in case you have one) and placed on a slide. This blood smear will be transferred, together with the bone marrow samples, to the study particular pathology laboratory to evaluate your MDS.</p>                                                                                                      |
| Evaluation of MDS Disease       | <p>The peripheral blood sample (for blood smear) and bone marrow samples mentioned above will be transferred to the study specific pathology laboratory at the time of screening, post 24 weeks and 48 weeks of treatment is completed by you, and then as deemed required by your study doctor until the end of study treatment visit (EOTx). At screening, a peripheral blood sample (for blood smear), bone marrow aspirate and bone marrow biopsy are needed and after 24 weeks of treatment is completed by you. After that, the bone marrow biopsy is optional. At the time of screening, to affirm your diagnosis of LR-MDS and to determine if you are eligible for the study, the MDS disease evaluation is performed. At the time of study treatment, the MDS disease evaluation is performed to understand your LR-MDS status and to evaluate how much your disease reacts to the study treatment.</p> |
| Randomization                   | <p>You will be allotted randomly by a computer program to one of two treatment options based on your disease stage and risk factors. When you are allotted randomly a treatment, this means you are put into a treatment group by chance (such as tossing a coin).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Dosing of the study drug        | <p>This is the investigational drug being tested in this study. It is given beneath the skin by injection (subcutaneous injection) every 28 days (one time per month).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Epoetin Alfa Dosing             | <p>This is the standard of care drug being compared to the investigational drug in this study. It is administered beneath the skin by injection (subcutaneous injection) every 7 days (one time per week).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Verification of Transfusion     | <p>You will be asked regarding you have received any blood transfusions since your last visit to the site. Any transfusions that might have been provided at a different clinic or hospital is included in this. In case a transfusion does takes place at a different clinic or hospital, then your study doctor will be required to acquire copies of a report documenting the transfusion method, as well as the results have to collected from any blood tests (which includes hemoglobin, platelets and iron related tests) performed before the transfusion.</p>                                                                                                                                                                                                                                                                                                                                            |
| Pharmacokinetic Assessment (PK) | <p>In case you are allotted to Study drug treatment, then blood samples taken by needle stick (or an intravenous (IV) line in case you have one) will be collected to measure how much Study drug is in your blood and evaluate how well your body absorbs and breaks down the study drug. A portion of this sample might be used for the objective of biomarker research. The total blood amount needed each time this test is carried out is around 16 mL or approximately 3 teaspoons per sample.</p>                                                                                                                                                                                                                                                                                                                                                                                                          |

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| Evaluation of Anti-Drug Antibody (ADA)     | In case you are allotted to Study drug treatment, then blood samples taken by needle stick (or an intravenous (IV) line in case you have one) will be collected to check whether your immune system is making antibodies (proteins) to Study drug. This would take place in case the study drug is perceived by your body as a foreign substance in your blood. The total blood amount needed each time this test is carried out is around 8 mL or 1½ teaspoons.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Biomarker Assessments                      | <p>Few blood samples will be taken by needle stick (or an intravenous (IV) line in case you have one) strictly for objectives of research. Biomarkers are biological or chemical “markers” that can be found in blood and tissue samples of patients with MDS. Biomarker research might assist us in learning which patients are more likely to react to the study drug or more likely to develop side effects to the study drug. It also assist us in determining what other effects the study drug is having on the body. This research will not benefit you, however it might help individuals in the future.</p> <p>The biomarker evaluations in this study consist of the given below:</p> <ul style="list-style-type: none"> <li>▪ A blood sample (around 8 mL or approximately 1½ teaspoons) will be collected one time per month while you are on study drug to test for known clinical biomarkers.</li> <li>▪ Another blood sample (around 11 mL or approximately 2 teaspoons) will be collected at 7 timepoints within the study treatment's first 12 weeks and then quarterly after that to test for exploratory biomarkers. This blood sample will also be used for disease-associated genetic tests of your ribonucleic acid (RNA).</li> <li>▪ An extra blood sample (around 3 mL or approximately ½ teaspoon) will be collected on your treatment's first day to test for disease specific genetic mutations.</li> </ul> |
| Healthcare Resource Utilization Assessment | At the time of regular study visits, information will be collected regarding the number, duration, and reasons for any hospitalizations that have occurred since your last visit to the site. In addition, data will be collected on the number of unplanned site visits, diagnostic methods, and treatment interventions that did not need hospitalization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Adverse Events                             | You will be asked whether any negative signs and symptoms or any changes are noticed by you in your health. These changes are known as adverse events.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Concomitant Medications/Methods            | <p>You will be asked regarding any medications you carry on to take or any new medications you have started taking. It is vital that you inform the study doctor regarding all the medications you are taking which includes: prescription drugs, over-the-counter medicines, vitamins, herbal supplements, vaccines and anything else you may take. Any other medications might not be taken by you for treating your LR-MDS or participate in another research study that involves taking medication while you are on this study treatment.</p> <p>You will also be asked regarding any blood transfusions or any other medical methods or surgeries that you have had or are expected to have.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Survival Follow-up and Disease Status      | Post completion of the safety follow-up period, you will enter the survival follow-up period where you will be reached out, typically by telephone,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

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|                      |                                                                                                                                                                         |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      | every 3 months to know how you are feeling and to give updates on your MDS disease status. You will also be asked to fill out the EQ-5D-5L questionnaire by phone.      |
| Subsequent Treatment | At the time of the survival follow-up period, you will be asked to report any treatments for MDS disease that you have started since discontinuing the study treatment. |

### Patient Reported Outcomes (PROs) Evaluations Needed At the time of the Study

|                                                    |                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EORTC QLQ-C30<br>(Questionnaire 1)                 | Physical function, shortness of breath, and tiredness are measured in this questionnaire. It is a 30-item, patient-reported multi-domain questionnaire designed to evaluate the functioning, well-being, and symptom experience of patients with cancer.<br><br>[European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30] |
| FACT-An Anemia scale<br>(Questionnaire 2)          | This questionnaire is used to evaluate the disease symptoms effects on functioning and well-being in patients with anemia<br><br>[Functional Evaluation of Cancer Therapy-Anemia]                                                                                                                                                                                  |
| EQ-5D-5L<br>(Questionnaire 3)                      | This questionnaire includes 2 components: a descriptive system and a VAS (visual analogue scale). The descriptive system of the instrument include 5 items measuring issues with mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The VAS instrument permits you to rate your own health on a 100-point scale.                      |
| Transfusion Burden Assessment<br>(Questionnaire 4) | This questionnaire include a single item measuring the participant-perceived burden of any red blood cell transfusions (which includes time commitment as well as physical and emotional burden) that have been carried out in earlier 4 weeks.                                                                                                                    |
| PGI-S items<br>(Questionnaire 5)                   | With this questionnaire, you are asked to rate the symptoms severity or functional limitations over the preceding week<br><br>[Patient Global Impression of Severity]                                                                                                                                                                                              |
| PGI-C items<br>(Questionnaire 6)                   | With this questionnaire, you are asked to assess changes in outcomes since the beginning of trial intervention<br><br>[Patient Global Impression of Change]                                                                                                                                                                                                        |

### Minimum Blood Volumes

The total blood quantity collected from you in the study will be based on how many cycles of treatment you get on the study. At each visit, the minimum approximate blood volume to be collected is below:

| Time Period      | Blood Volume (tablespoons)                   |
|------------------|----------------------------------------------|
| Screening Period | Around 35 mL or approximately 2½ tablespoons |

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|                                                                                                               |                                                               |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| Study Treatment Period (through End of Treatment (EOTx) visit)                                                | Around 50-125 mL or approximately 3½-8½ tablespoons per month |
| Safety Follow-Up Period                                                                                       | Around 18 mL or approximately 1 tablespoon per month          |
| Survival Follow-Up Period                                                                                     | None                                                          |
| Extra monthly testing up to 1 year in case you have antibodies to elritercept at end of the safety evaluation | About 8 mL or around ½ tablespoon each month                  |
| In case you have a transfusion, sample for hemoglobin and chemistry                                           | Around 10 mL or about 1 tablespoon prior to each transfusion  |

**Will there be devices and any type of technology utilized in the study?**

| Type of Electronic device and related technology              | What company is giving you with this electronic device [and/or] associated technology? | How is the electronic device [and/or] related technology being used? | When is this electronic device [and/or] related technology going to be used?             |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Tablets for Questionnaires (PROs – Patient reported outcomes) | Signant Health                                                                         | To record answers to questionnaires                                  | At the time of the screening, treatment, safety follow-up and survival follow-up periods |

Using the above recognized electronic devices and related technology all patient reported outcomes (PROs) evaluations should be completed. You will be unable to take part in this study in case you make a choice not to use the electronic devices and related technology.

By giving your consent, you consent to use the electronic devices and associated technology as requested. Kindly note that:

- Takeda will have access to information that recognizes you indirectly like your study ID number.
- To register you as a user of the electronic device and associated technology your personal information will be used.

You will be given with extra information on the electronic devices and associated technology in case you make a choice to enroll in the study. In case you have queries regarding the electronic devices and associated technology use, kindly ask your study doctor.

### **What will occur to your study samples and biomarker images?**

All blood, urine, and bone marrow sample(s) taken from you at the time of the study will be transferred to the designated laboratory of the Sponsor. The laboratory will store the sample(s) and arrange for tests that relate to this study temporarily. Labelling of the sample(s) will be done with a code and not your name.

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The Sponsor, its agents and affiliated companies will have access to the sample(s) collected. All sample(s) collected at the time of the study will be securely stored with limited access and the Sponsor will need anyone who works with the sample(s) to consent to hold the research information and any individual results in confidence. The testing/storage facility might change, you can always request to know your samples location.

### How will your samples be stored?

All blood and urine samples collected for standard clinical tests will be discarded at or prior to the end of the study when all the test data has been analyzed.

The Sponsor will store all bone marrow aspirate, bone marrow biopsy and peripheral blood samples collected for the biomarker research with its long-term storage partners. The bone marrow aspirate, bone marrow biopsy and peripheral blood samples collected for MDS disease evaluation and biomarker/PK/ADA evaluations are included in this. These samples will be kept for up to 15 years post the end of the study, unless there are local laws which need a shorter storage period, or you take back consent for sample storage and use. After that time, the samples will be discarded. As need by applicable law, the study doctor will keep records linking your identity with your samples.

### Can I take back my consent for using my samples?

In case you leave the study, you might also request that your sample(s), and material acquired from your sample(s), be discarded at any time by getting in touch with your study doctor. Your sample(s) can still be discarded, as long as the records linking your identity to your sample(s) exist. Though, the Sponsor will be entitled to keep and use any study results or information which was acquired from your sample(s) before your request to discontinue.

### Will I get my test results?

The samples collected from you for biomarker research, and the information and results from tests carried out with these samples, might be individually used or combined with other data. The tests carried out with these samples are not desired to make determinations regarding your health or the possibility you will develop any disease, so no test results will be given to your doctor or put into your medical record. By putting a signature on this consent form, you consent that we might store your samples and might use them for the research explained in this informed consent form.

### Who owns my samples and how will they be used?

The Sponsor will analyze and assess the information gathered from the sample(s) collected from you in this study, and might result in new discoveries, patents or products. You have no rights to and will not get payments of any kind for such discoveries, patents or products. By agreeing to take part in this clinical study, you are giving up any ownership rights that you might have in sample(s) collected from you at the time of this study to the study Sponsor.

In the event the Sponsor sells Study drug to another company carrying out clinical research, your samples collected as part of this study might be shared with that company as part of that transaction.

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### How will your personal information be secured for samples?

The confidentiality of your information will be secured by us to the fullest extent possible. To secure your identity, your samples and associated data will be coded. Only the study doctor will have the key to the code key that can link your samples to your recognizing information. The key will be stored securely and secured. For additional information regarding how we secure your privacy, kindly look at the section entitled <“How will your privacy be respected, and how your personal information confidentiality be maintained?”>.

### Analysis of Biomarker Image

Biomarker testing might include image analysis that is carried out on your tissue biopsy after it is sectioned and placed on a glass slide. Specialized image analysis computer software is used in this testing to count or measure different cell types in the tissue. This testing might help researchers learn how changes in cell populations might impact a disease or response to treatment. Samples analyses from a large number of individuals might also help researchers learn more regarding other diseases, possible links among diseases, and new avenues for drug development.

Kindly be aware that the biomarker images of bone marrow will be recorded and saved to a computer program and transferred in a secure way to the Sponsor and/or their commercial partners for central reading and analysis purposes. The recorded materials will be recognized by a unique code that is allotted to you. Your name or other recognizing information will not be utilized. These recordings might be viewed by the staff from the Sponsor and the Sponsor's partners for this study. The biomarker images will be kept private, and no other individual will have access to these images in so far as permitted by law. Every effort will be made to maintain the privacy of your information, within the limits imposed by technology and the law. Biomarker images will be maintained in a secure location with limited access. The biomarker images will be stored for a minimum of 25 years from the end of the study, or if less, the maximum period permitted under applicable law or stored until consent is withdrawn. Post that time, the biomarker images will be discarded.

### Genetic Testing

Genetic testing will be carried out on your diseased bone marrow tissue and/or blood samples to recognize mutations in key genes found in MDS and acute myeloid leukemia (AML). Genes are made of a type of molecule known as deoxyribonucleic acid, or DNA, and DNA differs widely from one individual to another. DNA is the genetic material that carries the instructions for development and function of your body. Each individual's body has tens of thousands of genes (“genome”). Testing of your genome or all of your genetic material will not be done. Only a limited set of chosen genes in your diseased bone marrow tissue and/or blood sample(s) will be tested.

The analysis of all ribonucleic acid (RNA) from the cells in your blood will be included in the biomarker testing. This will permit us to learn how genes are expressed in those cells at the time of collection. This testing might help researchers learn how changes in the expression of genes are associated with disease or study drug treatment response. The analysis of RNA is only for research objectives and is not a medical test. This means that the medical importance of the results might be unknown, or that they might not be associated with any medical condition. The results of tests on your sample will not be provided to you, the study doctor, any insurance company, your employer, your family, or any physician who treats you. These are research tests and not applicable to your medical care. The Sponsor and researchers will put measures in place to minimize the possibility for the results from this research being linked to you, however there is always the remote possibility that information from your participation in the research might be revealed.

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### What are the study drugs side effects and the risks of participating in the study?

At the time of the study, you might have discomforts and risks from Study drug and the study methods. These might differ from individual to individual. Everybody participating in the study will be carefully watched for side effects; though, doctors are not aware of all the discomforts and risks that might take place. There is always the likelihood that unknown risks might take place and some of which could be serious, life-threatening, or even fatal. It is vital that all symptoms/health problems should be reported by you to the study doctor/personnel, whether or not you think these issues are because of the study drug. In case it is an emergency and you are not able to reach the study team or doctor, you must right away call local emergency services. In case you have a severe reaction to the study drug, the study doctor might make a decision that you must be withdrawn from the study for your safety.

The more commonly happening discomforts and risks are listed below, as are the rare however serious discomforts and risks.

Furthermore, there is a likelihood of investigational product failing to give desired therapeutic effect. As this study's objective is to evaluate the safety and effectiveness of an unapproved investigational product (study drug), it is possible that the study drug might not have the desired therapeutic effect.

### What are the potential risks for taking the Takeda drug?

As of 03 April 2025, around 109 participants with MDS have received a minimum of 1 dose of elritercept in clinical trials with most participants getting elritercept for 12 months.

Elritercept (TAK-226, the study medication) is an experimental medication and the risks to human subjects have not been completely assessed. With all medications, there is the likelihood of complications and side effects that are unknown at this time. There might be other risks that are unknown which might be serious. You will be closely monitored at the time of the study.

You might have none, few or all of the side effects listed below, and they might be gentle, average or severe. Speak with the study doctor, in case you have any of these side effects, or are worried about them.

Many side effects go away shortly post treatment ends. Though, side effects can be at times serious, long lasting, or permanent. In case a severe side effect or reaction takes place, your study doctor might be required to stop your study drug treatment. Inform your study doctor right away regarding any new or unusual symptoms or changes in your health that you become aware of or have concerns. How to manage symptoms or side effects will be discussed with you by your study doctor. The side effects treatment will be based on the type and severity of the symptom(s).

At the time of screening prior to study treatment or at the time of participation with study drug treatment in case a earlier unknown medical condition is discovered, the study doctor will discuss:

- whether you are eligible to start or continue study treatment participation
- whether you need a referral to your usual physician or to a specialist

The study medication might be a risk to an unborn child or breast-feeding baby, so it is vital to carefully read the section on "Pregnancy, contraception and breast-feeding", whether you are a man or woman.

The given below side effects were reported very commonly (seen in more than 1 in 10 individuals) by the participants with myelodysplastic syndromes/neoplasms that received the study medication in another research study so far.

- Loose, watery stools
- Fatigue/weakness

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- COVID-19
- Low red blood cells: might lead to shortness of breath/breathing difficulty; feeling weak; lightheadedness; loss of appetite; numbness and tingling of hands and feet
- Dizziness (lightheadedness)
- Nosebleed
- Nausea (feeling sick to stomach)
- Shortness of breath
- Constipation (difficulty passing stools)
- Fall
- Hands, feet, or ankles swelling
- Cough
- Raised blood pressure
- Urinary tract infection (symptoms of infection might consist of fever, pain, redness, burning when peeing, difficulty peeing or blood in urine)
- Pain in the Joint
- Headache
- Pain in the Back
- Vomiting

There is a potential for developing antibodies to the study medication, specifying an immune reaction. At times, this might lead to the medication to not work effectively or might lead to allergic reactions (look at below extra information). It might also lead to a skin reaction where an injection (shot) was provided known as an injection site reaction, which might lead to few redness and swelling.

In addition, low platelets (might lead to bruising or bleeding), fever, neutropenia (a condition in which the number of white bloods cells known as neutrophils is abnormally low which might raise the infection risk), and lung infection (symptoms of infection might consist of fever, chest pain, cough, and/or breathing difficulty) have been reported very commonly in another research study by the participants with a blood condition known as myelofibrosis treated with Study drug alone.

### **What are the risks of epoetin alfa?**

In case you are allotted to get the comparator study drug epoetin alfa and not Study drug, you might have none, some or all of the side effects listed below that have been reported with epoetin alfa. The side effects to epoetin alfa study drug might be gentle, average or severe. There might be other risks that are unknown which might be serious. Inform your study doctor right away regarding any new or unusual symptoms or changes in your health that you become aware of or if you have concerns. How to manage symptoms or side effects will be discussed with you by your study doctor. The side effects treatment will be based on the type and severity of the symptom(s).

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- Loose, watery stools
- Nausea
- Vomiting
- Fever
- Headache
- High blood pressure and severe raise in blood pressure (called hypertensive crisis) could cause disorder of brain, seizures, stabbing migraine-like headaches and possible stroke
- Raised risk of blood clots in a vein (possible symptoms consist of pain, swelling, and/or redness), or in an artery (might cause organ damage like stroke, breathe failure, possible blindness, bleeding in brain, and/or heart attack) which can be fatal especially in patients with pre-existing risk factors like obesity and prior history of these events
- Chills, flu-like symptoms
- An allergic reaction of the skin at the site where an injection (shot) was provided, which might lead to some redness and swelling
- Swelling in arms and/ or legs
- Cough
- Seizure (especially in patients with history of epilepsy and conditions such as brain and spinal cord infection or brain cancer)
- Pain in the joint, bone pain, muscle pain and/or body aches, arm and/or leg pain
- High blood platelet count (might cause raised clotting)
- Potassium High blood levels (might cause kidney failure or heart effects)
- Respiratory tract congestion (blockage or stuffiness in the airways, frequently because of excess mucus or inflammation)
- Reduced bone marrow function and inability to make red blood cells leading to a low red blood cell count called anemia, which includes symptoms of tiredness, weakness, and pale skin
- Hypersensitivity and Anaphylactic reaction: Allergic reaction that might consist of a rash, hives, fever, breathing difficulty, swelling beneath the skin, frequently around the eyes, lips, tongue, and throat (angioneurotic oedema), and low blood pressure. Although usually reversible with treatment, it can be severe or fatal.
- Worsening of genetic disorder known as porphyria that might consist of symptoms like pain in the abdomen, confusion, anxiety, seizures, pain in the muscle, raised sensitivity to sunlight causing skin reactions like blisters and itching on sun-exposed areas.

Other adverse reactions reported with epoetin alfa consist of severe skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) which might show up as different blisters, hives, and other lesions in different locations on the body which includes palms and soles, face and other extremities. This is serious and might be fatal. Inform your study doctor right away, in case you have any of these side effects.

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Protocol Number: TAK-226-3001

Based on FORM-269793, Version 5

Sponsor Name: Takeda Development Center (TDC) Americas, Inc.

TAK-226-3001 Master ICF Version 2.0 24Sep2025

Back Translation of TAK-226-3001 Master India Participant Information Sheet and Consent Form Version 1.0(bn) 20Jan2026

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Risks of allergic reaction: Any medication has a potential risk of an allergic reaction, which in case not treated on time, could become fatal. They are gentle to average in severity. Though, at any medication dose fatal reactions might take place. In case you believe you are having a serious allergic reaction after getting Study drug or epoetin alfa, you must seek emergency medical assistance right away. Kindly inform the study doctor right away in case any of these symptoms are experienced by you. Few symptoms of allergic reactions are:

- Rash or itching
- Coughing, wheezing and breathing difficulty
- Dizziness (lightheadedness) and fainting
- Swelling around the mouth, lips, tongue, throat and/or eyes
- Rapid pulse
- Sweating

You will be monitored by your study doctor carefully for any signs or symptoms that you might be having an allergic reaction, and the study doctor will take suitable care. In case you do not understand what some of these side effects or risks mean, ask the study doctor to describe them to you.

### Are there any other potential risks for participating in this study?

While clinical studies are designed to make sure the safety and well-being of participants, there are still few risks and discomforts related to the study methods that you must be aware of:

**Collection of Blood Sample:** At the time of blood sample collection, you might feel slight pain and/or experience bruising where the needle was inserted into the skin. You might also experience excess (too much) bleeding, blood clots, and infections where the needle was inserted into the skin, however this is very rare. Fainting occasionally takes place at the time of, or shortly post, blood is taken. This event most often takes place if you get up quickly from a sitting or lying down position. In case you feel faint, you must inform study site personnel and lie down right away to avert possible injury caused by falling. Very rarely, few individuals have short and long-term damage of vessels and nerves, which can be irreversible and can cause long term pain and impairments.

**Bone Marrow Aspirate and Biopsy:** Bleeding, infection, bruising, pain, or discomfort at the needle stick site is included in the possible side effects. Based on the methods at your trial center you might get a numbing medicine that will be injected into the skin above the area of the bone to decrease the pain. In rare cases, nerve damage might take place. In extremely rare cases, individuals might have an allergic reaction to the local anesthetic (numbing medicine). The allergic reaction could consist of rash/hives, flushing of the face, itching, wheezing, and tightness in the throat. A scar might also form at the aspiration/biopsy site. You might have to put a signature and date on a separate consent form for the bone marrow biopsy and aspiration.

**Echocardiogram (ECHO):** Few individuals might feel uncomfortable having to lie in one position and you might develop gentle rash or skin irritation where the electrodes (sticky patches) were placed. **In case Transesophageal Echo (TEE) is carried out,** possible side effects consist of sore throat, infection, or aspiration in addition to potential esophageal injury, which includes bleeding or perforation (very rare).

**Electrocardiogram (ECG):** You might have gentle irritation, redness, or itching where the recording patches are placed.

**Subcutaneous Injection:** In a subcutaneous injection, to inject a treatment into the tissue layer between the skin and muscle a short needle is used. In case you have any of these reactions, your doctor must be

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reached out immediately. As with any type of injection, there is a possible risk of infection where the shot was provided. Other risks are an injection-site reaction, which is a localized reaction that might take place at the site where the study drug is injected. Symptoms related to an injection-site reaction might consist of pain, redness, tenderness, warmth, itching, swelling, discomfort, bleeding, hardening of the skin in the area surrounding where the study drug was given, and severe skin or tissue damage.

**Red Blood Cell (RBC) or Platelet Transfusions:** The possible risks of having an RBC or platelet transfusion are as follows:

- You might have a gentle allergic reaction with skin itching and hives, fever and chills; in rare cases a serious allergic reaction might take place with severe shortness of breath, rapid heart rate, pain in the chest, nausea and vomiting.
- In case you have heart or kidney conditions, you might have raised breathing difficulty and a cough; the additional fluid might put extra stress called overload on your heart or kidneys.
- In case you have had multiple RBC transfusions, antibodies (proteins in your blood) might be produced by you that attack the new red blood cells in your blood or you might wind up with too much iron in your body that might need medication to help your body remove the iron.
- In case you have had multiple platelet transfusions, antibodies (proteins in your blood) might be produced by you that attack and discard platelets in your blood. As a result, easy bruising, bleeding gums, nosebleeds or blood in your urine or feces might be experienced by you for around 5-12 days post your transfusion.
- All of the red blood cells (RBCs) might be discarded by your immune system in your body if the RBCs in the transfusion do not match own RBCs of your body. This might lead to a rare, however serious, reaction with chest pain, chills and fever, dark urine, lower back pain and nausea.
- In case you have a weakened immune system from transplants or other diseases, you might have an raised risk of fever, diarrhea and rash because of graft versus host disease when donated white blood cells attack your body tissues
- In rare cases, donated blood might carry harmful bacteria or viruses that lead to blood-borne infection

### What are the genetic/genomic tests risks?

When your blood or tissue for MDS genetic research is donated by you, you are sharing genetic information regarding yourself. Since some of your genes are shared by family members, this information could also disclose things regarding your blood related relatives. Though, it is extremely unlikely that genetic changes will be found by the Sponsor that can be passed down in families, as the research will only look at genes linked to MDS in diseased (not healthy) tissue. Still, there are few risks to think about. There is a small chance that one day information from this research could be traced back to you. In case that occurred, your privacy could be impacted by it, and there is a likelihood—though unlikely—that it could cause discrimination by employers or insurance companies against you or your family members. To secure your identity, your samples will only be labeled with your study number, not your name or other personal details. Though, because technology is always changing, all possible future uses or risks associated with genetic information cannot be predicted by us.

### Pregnancy, contraception, and breastfeeding

Both men and women will be invited to take part in this study, which includes women who are able to bear children.

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Kindly carefully read the given below instructions, there are few needs associated with contraception and pregnancy in order to participate in this study. Counselling will be given by the study doctor for proper birth control procedures throughout the study. You will be reminded of the importance of not becoming pregnant at the time of the study by the study doctor.

### For Men

It is unknown whether sperm or an unborn baby will be impacted by the study medication. For this reason, to be in the study you should consent not to father a child at the time of the study and for a minimum of 60 days post the study medication's last dose.

In case you are a male participant and sexually active with a female of who is pregnant, or could become pregnant, regardless of if you have had a vasectomy, you should consent to use condoms with or without spermicide each time you have sex at the time of the study and until a minimum of 60 days post the study medication's last dose.

In case while you are participating in the study drug treatment your partner does become pregnant, you should inform your study doctor right away who will be able to suggest you. In this situation, your partner must be under medical supervision at the time of her pregnancy, and the baby must be under supervision post the baby is born. Your partner might be asked to provide her consent to the collection of information associated with both herself and as well as the baby.

### For Women

In case you have been sterilized surgically or have been through the menopause (discuss this with your study doctor), you are not required to fulfill any contraception or pregnancy test needs to participate in this study. Otherwise you should consent not to become pregnant or breastfeed a baby at the time of the study and a minimum of 60 days post the study medication's last dose.

In case you could become pregnant and are sexually active with a male partner who has not been sterilized, you should consent to use highly effective contraception (listed below) from the time of putting a signature on the ICF and until a minimum of 60 days post the study medication's last dose:

- Combined (estrogen- and progesterone-containing) hormonal birth control (oral, or in the vagina [intravaginal], or on the skin [transdermal]) related to preventing ovulation
- Progesterone-only hormonal birth control (oral, injectable, implantable) related to the preventing ovulation.
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system
- Bilateral tubal ligation (having both of your uterine tubes tied)
- Partner with vasectomy, that is, surgically cut off the supply of sperm (given that partner is the sole sexual partner of the participant and that the vasectomized partner has received medical evaluation of surgical success)
- True sexual abstinence (avoidance) defined as refraining from heterosexual intercourse for the study duration until a minimum of 60 days post the study medication's last dose and only when this is in line with your preferred and usual lifestyle.

In order to be eligible for the study, you should have a pregnancy test to affirm that you are not pregnant. This test will be repeated just prior to you start taking the study medication and then regularly throughout the study until a minimum of 60 days post the study drug's last dose.

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In case a pregnancy test at the time of the study shows that you might be pregnant, the study drug treatment will be discontinued and the treatment will end. By putting a signature on this document, you provide consent to the collection of information associated with both yourself and your baby.

You will be asked for the results of any tests and methods conducted at the time of your pregnancy and up to the birth. You might also be asked for the results from any assessment of the baby post the birth.

### **What are the possible benefits of participating in this study?**

You might or might not benefit as a result of participating in this study. It is not guaranteed that your requirement to get blood transfusions will reduce; it might even worsen. This study is being carried out to gather additional information regarding a drug that might benefit others in the future.

### **What occurs in case anything goes wrong, or I get hurt?**

You shall comply with the directions from your study doctor. In case you suffer an adverse reaction in the study, kindly inform your study doctor right away, and free medical management will be given as long as needed, or till such time it is established that the injury and/or the adverse reaction is not associated with the study drug or the study method, whichever is earlier.

In the event of any trial-related injury or death (as defined in the applicable Indian regulations) emerging directly from the proper management of the study drug as per the protocol or the proper performance of the study method needed by the protocol, the Sponsor or its representative, as the case might be, shall give financial compensation for such injury or death as per the applicable regulations. In the event of a study related injury or death (as defined in the applicable Indian regulations) emerging from the protocol violation, misconduct or negligence by the study site or your study doctor, the study site, your study doctor or their representative, as the case might be, shall give financial compensation for such injury or death to you.

By putting a signature on this informed consent form, you will not lose any of your legal rights.

### **What are your choices in case you do not take part in the study?**

You do not have to participate in this study to get treatment for your anemia because of lower-risk myelodysplastic syndrome (LR-MDS).

There are other alternatives like: imetelstat, lenalidomide, luspatercept, or participation in another clinical trial. There might be benefits and risks associated with these treatments that will be discussed with you by the study doctor.

This study has a limit on the participants number that can be enrolled all over the study sites globally. So, there is a small likelihood that even though you consent to take part and fulfill all entry criteria, once the enrollment limit is reached, you will be unable to take part in the study. You must be informed by your study doctor in advance in case this could occur to you.

In case for any reason you are not permitted to participate in the study, your treatment options will be discussed with you by the study doctor and might refer you back to your primary care doctor or specialist.

### **What occurs in case new information is available regarding the study drug or study?**

New information regarding the study drug(s) that might impact your decision to stay in the study might become available at the time of the study. In case this occurs, this information will be shared with you by

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Protocol Number: TAK-226-3001

Based on FORM-269793, Version 5

Sponsor Name: Takeda Development Center (TDC) Americas, Inc.

TAK-226-3001 Master ICF Version 2.0 24Sep2025

Back Translation of TAK-226-3001 Master India Participant Information Sheet and Consent  
Form Version 1.0(bn) 20Jan2026

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

your study doctor promptly and ask you whether you want to carry on in the study. You might make a decision to stop participating in the study at that time. In case you stop participating, the steps you should follow will be discussed by your study doctor. In case you make a decision to carry on in the study, you might be asked to read and put a signature on a revised consent form that consist of the new information.

### Can you discontinue participating in the study?

At any time, you might leave the study, without penalty or loss of benefits to which you are else entitled. It is up to you whether you want to participate or not. The medical care you get from your doctors at present or in the future will not be changed by your decision.

There are a few ways to leave the study. You can take back your consent from all participation in the study, which includes the follow-up data's collection. You can also make a decision not to carry on taking the study drug (Study drug or epoetin alfa) however consent to carry on to take part in the non-treatment portion of the study and to the continued data collection. Such continued participation could consist of:

- An End of Treatment Visit
- Follow-up Visits or Telephone Calls

These options will be discussed with you by your study doctor. Any additional participation is voluntary. Even though you consent to carry on to take part in the study to gather your data, you can always change your mind and take back your consent.

In case for any reason you discontinue participating in the study, the study doctor might carry on to use and distribute any data collected up until that point in the study if it is for the objectives explained in the informed consent form. In case you take back your consent to take part in the study, then no additional information regarding you will be collected for this study. Though, all information you gave prior to quitting the study might still be used.

Your study doctor might make a decision that it is best for you to stop participating in the study. In case so, the reasons why you may have to leave the study will be discussed with you by them. E.g., you might have to stop taking part in the study against your wishes in case you require other treatment, do not comply with the study plan, have a study-related injury, or for any other reason. At any time, the Sponsor, regulatory authority, and/or [Ethics Committee](#) might also end the study.

### What occurs at the end of the study?

At the end of the study, the options for your continued care will be discussed with you by your study doctor or primary care doctor.

In case you were allotted to epoetin alfa treatment and had supplies dispensed to you for self-administration, then the necessary steps for returning any remaining epoetin alfa supplies to the site will be reviewed by your study doctor.

### Do I have access to the study drug after the study stops?

In case you were allotted to the study drug, Study drug and are still on treatment, then you might be permitted to carry on to get elritercept in case your study doctor determined that you are still getting clinical benefit from it more than the potential risk of side effects. The Sponsor might carry on to supply Study drug through a post study access process. Post study access to Study drug might be discontinued if the development of Study drug has been suspended or stopped by the Sponsor, and/or there is no longer supply available from the Sponsor.

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

In case you were allotted to epoetin alfa and are still on treatment, then you might be permitted to carry on to continue to get epoetin alpha in case your study doctor determined that you are still getting clinical benefit from epoetin alpha more than the potential risk of side effects. In case required, the Sponsor might carry on to supply epoetin alfa through a post-study access process.

### **Will it cost you anything to be in the study?**

No cost is there to you for participation in this study. The study medication, study-related methods and tests, and study visit will be given free of cost.

### **Will you have help with costs for travel?**

Reasonable travel costs for you and up to one caregiver might also be reimbursed. In addition, accommodation and meal costs might be reimbursed in case the study needs extended visits or certain methods. Your study doctor or his/her staff might reimburse you for these costs.

### **Will you be paid if you participate in the study?**

No payment will be given to you for participating in the study.

Reasonable actual **travel costs of up to INR 2000 and meal costs up to INR 435 and hotel costs up to INR 6000** in total associated with you attending the study clinic for the study will be reimbursed by your study doctor or his or her personnel or the site.

### **Will you have help at home for this study?**

In case you are allotted to epoetin alfa treatment, your study physician might permit you to get few of the weekly injections at home or at another permitted location. In case permitted, a home healthcare provider can provide these injections. You do not have to consent to home visits for you to take part in this study. In case you and your doctor consent to utilize home healthcare services, a clinician will get in touch with you to schedule the visits. The clinicians supporting this study have received particular training on this study and will communicate often with your doctor and the study personnel. In order to carry out the home visits, the clinician, the organization of the clinician, and the home healthcare service provider might have access to your individually recognizable secured health information, like your name, address or phone number. This type of information, which is stored in the United States and might be stored outside the United States, will only be used as required to schedule and carry out the home visits and will not be given to the Sponsor of this study. The data gathered at the time of a home healthcare visit will be shared with your study personnel and filed in your study medical records.

### **How will your privacy be respected, and the confidentiality of your personal information be maintained?**

In case you consent to participate in the study, personal information about your health and your treatment will be gathered and stored by the study doctor. This might consist information that might be used to recognize you, like your name, address, phone number, birth date, racial origin (to be used only for objectives of clinical research), new and existing medical records, or the types, dates, and results of different tests and methods, as well as information in your medical record and information created or collected at the time of the study.

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Under applicable data protection law which includes the “Digital Personal Data Protection Act 2023” (DPDPA) both the Sponsor and the study doctor/clinic might be solely or jointly be considered data fiduciaries of your personal information in the context of the study (based on the nature of the data) (that is, they determine how and for what purposes your personal information are used and revealed).

The Sponsor’s Data Protection Officer’s (“DPO”) contact details are as follows: [PrivacyOffice@takeda.com](mailto:PrivacyOffice@takeda.com)

To ensure that the study is being carried out appropriately, the Sponsor, the representatives of the Sponsor, health authorities and relevant institutional review boards and ethics committees might inspect your medical records, which might consist of your name, address and other personal information that could recognize you. In case required, few or all of your medical records might be copied at the time of these inspections.

All information regarding you which leaves the study clinic will be recognized by a code number and your initials, without your name and address. Confidentiality will be maintained in accessing, keeping, processing and publication of information associated with your participation in the study.

Your study doctor is responsible for keeping a list of codes to make it possible to link your code to your name. This list will be kept in a safe place to ensure that in an emergency you can be recognized and contacted. The list will be kept for a minimum of 25 years from the end of the study and then for as long as required to keep to the legal, regulatory, scientific or other needs. The list will then be discarded.

Coded information regarding your health and treatment at the time of the study might be used with your consent for the given below purposes:

- to carry out the research as explained in this informed consent form;
- for scientific meetings, presentations and/or publications regarding the study; and
- to make submissions to Regulatory agencies and other health authorities (e.g., the Health Products Regulatory Authority, the European Medicines Agency, and the United States Food and Drug Administration, the Indian Central Drugs Standard Control Organisation).

Your coded personal information might be revealed to other parties, in other countries outside of India, for the objectives explained in this information sheet. Few of these countries do not have data protection or privacy laws that offer the similar level of protection as the data protection and privacy laws in this country. Though, everything possible will be done by the Sponsor to keep your coded information confidential. With respect to transfers to its affiliates and business partners situated outside of India, Sponsor has put in place suitable contractual provisions, or is otherwise satisfied that there are measures in place to achieve the protection level of coded personal information equal to that under Indian law.

The parties that might get the coded information consist of the given below.

- The Sponsor and other companies and individuals acting for or with the Sponsor, which includes the business of the Sponsor and licensing partners
- Regulatory agencies and other health authorities
- Institutional review boards and ethics committees

You have the right to access, through your study doctor, all the information regarding you and, in case applicable, ask for corrections. In some circumstances, you have the additional rights to object to how your information is being handled, request your data deletion, limit aspects of the processing of your information or ask for a copy of your data to be given to you, or a third party, in digital format. Though, to ensure that the study is scientifically reliable, you might be unable to review few of your records associated with the study until the study has finished.

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You might also have a right to lodge a complaint regarding your personal information processing with your local data protection authority. At any time, you can take back your consent for data processing by sending written notice to the study doctor at the address shown on the first page of this information sheet. In case you take back your consent for data processing, you will no longer be able to participate in the study, and your information will no longer be used or shared by the study doctor under this consent, unless doing so is required to ensure that the study is scientifically reliable, to record when you withdrew your consent and/or to report any unexpected health concerns that started before when you withdrew your consent. No new information regarding you will be added to the study database, however the Sponsor can still use and distribute any information it received prior to you withdrew your consent for the objectives explained in this information sheet.

Look at the section regarding withdrawing the study, for additional information regarding taking back this consent.

This study might only be carried out by gathering and using personal information on study participants as explained in this form. By putting a signature on the informed consent form, you (or your legal representative) are authorizing the study doctor and Sponsor to use and share personal information regarding your health and treatment, as indicated in the informed consent form. This consent does not have an end date.

In case you have any queries, comments or complaints regarding how your information is handled in this study, you must firstly get in touch with your study doctor who will be able to direct your query where suitable to personnel responsible for data protection at the Sponsor or site, which includes the site Data Protection Officer.

In addition, in the event the Sponsor sells Study drug to another company carrying out clinical research, your coded data collected as part of this study might be shared with that company as part of completing that transaction.

As needed by U.S. Law, a description of this clinical trial will be available on <http://www.ClinicalTrials.gov> website. Information that can recognize you will not be included on this Web site. Mostly, a summary of the results will be included on the Web site. At any time, you can search this Web site.

In addition, this study's description will be available on <https://clinicaltrials.takeda.com/> and <https://euclinicaltrials.eu/>.

### **Is there possible Future Research?**

#### **How could your data be used in the future?**

Our goal is to advance medical science and improve patient care and, in case you consent, we would like to use your coded data gathered at the time of this study, for future scientific research. Takeda and/or researchers working with Takeda might carry out this future research. This future research might be about:

- diseases, conditions, or drugs that might, or might not be included in this study;
- the efficiency, design and procedures of future studies.

In case you consent to the future use of your coded study data, your data will be held by Takeda for at least 25 years after the end of this clinical study. The data will be securely stored in different locations and only be recognized by a unique code, without your name and personal information.

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study data will also be used by Takeda to create anonymized data that cannot be linked back to you. Independent researchers outside of Takeda might request access to this anonymized data. To utilize this data, these researchers should fulfill certain needs and acquire approval from Takeda. Takeda will consider the scientific purposes of the request prior to consenting to share this anonymized data.

### Benefits

In case you consent to your data's future use, any direct benefit will not be given to you. Though, your data might contribute to research that could help others in the future. As we are not able to recognize you, results from any future research will not be shared with you. The use of your data might cause new tests, drugs, devices, or other products or services with commercial value however you will not get payment or share in any financial profits if this take place.

### Your choice

In case you change your mind regarding your coded data being used for future scientific research, at any time you have the right to take back your consent. Kindly get in touch with your study doctor, to take back your consent. In case you take back your consent after analysis has already occurred, Takeda, researchers working with Takeda, or independent researchers might still use the results.

### How could your biospecimens and images be used in the future?

This study is collecting biospecimens and images from you. Blood, tissue, and other bodily samples are included in biospecimens. Images consist of images collected from tissue slides and sections from your biopsy. These images might be digitized and analyzed to deepen our understanding of the disease and effects of your treatment.

Our goal is for advancing medical science and improve patient care, and in case you consent, we would like to use your biospecimens and images collected at the time of this study for future scientific research. This future research might be about:

- the diseases, conditions or drugs that might, or might not be included in this study
- the effectiveness, design and procedures of future studies

### Biospecimens and images Storage

In case you consent to your biospecimens and images future use, your biospecimens will be kept by the Takeda for up to 15 years after the end of this clinical study, and your digitized tissue slide/section images for up to 25 years post the end of this clinical study, unless there are local laws that need a different storage period.

### Biospecimens and images Sharing

In case you consent to the future use of your biospecimens and images, these might be shared by Takeda with researchers all over the world. To use your biospecimens and images, future researchers should fulfill certain needs and acquire approval from Takeda.

### Confidentiality

The confidentiality of your information will be secured by us to the fullest extent possible. To secure your identity, your biospecimens, images, and associated data will be coded. Only the study doctor will have the key to the code key that can link your biospecimens and images to your recognizing information. The key will be stored securely and secured. In case your biospecimens are used in future research, extra safeguards will be put in place. These extra safeguards might consist of breaking the link with the 'code key.'

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

### Benefits

In case you consent to your biospecimens and images future use, any direct benefit will not be given to you. Though, your biospecimens and images might contribute to research that could help others in the future. As we are not able to recognize you, results from any future research will not be shared with you. Your biospecimens and images use might cause new tests, drugs, devices, or other products or services with commercial value however you will not get payment or share in any financial profits if this occurs.

### Your choice

It is your choice whether to let Takeda use your biospecimens and images for research in the future or not. In case you say "yes," you can change your mind later. In case you say "no," you can still completely take part in the main study.

In case you consent however later change your mind and no longer wish to let us store, use or share your biospecimens and images for objectives of future research, kindly get in touch with your study doctor. We will do our best to honour your request to discard any of your stored biospecimens and images. Though, there might be times we will not be able to do this. In case the biospecimens and images have been used already in any future research, the information and results from that research might still be used.

### Who do you get in touch with queries?

For additional information kindly get in touch with:

|                              |                                                   |
|------------------------------|---------------------------------------------------|
| Investigator Name:           | Dr. Arijit Nag                                    |
| Daytime telephone number(s): | +91- 033 6605 7622                                |
| 24-hour contact number(s):   | +91- 9051121161                                   |
| Investigator Email Address:  | drarijitnag@gmail.com & arijit.nag@tmckolkata.com |

|                                                |                                                                                                                                     |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Ethics Committee Chairperson Name:             | Prof. Partha Pratim Majumdar                                                                                                        |
| Ethics Committee address:                      | Institutional Review Board, Tata Medical Center, 14 Major Arterial Road, EW Rajarhat New Town, Kolkata - 700160, West Bengal, India |
| Ethics Committee Chairperson telephone number: | +91- 9831004230                                                                                                                     |
| Ethics Committee Chairperson Email Address:    | Parmaj2023@gmail.com                                                                                                                |

### Has this study been reviewed?

An independent group of individuals, known as a research ethics committee has reviewed all research studies to secure your safety, rights, well-being and dignity. This study has been reviewed and a favourable opinion has been given by the ethics committee.

At any time, the Sponsor, Regulatory Authorities or the Ethics Committee might stop the study where there is good reason.

# PARTICIPANT INFORMATION SHEET AND CONSENT FORM

## Consent Form

By putting a signature below, I affirm that I have read this Participant Information Sheet and Consent Form and understand it, and I voluntarily consent to participate in this research study and consent to the informed consent form.

|                 |                                                                                                                                                                                                                                                                                                            |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study Protocol: | TAK-226-3001                                                                                                                                                                                                                                                                                               |
| Study Title:    | A Phase 3, Multicenter, Open Label, Randomized Trial to Compare the Efficacy and Safety of Elritercept versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions |

|                                                             |                          |                             |               |
|-------------------------------------------------------------|--------------------------|-----------------------------|---------------|
| Study Participant Name:                                     |                          | Study Participant Initials: |               |
| Date of Birth / Age:                                        |                          | Study Participant ID:       |               |
| Study Participant's Address:                                |                          |                             |               |
| Qualification                                               |                          |                             |               |
| Occupation (Kindly tick as suitable)                        | Student                  | <input type="checkbox"/>    | Self-Employed |
|                                                             | <input type="checkbox"/> |                             | Service       |
|                                                             | <input type="checkbox"/> |                             | Housewife     |
|                                                             | <input type="checkbox"/> |                             | Others        |
| In case you choose Others in Occupation, kindly add details |                          |                             |               |
| Annual Income of the Study Participant:                     |                          |                             |               |

(For the objective of compensation in case of trial related death)

|                                    |  |
|------------------------------------|--|
| Name of Nominee(s):                |  |
| Relation to the Study Participant: |  |
| Address of the Nominee(s):         |  |

Kindly give initial each of the given below statements to specify your agreement

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

| Sr.    | Statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | (Study Participant) |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| (i)    | I have read and I understand all the information in this Participant Information Sheet and Consent Form (this "Form"). I have been provided the chance to discuss it and ask queries. All my queries have been answered to my satisfaction.                                                                                                                                                                                                                                                                                       |                     |
| (ii)   | I am aware that I am participating in this study voluntarily and at any time I can leave the study without penalty or losing any benefits or medical care I am entitled to.                                                                                                                                                                                                                                                                                                                                                       |                     |
| (iii)  | I am aware that I might have to quit the study in case I require other treatment, do not comply with the study plan, have a study-related injury, or for any other reason.                                                                                                                                                                                                                                                                                                                                                        |                     |
| (iv)   | I consent to allow my body samples/images to be collected, tested, stored and analyzed by the Sponsor or companies working for the Sponsor for this study's objective.                                                                                                                                                                                                                                                                                                                                                            |                     |
| (v)    | I authorize individuals who have a responsibility to scrutinize the carry out of this study (for example, study monitors, auditors, the ethics committee, and applicable regulatory authorities in other countries like United States Food and Drug Administration, Medicines and Health Care Products Regulatory Agency, European Medicines Agency, Pharmaceuticals and Medical Devices Agency and others) direct access to my original medical records which might consist of information that could recognize me.              |                     |
| (vi)   | I am aware that by putting a signature on this document, I am liberally and voluntarily authorizing the collection, use, and disclosure of my coded personal information for objectives of medical research, to be shared with Sponsor, its affiliates and business partners, regulatory authorities, and the ethics committee overseeing this study.                                                                                                                                                                             |                     |
| (vii)  | I am aware that by putting a signature on this Form I am authorizing the transfer of my coded personal data, which includes sensitive data, to other countries globally, which includes countries where the data protection and privacy laws might not give the similar level of data protection as the laws in my home country or the country where I am taking part in the study.                                                                                                                                               |                     |
| (viii) | I am aware that at any time I am at liberty to take back my consent to the collection, use, and disclosure of my coded personal information without penalty or loss of benefits to which I am otherwise entitled. Though, I will be unable to carry on my participation in the research study after I take back consent, and any data regarding me (which includes health information) that has already been collected might remain part of the study in order to satisfy regulatory needs and to safeguard scientific integrity. |                     |
| (ix)   | I am aware that by putting a signature on this informed consent form I will not lose any of my legal rights.                                                                                                                                                                                                                                                                                                                                                                                                                      |                     |
| (x)    | A signed and dated copy of this Form will be given to me.                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

|                                 |  |
|---------------------------------|--|
| Study Participant Name (print): |  |
|---------------------------------|--|

|                                                          |      |
|----------------------------------------------------------|------|
|                                                          |      |
| Signature (or Thumb impression) of the Study Participant | Date |

|                          |  |
|--------------------------|--|
| Name of the Investigator |  |
|--------------------------|--|

|                               |      |
|-------------------------------|------|
|                               |      |
| Signature of the Investigator | Date |

(\* In case a Study Participant has limited ability to read and write, a witness must be present at the time of the complete informed consent discussion). In these instances, the study participant places his/ her left thumb impression in the place of the signature.

Study Participant's Legally Acceptable ☐ Not Applicable  
Representative's Statement

I, as the legally acceptable representative of the Study Participant, was present at the time of the consenting method and understand the preceding information explaining this study. All of the queries regarding the study and the study participant's participation in it have been answered to my satisfaction and that of the study participant. I state that all study aspects were presented clearly at the time of the consent method. The study participant is ready to take part in the study and I put a signature below on his/her behalf testifying to this effect.

|                                                        |  |
|--------------------------------------------------------|--|
| Name of the Legally Acceptable Representative (print): |  |
| Relationship to the Study Participant:                 |  |
| Address of the legally acceptable representative:      |  |
| Phone No:                                              |  |

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

|  |  |
|--|--|
|  |  |
|--|--|

Signature (or Thumb Impression) of the Legally  
Acceptable Representative

Date

Witness Declaration of Study Participant's Informed  
Consent

☐

Not Applicable

By putting a signature on this consent form, I certify that the information was accurately described to and apparently understood by the study participant and the legally acceptable representative (in case applicable) and that informed consent was liberally provided by the Study Participant.

|                               |  |
|-------------------------------|--|
| Name of the Witness: (print): |  |
| Address of the witness:       |  |
| Phone No:                     |  |

|  |  |
|--|--|
|  |  |
|--|--|

Signature of the Witness

Date

|  |
|--|
|  |
|--|

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

### Informed Consent Form for Optional Future Research

Kindly give initial each of the given below statements to specify your agreement

| Sr.   | Statement                                                                                                                                                                                                                                                        | (Study Participant) |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| (i)   | I have read and I understand all the information regarding the optional future research of my data/samples in this form. I have been provided the chance to discuss it and ask queries. All my queries have been answered to my satisfaction.                    |                     |
| (ii)  | I am aware that my participation in this future research is voluntary, and at any time I can take back my consent without penalty or losing any benefits or medical care I am entitled to, and without it impacting my participation in the main research study. |                     |
| (iii) | I am aware that by putting a signature on this informed consent form I will not lose any of my legal rights.                                                                                                                                                     |                     |
| (iv)  | A signed and dated copy of this consent form will be given to me.                                                                                                                                                                                                |                     |

#### **Kindly check the box next to your choice regarding whether to participate in future research:**

|       |                                                                                                                                                                                                                                                                |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (i)   | I consent that my coded study data might be used by Takeda and/or researchers working with Takeda for the future research explained in this informed consent form.<br><input type="checkbox"/> Yes <input type="checkbox"/> No                                 |
| (ii)  | I consent that my study data can be anonymized, used and shared by Takeda with independent researchers for the future research explained in this informed consent form.<br><input type="checkbox"/> Yes <input type="checkbox"/> No                            |
| (iii) | I consent that my remaining biospecimens might be used by Takeda, researchers working with Takeda and/or independent researchers, for the future research explained in this informed consent form:<br><input type="checkbox"/> Yes <input type="checkbox"/> No |
| (iv)  | I consent that my images might be used by Takeda, researchers working with Takeda and/or independent researchers, for the future research explained in this informed consent form:<br><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No      |

|                                 |  |
|---------------------------------|--|
| Study Participant Name (print): |  |
|---------------------------------|--|

|  |  |
|--|--|
|  |  |
|--|--|

Signature (or Thumb impression) of the Study Participant

Date

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

|                               |      |
|-------------------------------|------|
| Name of the Investigator      |      |
|                               |      |
| Signature of the Investigator | Date |

(\* In case a Study Participant has limited ability to read and write, a witness must be present at the time of the complete informed consent discussion). In these instances, the study participant places his/ her left thumb impression in the place of the signature. Additionally, it shall be specified clearly in the ICF that the content of informed consent is completely presented to the Subject or LAR in oral with the attendance of the witness at the time of the complete informed consent discussion and the subject or LAR understands the content of the informed consent.

Study Participant's Legally Acceptable ☐ Not Applicable  
Representative's Statement

I, as the legally acceptable representative of the Study Participant, was present at the time of the consenting method and understand the preceding information explaining this study. All of the queries regarding the study and the participation of the study participant in it have been answered to my satisfaction and that of the Study Participant. I state that all study aspects were presented clearly at the time of the consent method. The study participant is ready to take part in the study and I put a signature below on his/her behalf testifying to this effect.

|                                                        |  |
|--------------------------------------------------------|--|
| Name of the Legally Acceptable Representative (print): |  |
| Relationship to the Study Participant:                 |  |
| Address of the legally acceptable representative:      |  |
| Phone No:                                              |  |

|                                                                          |      |
|--------------------------------------------------------------------------|------|
|                                                                          |      |
| Signature (or Thumb Impression) of the Legally Acceptable Representative | Date |

## PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Witness Declaration of Study Participant's Informed Consent

☐

Not Applicable

By putting a signature on this consent form, I certify that the information was accurately described to and apparently understood by the study participant and the legally acceptable representative (in case applicable) and that informed consent was liberally provided by the Study Participant.

|                               |  |
|-------------------------------|--|
| Name of the Witness: (print): |  |
| Address of the witness:       |  |
| Phone No:                     |  |

|                          |      |
|--------------------------|------|
|                          |      |
| Signature of the Witness | Date |

(A copy of the participant information sheet and properly completed consent form shall be given to the study participant or his/her attendant)