

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), referred throughout the document as the “study drug”
Sponsor of the study:	Takeda Development Center Americas, Inc. 500 Kendall Street Cambridge, MA 02142 USA
Phase of the study:	III

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

Introduction

We are inviting you to take part in a clinical research study for Study drug (the “Takeda Study Medication(s)”) because you have anemia due to diagnosis of lower-risk myelodysplastic syndrome (MDS) requiring blood transfusions. Takeda (“Sponsor”) is the company that is paying for the study.

Taking part in the study is entirely voluntary. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. It is up to you if you do or do not want to take part.

Please take time to read this form carefully.

This form tells you important information about the research study. It is important for you to understand why the research is being done, the potential risks and benefits involved, and what you have to do before you decide if you want to take part in this research study. Please take time to read and discuss the information on this form carefully.

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

Your study doctor or a member of the study team will explain the study to you. Please ask your study doctor or a member of the study team if there is anything that is not clear. They can also provide more information if you need it.

Your decision will not change the medical care you get from your doctors now or in the future.

If you decide to take part, you must sign and date the consent at the end of this form. Even after signing the consent, you are free to leave the study at any time without giving a reason. This form will tell you how to withdraw and what that means to you.

If anything changes about the research study, you will be informed and asked to sign again if you agree to the changes.

Why is this study being done?

We are asking you to take part in a research study for an investigational treatment of anemia due to lower-risk myelodysplastic syndrome (LR-MDS). LR-MDS affects your bone marrow causing it to not produce enough mature red blood cells resulting in low hemoglobin levels and symptoms of anemia. You are being

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offered this research study because you need red-blood cell (RBC) transfusions to treat 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 the drug has not yet been approved by regulatory authorities for treatment of anemia due to LR-MDS. Earlier studies in patients with LR-MDS showed the study drug could be administered at a safe dose with manageable side effects. The earlier studies in LR-MDS patients also showed some improvements in hemoglobin and reduced need for blood transfusions. This study will evaluate the use of study treatment compared to a commonly used treatment.

This study is being done to help answer the following question(s):

- How safe is Study drug and what are the side effects that might be related to 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 need for RBC transfusions compared to epoetin alfa?
- How much does Study drug improve quality of life compared to epoetin alfa?

This research may allow study doctors to better understand the study drug effects on the body and to identify future patients who may benefit.

What is the Takeda study drug?

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

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

This study drug is given by injection into the fat under the skin called a subcutaneous injection. It is given once every 28 days (once per month). The dose of study drug will not be given if your hemoglobin level is increasing quickly or is at a high level, or if the study drug is causing significant side effects.

What is the other study drug(s)?

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

Epoetin alfa is a manufactured protein known as an erythropoiesis-stimulating agent (ESA) designed to act like a hormone (specialized protein called erythropoietin) which stimulates the bone marrow to produce more red blood cells. Epoetin alfa was chosen as the comparator drug because it is commonly used for initial treatment of anemia due to LR-MDS. Epoetin alfa is recommended by international clinical practice guidelines.

Epoetin alfa is given by injection into the fat under the skin called a subcutaneous injection. It is given once every 7 days (once a week). The dose of study drug will not be given if your hemoglobin level is increasing quickly or is at a high level, or if the study drug is causing significant side effects.

If you are assigned to epoetin alfa treatment, your study physician may allow you to receive some of the weekly injections at home or at another approved location. If allowed, these injections can be given by a home healthcare provider or, if you have been appropriately trained, by yourself. If you are allowed to self-administer the epoetin alfa, then you will be asked to complete a medication diary card and return it to the site at your next study visit.

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How is the study set up?

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

You will be randomly selected to get one of the following two study treatments:

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

When you are randomly assigned a treatment, this means you are put into a treatment group by chance (like tossing a coin).

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

There will be 210 to 300 patients who will be participating in this study. Patients must be adults aged 18 years or older with anemia requiring blood transfusions due to LR-MDS who have not received other treatment. The study will take place at about 150 clinical sites in 28 countries across the world. You will be in the study about 5-8 years depending on how many patients are enrolled before you.

What will happen during the study visits and what do you have to do?

If you choose to participate in this study, the study doctor and study staff will collect certain personal information. This section explains what procedures will be done to collect this information.

To participate in the study, you might also be asked to discontinue certain medicines you are currently taking. The study doctor will discuss the medications you take now before you start the study and tell you if you need to stop taking any of them before you take the study drug.

This study will collect blood, urine and bone marrow samples from you as part of this study. The samples will be used to monitor your health status during the study.

In addition, some of these samples may be used for further research on MDS looking at “markers” of the disease that can be found in the blood and bone marrow. These sample(s) and test data may be used by the Sponsor, its agents and its affiliated companies:

- To help develop new ways to monitor and treat anemia due to diagnosis of LR-MDS.
- To generate information needed for further research and diagnostic tests related to diseases or conditions that Study drug might treat.
- To help obtain 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 effectiveness of Study drug and MDS disease states.

This study consists of 4 time periods:

1. **Screening Period:** This period starts at the time you give consent to participate in the study and ends when your study doctor has confirmed whether or not you are eligible for the study and can be randomized to the study treatment. During this time several assessments and tests will be done and your medical history information will be reviewed by the study doctor. This period may take up to 6 weeks and can be increased by an additional 6 weeks (for a total of 12 weeks) if needed for your doctor to confirm whether you are eligible for the study treatment.
 - Rescreening: If during the screening period your study doctor determines you have the applicable diagnosis of LR-MDS but you are not eligible for the study for other reasons you will not be allowed to start the study. But if these reasons are conditions that may change or improve

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over time, your study doctor may offer to you to repeat the screening for the study. You would have to start from the beginning with giving your consent and repeat the assessments and tests, but you may not have to repeat the bone marrow test.

- **Randomization:** If you are eligible for the study, then your study doctor will enter your information into an electronic system that is programmed to automatically assign you to either Study drug or epoetin alfa treatment. Your study treatment will be started within 3 days of randomization.
2. **Treatment Period:** This is the time period from start of study treatment until your study doctor and you decide to permanently stop the study treatment. During this time you will be seen at the site or, if allowed, by a home healthcare provider every other week and sometimes weekly. During these visits there will be regularly repeated assessments and tests performed, the study staff will record any side effects or blood transfusions you have and you will complete questionnaires about how you feel. The study drug will be administered to you during this time on a monthly basis if you are assigned to Study drug treatment or on a weekly basis if you are assigned to epoetin alfa treatment.
 - If your study treatment stops before 6 months: You will be asked to still complete the questionnaires and information about blood transfusions up to 6 months.
 - **End of Treatment Visit:** When your study doctor and you decide to stop the study treatment you will be asked to return for a study visit to complete some assessments and tests to assess any effects from the treatment.
 3. **Safety Follow-Up Period:** This time period will last approximately 60 days starting from the day after your End of Treatment Visit. You will be asked to visit the site at 1 month and 2 months after you complete the End of Treatment Visit for some assessments and tests to assess any continuing effects from the treatment.
 4. **Survival Follow-Up Period:** This time period will start on the day following your last safety follow-up visit last and will continue until you have been on the study about 5-8 years or the study is stopped. During this time you will be contacted every 3 months to check on your disease status, to report any other treatment you are receiving and to answer some questions about your health status.

Please refer to **Table 1** on the next page for the schedule of all tests and assessments to be performed during the study. An explanation for each test and assessment is provided in **Table 2**.

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Table 1: Schedule of Activities

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

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Adverse Event and Concomitant Treatment Assessment	X	X	X	
Survival and Disease Status				X
Subsequent Treatment				X

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Details of the tests and assessments are provided in Table 2.

Table 2: Activity Details

Informed Consent	Before you can start the study, the study staff will talk to you about the study and you will have to sign a consent form if you wish to participate.
Medical History	You will be asked how you are feeling, about your medical history, demographics (such as year of birth, age, sex, race, and ethnicity), and about any medicines you are taking. This will include any prescription or non-prescription medications. This helps us understand your overall health and whether this study is right for you.
MDS Disease and Transfusion History	Your study doctor will collect information about your diagnosis of MDS, including when you were diagnosed, the type of MDS you have, and how it has been treated. Tests to confirm the status of your MDS disease will be performed during the screening period including bone marrow and blood tests. Your study doctor will also collect information about your previous treatments with red blood cell or platelet transfusions, including the results of any blood work obtained beforehand to see how much hemoglobin was in your blood before each transfusion. The number of transfusions given to you in the past 2 months when your hemoglobin was low will be counted. All of this information helps your study doctor to understand the status of your disease and whether this study may be an option for treatment.
Physical Exam	A physical examination is a routine assessment by your study doctor to check your overall physical health. It usually includes: looking at the body, feeling and tapping areas of the body, such as your belly, and listening to sounds, such as your lungs. After the first complete physical examination later repeat assessments may be limited to a few areas of your body based on your symptoms or physical complaints.
Vital Signs	Vital signs are measurements of your blood pressure, heart rate, respiratory rate (number of breaths per minute), and temperature.
Height and Weight	Your height will be measured once at the beginning of the study. Your weight will be checked every month to make sure the correct dose of study drug is given. To measure your weight, you will be asked to remove 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 working. You will have small, soft pads placed temporarily on the chest, wrists and ankles and connected to a monitor that will show the electrical activity of your heart.
Echocardiogram (ECHO)	An echocardiogram (ECHO) is a test that uses sound waves (ultrasound) to make pictures of your heart to show how well the heart muscle and the structure of the heart is working. A probe called a transducer is passed over your chest (transthoracic) or in your throat (transesophageal) to take pictures of your heart shown on a video monitor. This exam may take up to 30 minutes to 1 hour to complete. If a transesophageal ECHO (TEE) is performed, a thin, flexible tube with a small probe will be gently placed down your throat into your food pipe (esophagus), which sits behind your heart, to take clear pictures using sound waves. You will receive medicine to relax and numb your throat beforehand.

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Coagulation	A blood sample will be taken by needle stick (or an intravenous (IV) line if 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 if you have one) to measure the number and types of cells in your blood, such as red blood cells, white blood cells, and platelets. The total amount of blood required each time this test is performed is about 4 mL or about 1 teaspoon. This test will be repeated at least every 2 weeks or more often if needed. The hemoglobin results from this test will be used to monitor your response to the study drug and to assess whether you may need blood transfusions.
Chemistry	A blood sample will be taken by needle stick (or an intravenous (IV) line if you have one) to check your general health and to measure components of your blood to see how well your liver and kidneys are working. The total amount of blood required each time this test is performed is about 6 mL or about 1½ teaspoons.
Urinalysis	You will be given a cup to take to bathroom. You will be asked to pee into this cup. The urine collected will be used to do some tests. Some of the urine will also be sent to a clinical laboratory for testing.
Pregnancy Testing	If you are a woman who can have children, a urine sample is required to test if you are pregnant. If the test is positive, then a blood test (about 5 mL or 1 teaspoon) will be required to confirm. If you are pregnant, you will not be able to start the study or will have to stop the study treatment if you have already started.
Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV) Status Check	You will be asked about your history of HBV, HCV and HIV infection. If you have any of these viruses you will not be able to participate in the study. If you have never been tested or are unsure of your status, then your study doctor may need a blood sample taken by needle stick (or an intravenous (IV) line if you have one) to test your blood for HBV, HCV and/or HIV. If the results show that you have hepatitis B, hepatitis C, and human immunodeficiency virus, you will be told this in confidence and be given information about medical follow-up. Positive results for certain viruses causing these infectious diseases may need to be reported to the local health authorities in your country, if required by law.
Serum Erythropoietin (EPO)	A blood sample will be taken by needle stick (or an intravenous (IV) line if you have one) to assess how much of the hormone erythropoietin (serum EPO) is present in your blood. This hormone helps to balance the amount of red blood cells produced in the bone marrow. If the level is too high this study treatment may not be a good option and you would not be eligible.
Peripheral Blood (for Blood Smear) and Bone Marrow Sample Collection	Bone marrow sample collection includes bone marrow aspirate and bone marrow biopsy. These procedures are done 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 about 5 mL (1 teaspoon) of bone marrow fluid. For the bone marrow biopsy, a special hollow needle is inserted into the hip bone to withdraw a small piece (about 1.5 cm or 0.5 inches long) of the solid part of the bone and bone marrow. This is about the thickness of a lead pencil. You may be given some sedation or local anesthesia to numb your skin to minimize any pain associated with these procedures, but there may still be discomfort and bone pain for some time after these procedures. Your study doctor may provide you with medication if needed for the discomfort.

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	In addition to the bone marrow assessment, a few drops of blood will be taken by needle stick (or an intravenous (IV) line if you have one) and placed on a slide. This blood smear will be sent, along with the bone marrow samples, to the study specific pathology laboratory to assess your MDS.
MDS Disease Assessment	The peripheral blood sample (for blood smear) and bone marrow samples referred to above will be sent to the study specific pathology laboratory during screening, after you complete 24 weeks and 48 weeks of treatment, and then as deemed necessary by your study doctor until the end of study treatment visit (EOTx). A peripheral blood sample (for blood smear), bone marrow aspirate and bone marrow biopsy are required at screening and after you complete 24 weeks of treatment. The bone marrow biopsy is optional thereafter. During screening, the MDS disease assessment is done to confirm your diagnosis of LR-MDS and to determine if you are eligible for the study. During study treatment, the MDS disease assessment is done to understand the status of your LR-MDS and to assess how much your disease responds to the study treatment.
Randomization	You will be randomly assigned to one of two treatment options by a computer program depending on your disease stage and risk factors. When you are randomly assigned a treatment, this means you are put into a treatment group by chance (like tossing a coin).
Study drug Dosing	This is the investigational drug being tested in this study. It is administered under the skin by injection (subcutaneous injection) every 28 days (once per month).
Epoetin Alfa Dosing	This is the standard of care drug being compared to the investigational drug in this study. It is administered under the skin by injection (subcutaneous injection) every 7 days (once per week).
Transfusion Verification	You will be asked about any blood transfusions you have received since your last visit to the site. This includes any transfusions that may have been given at a different clinic or hospital. If a transfusion does occur at a different clinic or hospital, then your study doctor will need to obtain copies of a report documenting the transfusion procedure, as well as the results from any blood tests (including hemoglobin, platelets and iron related tests) done prior to the transfusion.
Pharmacokinetic Assessment (PK)	If you are assigned to Study drug treatment, then blood samples taken by needle stick (or an intravenous (IV) line if you have one) will be collected to measure how much Study drug is in your blood and assess how well your body absorbs and breaks down the study drug. A portion of this sample may be used for biomarker research purposes. The total amount of blood required each time this test is performed is about 16 mL or about 3 teaspoons per sample.
Anti-Drug Antibody (ADA) Assessment	If you are assigned to Study drug treatment, then blood samples taken by needle stick (or an intravenous (IV) line if you have one) will be collected to check if your immune system is making antibodies (proteins) to Study drug. This would occur if your body perceives the study drug as a foreign substance in your blood. The total amount of blood required each time this test is performed is about 8 mL or 1½ teaspoons.
Biomarker Assessments	Some blood samples will be taken by needle stick (or an intravenous (IV) line if you have one) strictly for research purposes. Biomarkers are biological or chemical “markers” that can be found in blood and tissue samples of patients with MDS. Biomarker research may help us learn

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	which patients are more likely to respond to the study drug or more likely to develop side effects to the study drug. It also helps us determine what other effects the study drug is having on the body. This research will not benefit you, but it may help people in the future. The biomarker assessments in this study include the following: ▪ A blood sample (about 8 mL or about 1½ teaspoons) will be collected once per month while you are on study drug to test for known clinical biomarkers. ▪ Another blood sample (about 11 mL or about 2 teaspoons) will be collected at 7 timepoints within the first 12 weeks of study treatment and then quarterly thereafter to test for exploratory biomarkers. This blood sample will also be used for disease-associated genetic tests of your ribonucleic acid (RNA). ▪ An additional blood sample (about 3 mL or about ½ teaspoon) will be collected on your first day of treatment to test for disease specific genetic mutations.
Healthcare Resource Utilization Assessment	During routine 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. Additionally, data will be gathered on the number of unplanned site visits, diagnostic procedures, and treatment interventions that did not require hospitalization.
Adverse Events	You will be asked if you have noticed any negative signs and symptoms or any changes in your health. These changes are called adverse events.
Concomitant Medications/Procedures	You will be asked about any medications you continue to take or any new medications you have started taking. It is important that you tell the study doctor about all the medications you are taking including: prescription drugs, over-the-counter medicines, vitamins, herbal supplements, vaccines and anything else you may take. You may not take any other medications to treat your LR-MDS or take part in another research study that involves taking medication while you are on this study treatment. You will also be asked about any blood transfusions or any other medical procedures or surgeries that you have had or are expected to have.
Survival Follow-up and Disease Status	After completion of the safety follow-up period, you will enter the survival follow-up period where you will be contacted, typically by telephone, every 3 months to see how you are feeling and to provide updates on your MDS disease status. You will also be asked to complete the EQ-5D-5L questionnaire by phone.
Subsequent Treatment	During the survival follow-up period, you will be asked to report any treatments for MDS disease that you have started since stopping the study treatment.

Patient Reported Outcomes (PROs) Assessments Required During the Study

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

Minimum Blood Volumes

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

Time Period	Blood Volume (tablespoons)
Screening Period	Approximately 35 mL or about 2½ tablespoons
Study Treatment Period (through End of Treatment (EOTx) visit)	Approximately 50-125 mL or about 3½-8½ tablespoons per month
Safety Follow-Up Period	Approximately 18 mL or about 1 tablespoon per month
Survival Follow-Up Period	None
Additional monthly testing up to 1 year if you have antibodies to elriterccept at end of the safety assessment	Approximately 8 mL or about ½ tablespoon each month
If you have a transfusion, sample for hemoglobin and chemistry	Approximately 10 mL or about 1 tablespoon before each transfusion

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

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

All patient reported outcomes (PROs) assessments must be completed using the above identified electronic devices and associated technology. You will not be able to participate in this study if you choose not to use the electronic devices and associated technology.

By providing your consent, you agree to use the electronic devices and associated technology as requested. Please note that:

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

You will be provided with additional information on the electronic devices and associated technology if you choose to enroll in the study. If you have questions about the use of the electronic devices and associated technology, please ask your study doctor.

What will happen to your study samples and biomarker images?

All blood, urine, and bone marrow sample(s) taken from you during the study will be sent to the Sponsor's designated laboratory. The laboratory will temporarily store the sample(s) and arrange for tests that relate to this study. The sample(s) will be labeled with a code and not your name.

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

How will your samples be stored?

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

All bone marrow aspirate, bone marrow biopsy and peripheral blood samples collected for the biomarker research will be stored by the Sponsor with its long-term storage partners. This includes the bone marrow aspirate, bone marrow biopsy and peripheral blood samples collected for MDS disease assessment and biomarker/PK/ADA assessments. These samples will be kept for up to 15 years after the end of the study, unless there are local laws which require a shorter storage period, or you withdraw consent for sample storage and use. After that time, the samples will be destroyed. The study doctor will keep records linking your identity with your samples as required by applicable law.

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Can I withdraw my consent for using my samples?

If you withdraw from the study, you may also request that your sample(s), and material obtained from your sample(s), be destroyed at any time by contacting your study doctor. As long as the records linking your identity to your sample(s) exist, your sample(s) can still be destroyed. However, the Sponsor will be entitled to keep and use any study results or information which was obtained from your sample(s) prior to 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 performed with these samples, may be used individually or combined with other data. The tests performed with these samples are not intended to make determinations about your health or the likelihood you will develop any disease, so no test results will be provided to your doctor or put into your medical record. By signing this consent form, you agree that we may store your samples and may use them for the research described in this informed consent form.

Who owns my samples and how will they be used?

The information gathered from the sample(s) collected from you in this study will be analyzed and evaluated by the Sponsor, and may result in new discoveries, patents or products. You have no rights to and will not receive payments of any kind for such discoveries, patents or products. By consenting to participate in this clinical study, you are giving up any ownership rights that you may have in sample(s) collected from you during this study to the study Sponsor.

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

How will your personal information be protected for samples?

We will protect the confidentiality of your information to the fullest extent possible. Your samples and associated data will be coded to protect your identity. Only the study doctor will have the key to the code key that can link your samples to your identifying information. The key will be securely stored and protected. For more information about how we protect your privacy, please see the section entitled <“How will your privacy be respected, and the confidentiality of your personal information be maintained?”>.

Biomarker Image Analysis

Biomarker testing may involve image analysis that is performed on your tissue biopsy after it is sectioned and placed on a glass slide. This testing utilizes specialized image analysis computer software to count or measure different cell types in the tissue. This testing may help researchers learn how changes in cell populations may affect a disease or response to treatment. Analyses of samples from a large number of people may also help researchers learn more about other diseases, possible links among diseases, and new avenues for drug development.

Please be aware that the biomarker images of bone marrow will be recorded and saved to a computer program and sent in a secure way to the Sponsor and/or their commercial partners for central reading and analysis purposes. A unique code that is assigned to you will identify the recorded materials. Your name or other identifying information will not be used. Personnel from the Sponsor and the Sponsor's partners for this study may view these recordings. The biomarker images will be kept private, and no other person will have access to these images in so far as permitted by law. Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your information. Biomarker images will be maintained in a secure location with limited access. The biomarker images will be stored for at least 25

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years from the end of the study, or if less, the maximum period permitted under applicable law or until consent is withdrawn. After that time, the biomarker images will be destroyed.

Genetic Testing

Genetic testing will be performed on your diseased bone marrow tissue and/or blood samples to identify mutations in key genes found in MDS and acute myeloid leukemia (AML). Genes are made of a type of molecule called deoxyribonucleic acid, or DNA, and DNA varies widely from one person to another. DNA is the genetic material that carries the instructions for your body's development and function. Each person's body has tens of thousands of genes ("genome"). Your genome or all of your genetic material will not be tested. Only a limited set of selected genes in your diseased bone marrow tissue and/or blood sample(s) will be tested.

Biomarker testing will involve the analysis of all ribonucleic acid (RNA) from the cells in your blood. This will allow us to learn how genes are expressed in those cells at the time of collection. This testing may help researchers learn how changes in the expression of genes are related to disease or study drug treatment response. The RNA analysis is for research purposes only and is not a medical test. This means that the medical importance of the results may not be known, or that they may not be related to any medical condition. The results of tests on your sample will not be given 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, but there is always the remote possibility that information from your participation in the research may be disclosed.

What are the side effects of the study drugs and the risks of taking part in the study?

During the study, you may have discomforts and risks from Study drug and the study procedures. These may vary from person to person. Everyone taking part in the study will be watched carefully for side effects; however, doctors do not know all the discomforts and risks that may happen. There is always the possibility that unknown risks may occur and some of which could be serious, life-threatening, or even fatal. It is important that you report all symptoms/health problems to the study doctor/staff, whether you think these problems are due to the study drug or not. If it is an emergency and you cannot reach the study team or doctor, you should call local emergency services immediately. If you have a severe reaction to the study drug, the study doctor may decide that you should be withdrawn from the study for your safety.

The more commonly occurring discomforts and risks are listed below, as are the rare but serious discomforts and risks.

Furthermore, there is a possibility of failure of investigational product to provide intended therapeutic effect. As the purpose of this study is to assess the safety and efficacy of an unapproved investigational product (study drug), it is possible that the study drug may not have the intended therapeutic effect.

What are the potential risks for taking the Takeda drug?

As of 03 April 2025, approximately 109 participants with MDS have received at least 1 dose of elritercept in clinical trials with most participants receiving elritercept for 12 months.

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

You may have none, some or all of the side effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the study doctor.

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Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your study drug treatment. Tell your study doctor immediately about any new or unusual symptoms or changes in your health that you become aware of or have concerns. Your study doctor will discuss with you how to manage symptoms or side effects. The treatment of the side effects will depend on the type and severity of the symptom(s).

During screening before study treatment or during participation with study drug treatment if a previously unknown medical condition is discovered, the study doctor will discuss:

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

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

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

- Loose, watery stools
- Tiredness/weakness
- COVID-19
- Low red blood cells: may cause shortness of breath/difficulty in breathing; 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
- Swelling in hands, feet, or ankles
- Cough
- Increased blood pressure
- Urinary tract infection (symptoms of infection may include fever, pain, redness, burning when peeing, difficulty peeing or blood in urine)
- Joint pain
- Headache
- Back pain
- Vomiting

There is a potential for developing antibodies to the study medication, indicating an immune reaction. Sometimes, this may cause the medication to not work effectively or may cause allergic reactions (see below additional information). It may also cause a skin reaction where an injection (shot) was given called an injection site reaction, which may cause some redness and swelling.

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Additionally, low platelets (may cause bruising or bleeding), fever, neutropenia (a condition in which the number of white blood cells called neutrophils is abnormally low which may increase the risk of infection), and lung infection (symptoms of infection may include fever, chest pain, cough, and/or difficulty in breathing) have been reported very commonly in another research study by the participants with a blood condition called myelofibrosis treated with Study drug alone.

What are the risks of epoetin alfa?

If you are assigned to receive the comparator study drug epoetin alfa and not Study drug, you may 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 may be mild, moderate or severe. There may be other risks that are not known which may be serious. Tell your study doctor immediately about any new or unusual symptoms or changes in your health that you become aware of or if you have concerns. Your study doctor will discuss with you how to manage symptoms or side effects. The treatment of the side effects will depend on the type and severity of the symptom(s).

- Loose, watery stools
- Nausea
- Vomiting
- Fever
- Headache
- High blood pressure and severe increase in blood pressure (known as hypertensive crisis) could lead to brain disorder, seizures, stabbing migraine-like headaches and possible stroke)
- Increased risk of blood clots in a vein (possible symptoms include pain, swelling, and/or redness), or in an artery (may lead to organ damage such as stroke, failure to breathe, possible blindness, bleeding in brain, and/or heart attack) which can be life-threatening 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 given, which may cause some redness and swelling
- Swelling in arms and/ or legs
- Cough
- Seizure (especially in patients with history of epilepsy and conditions like brain and spinal cord infection or brain cancer)
- Joint pain, bone pain, muscle pain and/or body aches, arm and/or leg pain
- High blood platelet count (may lead to increased clotting)
- High blood levels of potassium (may lead to kidney failure or heart effects)
- Respiratory tract congestion (blockage or stuffiness in the airways, often due to excess mucus or inflammation)
- Decreased bone marrow function and inability to make red blood cells causing a low red blood cell count known as anemia, including symptoms of fatigue, weakness, and pale skin
- Hypersensitivity and Anaphylactic reaction: Allergic reaction that may include a rash, hives, fever, difficulty breathing, swelling beneath the skin, often around the eyes, lips, tongue, and

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throat (angioneurotic oedema), and low blood pressure. Although usually reversible with treatment, it can be severe or life threatening.

- Worsening of genetic disorder called porphyria that may include symptoms such as abdominal pain, confusion, anxiety, seizures, muscle pain, increased sensitivity to sunlight leading to skin reactions such as blisters and itching on sun-exposed areas.

Other adverse reactions reported with epoetin alfa includes severe skin reactions like Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) which may show up as various blisters, hives, and other lesions in various locations on the body including palms and soles, face and other extremities. This is serious and may be life threatening. If you have any of these side effects, inform your study doctor immediately.

Allergic reaction risks: Any medication has a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. They are mild to moderate in severity. However, life-threatening reactions may occur at any medication dose. If you believe you are having a serious allergic reaction after receiving Study drug or epoetin alfa, you should seek emergency medical assistance immediately. Please notify the study doctor immediately if you experience any of these symptoms. Some symptoms of allergic reactions are:

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

Your study doctor will monitor you carefully for any signs or symptoms that you may be having an allergic reaction, and appropriate care will be taken by the study doctor. If you do not understand what some of these side effects or risks mean, ask the study doctor to explain them to you.

Are there any other potential risks for taking part in this study?

While clinical studies are designed to ensure the safety and well-being of participants, there are still some risks and discomforts associated with the study procedures that you should be aware of:

Blood Sample Collection: During blood sample collection, you may feel slight pain and/or experience bruising where the needle was inserted into the skin. You may also experience excess (too much) bleeding, blood clots, and infections where the needle was inserted into the skin, but this is very rare. Fainting occasionally occurs during, or shortly after, blood is drawn. This event most frequently occurs if you get up quickly from a sitting or lying down position. If you feel faint, you should notify study site staff and lie down immediately to avoid possible injury caused by falling. Very rarely, some people have short and long-term damage of vessels and nerves, which can be irreversible and can lead to long term pain and impairments.

Bone Marrow Aspirate and Biopsy: Possible side effects include bleeding, infection, bruising, pain, or discomfort at the needle stick site. Depending on the procedures at your trial center you might receive a numbing medicine that will be injected into the skin above the area of the bone to reduce the pain. Rarely, nerve damage may occur. In very rare cases, people might have an allergic reaction to the local anesthetic (numbing medicine). The allergic reaction could include rash/hives, flushing of the face, itching, wheezing, and tightness in the throat. A scar may also form at the aspiration/biopsy site. You may have to sign and date a separate consent form for the bone marrow biopsy and aspiration.

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Echocardiogram (ECHO): Some people may feel uncomfortable having to lie in one position and you may develop mild rash or skin irritation where the electrodes (sticky patches) were placed. [If Transesophageal Echo \(TEE\) is performed](#), possible side effects include sore throat, infection, or aspiration in addition to potential esophageal injury, including bleeding or perforation (very rare).

Electrocardiogram (ECG): You may have mild irritation, redness, or itching where the recording patches are placed.

Subcutaneous Injection: In a subcutaneous injection, a short needle is used to inject a treatment into the tissue layer between the skin and muscle. If you have any of these reactions, your doctor should be contacted right away. As with any type of injection, there is a possible risk of infection where the shot was given. Other risks are an injection-site reaction, which is a localized reaction that may occur at the site where the study drug is injected. Symptoms associated with an injection-site reaction may include pain, redness, tenderness, warmth, itching, swelling, discomfort, bleeding, hardening of the skin in the area surrounding where the study drug was administered, and severe skin or tissue damage.

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

- You may have a mild allergic reaction with skin itching and hives, fever and chills; rarely a serious allergic reaction may occur with severe shortness of breath, fast heart rate, chest pain, nausea and vomiting.
- If you have heart or kidney conditions, you may have increased difficulty breathing and a cough; the additional fluid may put extra stress known as overload on your heart or kidneys.
- If you have had multiple RBC transfusions, you may produce antibodies (proteins in your blood) that attack the new red blood cells in your blood or you may wind up with too much iron in your body that may require medication to help your body remove the iron.
- If you have had multiple platelet transfusions, you may produce antibodies (proteins in your blood) that attack and destroy platelets in your blood. As a result, you may experience easy bruising, bleeding gums, nosebleeds or blood in your urine or feces for about 5-12 days after your transfusion.
- Your immune system may destroy all of the red blood cells (RBCs) in your body if the RBCs in the transfusion do not match your body's own RBCs. This may cause a rare, but serious, reaction with chest pain, chills and fever, dark urine, lower back pain and nausea.
- If you have a weakened immune system from transplants or other diseases, you may have an increased risk of fever, diarrhea and rash due to graft versus host disease when donated white blood cells attack your body tissues
- Rarely, donated blood may carry harmful bacteria or viruses that cause blood-borne infection

What are the risks of the genetic/genomic tests?

When you donate your blood or tissue for MDS genetic research, you are sharing genetic information about yourself. Because family members share some of your genes, this information could also reveal things about your biological relatives. However, it is extremely unlikely that the Sponsor will find genetic changes that can be passed down in families, since the research will only look at genes linked to MDS in diseased (not healthy) tissue. Still, there are some risks to consider. There is a small chance that information from this research could one day be traced back to you. If that happened, it could affect your privacy, and there is a possibility—though unlikely—that it could lead to discrimination by employers or insurance companies against you or your family members. To protect your identity, your samples will only be labeled with your study number, not your name or other personal details. However, because technology is always changing, we cannot predict all possible future uses or risks related to genetic information.

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Pregnancy, contraception, and breastfeeding

Both men and women will be invited to participate in this study, including women who are able to have children.

Please read the following instructions carefully, there are some requirements related to contraception and pregnancy in order to take part in this study. The study doctor will provide counselling for appropriate birth control methods throughout the study. The study doctor will remind you of the importance of not becoming pregnant during the study.

For Men

It is not known whether the study medication will affect sperm or an unborn baby. For this reason, to be in the study you must agree not to father a child during the study and for at least 60 days after the last dose of the study medication.

If you are a male participant and sexually active with a female of who is pregnant, or could get pregnant, regardless of if you have had a vasectomy, you must agree to use condoms with or without spermicide each time you have sex during the study and until at least 60 days after the last dose of the study medication.

If your partner does become pregnant while you are taking part in the study drug treatment, you must tell your study doctor immediately who will be able to advise you. In this situation, your partner should be under medical supervision during her pregnancy, and the baby should be under supervision after it is born. Your partner may be asked to give her consent to the collection of information related to both herself as well as the baby.

For Women

If you have been surgically sterilized or have been through the menopause (discuss this with your study doctor), you do not need to meet any contraception or pregnancy test requirements to take part in this study. Otherwise you must agree not to become pregnant or breastfeed a baby during the study and at least 60 days after the last dose of study medication.

If you could get pregnant and are sexually active with a male partner who has not been sterilized, you must agree to use highly effective contraception (listed below) from the time of signing the ICF and until at least 60 days after the last dose of the study medication:

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

In order to be eligible for the study, you must have a pregnancy test to confirm that you are not pregnant. This test will be repeated just before you start taking the study medication and then regularly throughout the study until at least 60 days after the last dose of study drug.

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If a pregnancy test during the study shows that you may be pregnant, the study drug treatment will be stopped and the treatment will end. By signing this document, you give consent to the collection of information related to both yourself and your baby.

You will be asked for the results of any tests and procedures carried out during your pregnancy and up to the birth. You may also be asked for the results from any evaluation of the baby after the birth.

What are the possible benefits of taking part in this study?

You may or may not benefit as a result of taking part in this study. It is not guaranteed that your need to receive blood transfusions will decrease; it may even get worse. This study is being conducted to collect more information about a drug that may benefit others in the future.

What happens if something goes wrong, or I get hurt?

You shall follow the instructions from your study doctor. If you suffer an adverse reaction in the study, please notify your study doctor immediately, and free medical management will be provided as long as required, or till such time it is established that the injury and/or the adverse reaction is not related to the study drug or the study procedure, whichever is earlier.

In the event of any trial-related injury or death (as defined in the applicable Indian regulations) arising directly from the proper management of the study drug according to the protocol or the proper performance of the study procedure required by the protocol, the Sponsor or its representative, as the case may be, shall provide financial compensation for such injury or death in accordance with the applicable regulations. In the event of a study related injury or death (as defined in the applicable Indian regulations) arising from the violation of the protocol, misconduct or negligence by the study site or your study doctor, the study site, your study doctor or their representative, as the case may be, shall provide financial compensation for such injury or death to you.

You will not lose any of your legal rights as by signing this informed consent form.

What are your options if you do not participate in the study?

You do not have to take part in this study to receive treatment for your anemia due to lower-risk myelodysplastic syndrome (LR-MDS).

There are other alternatives such as: imetelstat, lenalidomide, luspatercept, or participation in another clinical trial. There may be benefits and risks related to these treatments that the study doctor will discuss with you.

This study has a limit on the number of participants that can be enrolled across all the study sites worldwide. So, there is a small possibility that even if you agree to participate and meet all entry criteria, once the enrollment limit is reached, you will not be able to participate in the study. Your study doctor should notify you in advance if this could happen to you.

If you are not allowed to take part in the study for any reason, the study doctor will discuss your treatment options with you and may refer you back to your primary care doctor or specialist.

What happens if new information is available about the study drug or study?

New information about the study drug(s) that might affect your decision to stay in the study may become available during the study. If this happens, your study doctor will share this information with you in a timely manner and ask you whether you want to continue in the study. You may decide to stop taking part in the study at that time. If you stop taking part, your study doctor will discuss the steps you should follow. If you

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decide to continue in the study, you may be asked to read and sign a revised consent form that contains the new information.

Can you stop taking part in the study?

You may withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. It is up to you if you do or do not want to take part. Your decision will not change the medical care you get from your doctors now or in the future.

There are a few ways to withdraw from the study. You can withdraw your consent from all participation in the study, including the collection of follow-up data. You can also decide not to continue taking the study drug (Study drug or epoetin alfa) but agree to continue to participate in the non-treatment portion of the study and to the continued collection of data. Such continued participation could include:

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

Your study doctor will discuss these options with you. Any further participation is voluntary. Even if you agree to continue to participate in the study to collect your data, you can always change your mind and withdraw your consent.

If you stop taking part in the study for any reason, the study doctor may continue to use and distribute any data collected up until that point in the study if it is for the purposes described in the informed consent form. If you withdraw your consent to participate in the study, then no more information about you will be collected for this study. However, all information you gave before leaving the study may still be used.

Your study doctor may decide that it is best for you to stop taking part in the study. If so, they will discuss with you the reasons why you may have to leave the study. For example, you may have to discontinue participating in the study against your wishes if you need other treatment, do not follow the study plan, have a study-related injury, or for any other reason. The Sponsor, regulatory authority, and/or [Ethics Committee](#) may also end the study at any time.

What happens at the end of the study?

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

If you were assigned to epoetin alfa treatment and had supplies dispensed to you for self-administration, then your study doctor will review the necessary steps for returning any remaining epoetin alfa supplies to the site.

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

If you were assigned to the study drug, Study drug and are still on treatment, then you may be allowed to continue to receive elritercept if your study doctor determined that you are still receiving clinical benefit from it more than the potential risk of side effects. The Sponsor may continue to supply Study drug through a post study access process. Post study access to Study drug may be stopped 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.

If you were assigned to epoetin alfa and are still on treatment, then you may be allowed to continue to receive epoetin alfa if your study doctor determined that you are still receiving clinical benefit from it more than the potential risk of side effects. The Sponsor may continue to supply epoetin alfa through a post-study access process if needed.

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Will it cost you anything to be in the study?

There is no cost to you for participation in this study. The study medication, study-related procedures and tests, and study visit will be provided free of charge.

Will you have help with costs for travel?

Reasonable travel costs for you and up to one caregiver may also be reimbursed. Additionally, accommodation and meal costs may be reimbursed if the study requires extended visits or certain procedures. You may be reimbursed for these costs by your study doctor or his/her staff. **Will you be paid if you take part in the study?**

You will not be paid for taking part 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 relating to you attending the study clinic for the study will be reimbursed by your study doctor or his or her staff or the site.

Will you have help at home for this study?

If you are assigned to epoetin alfa treatment, your study physician may allow you to receive some of the weekly injections at home or at another approved location. If allowed, these injections can be given by a home healthcare provider. You do not have to agree to home visits for you to participate in this study. If you and your doctor agree to utilize home healthcare services, a clinician will contact you to schedule the visits. The clinicians supporting this study have received specific training on this study and will communicate frequently with your doctor and the study staff. In order to conduct the home visits, the clinician, the clinician's organization, and the home healthcare service provider may have access to your individually identifiable protected health information, such as your name, address or phone number. This type of information, which is stored in the United States and may be stored outside the United States, will only be used as necessary to schedule and conduct the home visits and will not be provided to the Sponsor of this study. The data collected during a home healthcare visit will be shared with your study staff and filed in your study medical records.

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

If you agree to take part in the study, the study doctor will gather and store personal information about your health and your treatment. This may include information that may be used to identify you, such as your name, address, phone number, date of birth, racial origin (to be used only for clinical research purposes), new and existing medical records, or the types, dates, and results of various tests and procedures, as well as information in your medical record and information created or collected during the study.

Under applicable data protection law including the "Digital Personal Data Protection Act 2023" (DPDPA) both the Sponsor and the study doctor/clinic may be solely or jointly be considered data fiduciaries of your personal information in the context of the study (depending on the nature of the data) (i.e. they determine how and for what purposes your personal information are used and disclosed).

The Sponsor's Data Protection Officer's ("DPO") contact details are as follows: PrivacyOffice@takeda.com

To make sure that the study is being conducted correctly, the Sponsor, the Sponsor's representatives, health authorities and relevant institutional review boards and ethics committees may inspect your medical

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records, which may include your name, address and other personal information that could identify you. If necessary, some or all of your medical records may be copied during these inspections.

All information about you which leaves the study clinic will be identified by a code number and your initials, without your name and address. Confidentiality will be maintained in accessing, keeping, processing and publication of information related to your taking part 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 make sure that in an emergency you can be identified and contacted. The list will be kept for at least 25 years from the end of the study and then for as long as necessary to keep to the legal, regulatory, scientific or other requirements. The list will then be destroyed.

Coded information about your health and treatment during the study may be used with your consent for the following purposes:

- to conduct the research as described in this informed consent form;
- for scientific meetings, presentations and/or publications about the study; and
- to make submissions to Regulatory agencies and other health authorities (for example, 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 may be disclosed to other parties, in other countries outside of India, for the purposes described in this information sheet. Some of these countries do not have data protection or privacy laws that offer the same level of protection as the data protection and privacy laws in this country. However, the Sponsor will do everything possible to keep your coded information confidential. With respect to transfers to its affiliates and business partners located outside of India, Sponsor has put in place appropriate contractual provisions, or is otherwise satisfied that there are measures in place to achieve the level of protection of coded personal information equivalent to that under Indian law.

The parties that may receive the coded information include the following.

- The Sponsor and other companies and people acting for or with the Sponsor, including the Sponsor's business 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 about you and, if applicable, ask for corrections. In certain circumstances, you have the additional rights to object to how your information is being handled, request deletion of your data, restrict aspects of the processing of your information or ask for a copy of your data to be provided to you, or a third party, in digital format. However, to make sure that the study is scientifically reliable, you might not be able to review some of your records relating to the study until the study has ended.

You may also have a right to lodge a complaint about the processing of your personal information with your local data protection authority.] You can withdraw your consent for data processing at any time by sending written notice to the study doctor at the address shown on the first page of this information sheet. If you withdraw your consent for data processing, you will no longer be able to take part in the study, and the study doctor will no longer use or share your information under this consent, unless doing so is necessary to make sure that the study is scientifically reliable, to record when you withdrew your consent and/or to report any unexpected health concerns that started prior to when you withdrew your consent. No new information about you will be added to the study database, but the Sponsor can still use and distribute any information it received before you withdrew your consent for the purposes described in this information sheet.

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For more information about withdrawing this consent, see the section about leaving the study.

This study may only be performed by collecting and using personal information on study participants as described in this form. By signing the informed consent form, you (or your legal representative) are authorizing the study doctor and Sponsor to use and share personal information about your health and treatment, as specified in the informed consent form. This consent does not have an end date.

If you have any questions, comments or complaints about how your information is handled in this study, you should firstly contact your study doctor who will be able to direct your query where appropriate to staff responsible for data protection at the Sponsor or site, including the site Data Protection Officer

Additionally, in the event the Sponsor sells Study drug to another company conducting clinical research, your coded data collected as part of this study may be shared with that company as part of completing that transaction.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Additionally, a description of this study 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, if you agree, we would like to use your coded data collected during this study, for future scientific research. This future research may be performed by Takeda and/or researchers working with Takeda. This future research may be about:

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

If you agree to the future use of your coded study data, your data will be held by Takeda for a minimum of 25 years after the end of this clinical study. The data will be stored securely in various locations and only be identified by a unique code, without your name and personal information.

Takeda will also use study data to create anonymized data that cannot be linked back to you. Independent researchers outside of Takeda may request access to this anonymized data. To use this data, these researchers must meet certain requirements and obtain approval from Takeda. Takeda will consider the scientific purposes of the request before agreeing to share this anonymized data.

Benefits

If you agree to the future use of your data, you will not receive any direct benefit. However, your data may contribute to research that could help others in the future. Because we cannot identify you, results from any future research will not be shared with you. The use of your data may lead to new tests, drugs, devices, or other products or services with commercial value but you will not receive payment or share in any financial profits if this occurs.

Your choice

If you change your mind about your coded data being used for future scientific research, you have the right to withdraw your consent at any time. To withdraw your consent please contact your study doctor. If you

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withdraw your consent after analysis has already occurred, the results may still be used by Takeda, researchers working with Takeda, or independent researchers.

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

This study is collecting biospecimens and images from you. Biospecimens include blood, tissue, and other bodily samples. Images include images collected from tissue slides and sections from your biopsy. These images may be digitized and analyzed to deepen our understanding of the disease and effects of your treatment.

Our goal is to advance medical science and improve patient care, and if you agree, we would like to use your biospecimens and images collected during this study for future scientific research. This future research may be about:

- the diseases, conditions or drugs that may, or may not be included in this study
- the efficacy, design and methods of future studies

Storage of biospecimens and images

If you agree to the future use of your biospecimens and images, Takeda will keep your biospecimens for up to 15 years after the end of this clinical study, and your digitized tissue slide/section images for up to 25 years after the end of this clinical study, unless there are local laws that require a different storage period.

Sharing of biospecimens and images

If you agree to the future use of your biospecimens and images, these may be shared by Takeda with researchers around the world. To use your biospecimens and images, future researchers must meet certain requirements and obtain approval from Takeda.

Confidentiality

We will protect the confidentiality of your information to the fullest extent possible. Your biospecimens, images, and associated data will be coded to protect your identity. Only the study doctor will have the key to the code key that can link your biospecimens and images to your identifying information. The key will be securely stored and protected. If your biospecimens are used in future research, additional safeguards will be put in place. These additional safeguards may include breaking the link with the 'code key.'

Benefits

If you agree to the future use of your biospecimens and images, you will not receive any direct benefit. However, your biospecimens and images may contribute to research that could help others in the future. Because we cannot identify you, results from any future research will not be shared with you. The use of your biospecimens and images may lead to new tests, drugs, devices, or other products or services with commercial value but you will not receive payment or share in any financial profits if this occurs.

Your choice

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

If you agree but later change your mind and no longer wish to let us store, use or share your biospecimens and images for future research purposes, please contact your study doctor. We will do our best to honor your request to destroy any of your stored biospecimens and images. However, there may be times we cannot do this. If the biospecimens and images have already been used in any future research, the information and results from that research may still be used.

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Who do you contact with questions?

For more information please contact:

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?

All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favorable opinion by Ethics Committee.

The Sponsor, Regulatory Authorities or the Ethics Committee may stop the study at any time where there is good reason.

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Consent Form

By signing below, I confirm that I have read this Participant Information Sheet and Consent Form and understand it, and I voluntarily consent to take part in this research study and agree 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 (Please tick as appropriate)	Student	☐	Self-Employed
	☐		Service
	☐		Housewife
	☐		Others
	☐		☐
If you select Others in Occupation, please add details			
Annual Income of the Study Participant:			

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

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

Please provide initial each of the following statements below to indicate 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 given the chance to discuss it and ask questions. All my questions have been answered to my satisfaction.	
(ii)	I understand that I am taking part in this study voluntarily and I can withdraw from the study at any time without penalty or losing any benefits or medical care I am entitled to.	
(iii)	I understand that I may have to leave the study if I need other treatment, do not follow the study plan, have a study-related injury, or for any other reason.	
(iv)	I agree to allow my body samples/images to be collected, tested, stored and analyzed by the Sponsor or companies working for the Sponsor for the purposes of this study.	
(v)	I authorize people who have a responsibility to verify the conduct of this study (e.g., study monitors, auditors, the ethics committee, and applicable regulatory authorities in other countries such as 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 may include information that could identify me.	
(vi)	I understand that by signing this document, I am freely and voluntarily authorizing the collection, use, and disclosure of my coded personal information for medical research purposes, to be shared with Sponsor, its affiliates and business partners, regulatory authorities, and the ethics committee overseeing this study.	
(vii)	I understand that by signing this Form I am authorizing the transfer of my coded personal data, including sensitive data, to other countries worldwide, including countries where the data protection and privacy laws may not provide the same level of data protection as the laws in my home country or the country where I am participating in the study	
(viii)	I understand that I am free to withdraw my consent to the collection, use, and disclosure of my coded personal information at any time without penalty or loss of benefits to which I am otherwise entitled. However, I will not be able to continue my participation in the research study after I withdraw consent, and any data about me (including health information) that has already been collected may remain part of the study in order to satisfy regulatory requirements and to safeguard scientific integrity.	
(ix)	I understand that I will not lose any of my legal rights by signing this informed consent form.	
(x)	I will receive a signed and dated copy of this Form.	

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Study Participant Name (print):	
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Signature (or Thumb impression) of the Study Participant	Date

Name of the Investigator	
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Signature of the Investigator	Date

(* If a Study Participant has limited ability to read and write, a witness should be present during the entire 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 Study Participant's legally acceptable representative, was present during the consenting procedure and understand the preceding information describing this study. All of the questions 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 aspects of the study were clearly presented during the consent procedure. The study participant is willing to participate in the study and I sign 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:	

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Signature (or Thumb Impression) of the Legally
Acceptable Representative

Date

Witness Declaration of Study Participant's Informed
Consent

☐

Not Applicable

By signing this consent form, I attest that the information was accurately explained to and apparently understood by the study participant and the legally acceptable representative (if applicable) and that informed consent was freely given by the Study Participant.

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

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Signature of the Witness

Date

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Informed Consent Form for Optional Future Research

Please provide initial each of the following statements below to indicate your agreement

Sr.	Statement	(Study Participant)
(i)	I have read and I understand all the information about the optional future research of my data/samples in this form. I have been given the chance to discuss it and ask questions. All my questions have been answered to my satisfaction.	
(ii)	I understand that my participation in this future research is voluntary, and I can withdraw my consent at any time without penalty or losing any benefits or medical care I am entitled to, and without it affecting my participation in the main research study.	
(iii)	I understand that I will not lose any of my legal rights by signing this informed consent form.	
(iv)	I will receive a signed and dated copy of this consent form.	

Please check the box next to your choice regarding whether to take part in future research:

(i)	I agree that my coded study data may be used by Takeda and/or researchers working with Takeda for the future research described in this informed consent form. ☐ Yes ☐ No
(ii)	I agree that my study data can be anonymized, used and shared by Takeda with independent researchers for the future research described in this informed consent form. ☐ Yes ☐ No
(iii)	I agree that my leftover biospecimens may be used by Takeda, researchers working with Takeda and/or independent researchers, for the future research described in this informed consent form: ☐ Yes ☐ No
(iv)	I agree that my images may be used by Takeda, researchers working with Takeda and/or independent researchers, for the future research described in this informed consent form: ☒ Yes ☒ No

Study Participant Name (print):	
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Signature (or Thumb impression) of the Study Participant

Date

Name of the Investigator	
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Signature of the Investigator

Date

(* If a Study Participant has limited ability to read and write, a witness should be present during the entire informed consent discussion). In these instances, the study participant places his/ her left thumb impression in the place of the signature. In addition, it shall be clearly indicated in the ICF that the content of informed consent is fully presented to the Subject or LAR in oral with the attendance of the witness during the entire 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 Study Participant's legally acceptable representative, was present during the consenting procedure and understand the preceding information describing this study. All of the questions 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 aspects of the study were clearly presented during the consent procedure. The study participant is willing to participate in the study and I sign 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:	

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Signature (or Thumb Impression) of the Legally Acceptable Representative

Date

Witness Declaration of Study Participant's Informed Consent ☐ Not Applicable

By signing this consent form, I attest that the information was accurately explained to and apparently understood by the study participant and the legally acceptable representative (if applicable) and that informed consent was freely given by the Study Participant.

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

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Signature of the Witness

Date

(Copy of the participant information sheet and duly filled consent form shall be handed over to the study participant or his/her attendant)

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