



Pregnant Partner Authorization for Pregnancy Follow-up

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 (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

Introduction:

Presently your partner is taking part, or recently took part, as a study participant in study TAK-226-3001 (“Study”) as a study participant and has specified that you are pregnant, or became pregnant, while he was enrolled in the Study. Your partner was told to make sure the use of contraceptives while enrolled in the Study since the Study Drug’s effects on pregnancy and the developing fetus are unknown or are not completely understood at this time. The Sponsor and the Study Doctor would like to gather information from you, your doctors, and your baby’s doctors regarding your pregnancy and your baby to improve understanding of the Sponsor regarding the effects of exposure to Study Drug at the time of pregnancy. Permitting us to have access to this information is completely voluntary.

By putting a signature on this authorization, you permit Sponsor, through the Study Doctor, to ask you queries in order to collect from you some details of your personal health information associated with your health history, pregnancy, labour and your pregnancy’s outcome, and the condition of your baby at birth and up to 12 months post birth and have that information forwarded to us. Information regarding you that could be utilized to recognize you, like your name, address, telephone number, birth date, new and existing health records, or the types, dates and results of different tests and methods is included in your “Personal Health Information”. By putting a signature, you also permit the Study Doctor to get in touch with your and your baby’s healthcare providers to acquire extra information, which includes medical records, associated with your health history, pregnancy, labor and delivery, your pregnancy’s outcome, and the condition of your baby at birth and up to 12 months post birth. This information will be revealed by the Study Doctor to the Sponsor or its agents.

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

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To additionally secure your privacy, any information gathered regarding your pregnancy or your baby that is sent to Sponsor will not consist of your name, your baby's name, or your partner's name and instead will be linked to a code number that has been allotted to your partner. Study Doctor of your partner will keep the link between your name and your partner's code number.

This coded information will be utilized by the Sponsor to better understand and assess the Study Drug's safety. This coded information might be processed by or sent to other parties in other countries for clinical research, safety reporting, and any other study-related uses explained in this form. The parties that might get the coded information consist of the given below: (1) Sponsor and other companies and individuals acting for or with the Sponsor, which includes its affiliates, business partners, and licensing partners; (2) regulatory agencies and other health authorities; and (3) institutional review boards/ethics committees. It is possible coded health information of you/your baby might be processed and sent to countries that might not have data protection or privacy laws that offer the similar protection level as the data protection and privacy laws within this country. Though, every effort will be made by the Sponsor to keep your/your baby's coded data confidential.

As needed by U.S. Law., a narration of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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, a narration of this study will be available on other publicly available clinical trial registries, like <https://clinicaltrials.takeda.com/> and <https://euclinicaltrials.eu/>. Information that can recognize you will not be included on these websites. Mostly, a summary of the results will be included on the websites. At any time, you can search the websites.

This study's results might be presented at meetings or in publications, however in any presentations or publications your/your baby's name will not appear.

You have the right to see and copy your/your baby's personal information that is gathered for as long as this information is held by the Study Doctor.

Your authorization with regard to the disclosure of information is completely voluntary, and at any time you can take back your consent liberally by sending a written notice to the study doctor's address listed on the first page. In case this consent is cancelled by you, your/your baby's information will not be used or shared by the Study Doctor nor your/your baby's doctor under this consent, unless doing so is required to follow safety regulations. No new information regarding you/your baby will be shared, however any information it received prior to you cancelled your consent can still used and distributed by the Sponsor for the objectives explained in this authorization form.

By putting a signature on this authorization, you are authorizing the uses and disclosures of personal information regarding health and treatment of you/your baby recognized in this authorization. This approval has no end date.

Who has reviewed this pregnant partner form?

An Ethics Committee had reviewed and permitted this form.

Who must I get in touch with for additional information?

In case you have any queries regarding participation of you or your baby in this pregnancy follow-up, kindly get in touch with the study doctor or study team.

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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

In case you have any queries associated with privacy, ethical problems, potential conflicts of interest of the study doctor, or your rights:

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

Thank you for reading this information sheet and thinking about participating in this pregnancy follow-up.

Kindly ask the study doctor in case anything is unclear, or whether you would like additional information.

By putting a signature below, I provide my authorization to the collection of, and access to, and processing and transferring of information regarding myself, my pregnancy and my baby as explained above.

A fully signed and dated copy of this authorization form will be given to me.

Study Participant's Partner Name (print):	
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Signature (or Thumb impression) of the Partner,
on behalf of herself and her baby

Date

Name of Investigator:	
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Signature of Investigator

Date

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Partner Legally Acceptable Representative's*
Statement

☐

Not Applicable

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

Name of the Legally Acceptable Representative of partner (print):	
Relationship to the partner:	
Address of the legally acceptable representative partner:	
Phone No.:	

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Signature (or Thumb Impression) of the
Legally Acceptable Representative of partner

Date

Witness
Declaration of
Partner's
Informed
Authorization**

☐

Not Applicable

By putting a signature on this authorization form, I certify that the information was precisely explained to and apparently understood by the partner and the legally acceptable representative (in case applicable) and that the partner had given informed consent liberally.

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

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Signature of the Witness

Date

***In case a partner or her Legally Acceptable Representative has limited reading and writing ability, a witness must be present at the time of the complete informed consent discussion. In these instances, the partner or Legally Acceptable Representative places his left thumb impression in the place of the signature, and it shall be specified in the ICF clearly that the content of informed consent is completely presented to the partner or LAR in oral with the attendance of the witness at the time of the complete informed consent discussion and the partner or LAR understands the content of the informed consent.*

(A copy of the partner's information sheet and properly completed consent form shall be given to the partner or her attendant)

****NOTE: As determined by local law a witness signature might be needed.**