



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 Medication:	Elritercept (TAK-226), referred throughout the document as the “study medication”
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:

Your partner is presently taking part, or recently taken part, as a study participant in study TAK-226-3001 (“Study”) as a study participant and has shown that you are pregnant, or got pregnant, while he was joining in the study. Your partner was told to make sure of the use of contraceptives while participating in the study because the effects of the study drug on pregnancy and the developing fetus are unknown or are not completely understood at this time. The sponsor and the study doctor wish to gather information from you, your doctors, and your baby’s doctors regarding your pregnancy and your baby to improve sponsor’s understanding about the effects of exposure to study drug during pregnancy. Permitting us to have access to this information is totally voluntary.

By putting a signature on this authorization, you allow Sponsor, through the Study Doctor, to ask you queries in order to collect from you certain details of your personal health information associated with your health history, pregnancy, labour and the result of your pregnancy, and the condition of your **baby at birth and up to 12 months following birth** and have that information forwarded to us. Your “Personal Health Information” involves information about you that may be used to identify you, like your name, address, telephone number, date of birth, new and prevailing health records, or the types, dates and results of different tests and procedures. By putting a signature you also let the study doctor to get in touch with your and your baby’s healthcare providers to get additional information, including medical records, associated with your health history, pregnancy, labor and delivery, the result of your pregnancy, and the condition of your **baby at birth and up to 12 months after birth**. The study doctor will reveal this information to the sponsor or its agents.

To ensure the study is being performed appropriately, the Sponsor, Sponsor representatives, health authorities and relevant institutional review boards/ethics committees might inspect your partner’s medical records which will involve your medical records which may involve your name, address and other personal

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information that could identify you. If needed, some or all of your medical records might be copied during these inspections.

To further safeguard your privacy, any information taken about your pregnancy or your baby that is transferred to Sponsor will not involve your name, your baby's name, or your partner's name and instead will be connected to a code number that has been allotted to your partner. The link between your name and your partner's code number will be kept by your partner's study doctor.

This coded information will be used by the sponsor to better know about and assess the safety of the study drug. This coded information can be processed by or transferred to other parties in other countries for clinical research, safety reporting, and any other study-related uses explained in this form. The parties that may get the coded information involve the following: (1) Sponsor and other companies and people that act 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. There is a possibility that your/your baby's coded health information might be processed and transferred to countries that might not have data protection or privacy laws that offer the same level of protection as the data protection and privacy laws within this country. However, Sponsor will make every effort to keep your/your baby's coded data confidential.

An explanation of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as needed by U.S. Law. Information that may identify you will not be included in this web site. Mostly, a summary of the results will be included in the web site. At anytime, you may search this web site.

Also, an explanation of this study will be available on other publicly available clinical trial registries, like <https://clinicaltrials.takeda.com/> and <https://euclinicaltrials.eu/>. Information that may identify you will not be included in these web sites. Mostly, a summary of the results will be included in the websites. At any time, you may search the websites.

The results of this study might be presented at meetings or in publications, but your/your baby's name will not appear in any presentations or publications.

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

Your authorization with regard to the disclosure of information is totally voluntary, and you may withdraw your consent freely at any time by sending a written notice to the study doctor at his/her address given on the first page. If you cancel this consent, the study doctor or your/your baby's doctor will not use or share your/your baby's information under this consent, unless doing so is needed to follow safety regulations. New information about you/your baby will not be shared, but the sponsor may still use and distribute any information received before you cancelled your consent for the purposes explained in this authorization form.

By putting a signature on this authorization, you are authorizing the uses and disclosures of personal information regarding your/your baby's health and treatment recognized in this authorization. This authorization does not have a completion date.

Who has reviewed this pregnant partner form?

An Ethics Committee have reviewed and approved this form.

Who must I get in touch with for more information?

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If you have any queries about your or your baby's participation in this pregnancy follow-up, kindly get in touch with the study doctor or study team.

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

If you have any queries associated with privacy, ethical issues, possible 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 if anything is unclear, or if you wish to have additional information.

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

I will get a copy of this authorization form fully signed and dated.

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

Partner's Legally Acceptable Representative's*
Statement

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Not Applicable

As the partner's legally acceptable representative, I was there during the consenting procedure and know about the preceding information explaining this study. All of the questions about the authorization and the partner's participation in it have been answered to my satisfaction and that of the participant's partner. I mention that all aspects of the study were clearly presented during the consent procedure. The partner agrees to take part in the pregnancy follow-up and I put my signature below on her behalf testifying to this effect.

Name of the Legally Acceptable Representative of partner (print):	
Relationship to the partner:	
Address of the legally acceptable representative of partner:	
Phone Number:	

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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 attest that the information was correctly described to the partner and the legally acceptable representative (if applicable) and apparently understood by them and that informed consent was freely provided by the partner.



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Name of the Witness: (print):	
Address of the witness	
Phone Number:	

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Signature of the Witness

Date

***If a partner or her Legally Acceptable Representative has limited ability to read and write, a witness must be there during the entire informed consent discussion. In these cases, the partner or Legally Acceptable Representative will put his left thumb impression in the place of the signature, and it shall be clearly indicated in the ICF that the content of informed consent is fully presented to the partner or LAR in oral with the attendance of the witness during the entire informed consent discussion and the partner or LAR knows about the content of the informed consent.*

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

****NOTE: A witness signature may be required as determined by local law.**