



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 (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 currently participating, or recently participated, as a study participant in study TAK-226-3001 (“Study”) as a study participant and has indicated that you are pregnant, or became pregnant, while he was enrolled in the Study. Your partner was told to ensure the use of contraceptives while enrolled in the Study because the effects of the Study Drug on pregnancy and the developing fetus are not known or are not fully understood at this time. The Sponsor and the Study Doctor would like to collect information from you, your doctors, and your baby’s doctors about your pregnancy and your baby to improve Sponsor’s understanding about the effects of exposure to Study Drug during pregnancy. Allowing us to have access to this information is entirely voluntary.

By signing this authorization, you allow Sponsor, through the Study Doctor, to ask you questions in order to collect from you certain details of your personal health information related to your health history, pregnancy, labour and the outcome of your pregnancy, and the condition of your baby at birth and up to 12 months after birth and have that information forwarded to us. Your “Personal Health Information” includes information about you that could be used to identify you, such as your name, address, telephone number, date of birth, new and existing health records, or the types, dates and results of various tests and procedures. By signing you also allow the Study Doctor to contact your and your baby’s healthcare providers to obtain additional information, including medical records, relating to your health history, pregnancy, labor and delivery, the outcome of your pregnancy, and the condition of your baby at birth and up to 12 months after birth. The Study Doctor will disclose this information to the Sponsor or its agents.

To make sure the study is being conducted correctly, the Sponsor, representatives of Sponsor, health authorities and relevant institutional review boards/ethics committees may inspect your partner’s medical records which will include your medical 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.

To further protect your privacy, any information collected about your pregnancy or your baby that is transferred to Sponsor will not include your name, your baby’s name, or your partner’s name and instead

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will be linked to a code number that has been assigned to your partner. Your partner's Study Doctor will keep the link between your name and your partner's code number.

Sponsor will use this coded information to better understand and evaluate the safety of the Study Drug. This coded information may be processed by or transferred to other parties in other countries for clinical research, safety reporting, and any other study-related uses described in this form. The parties that may receive the coded information include the following: (1) Sponsor and other companies and people acting for or with the Sponsor, including its affiliates, business partners, and licensing partners; (2) regulatory agencies and other health authorities; and (3) institutional review boards/ethics committees. It is possible your/your baby's coded health information may be processed and transferred to countries that may 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.

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 other publicly available clinical trial registries, such as <https://clinicaltrials.takeda.com/> and <https://euclinicaltrials.eu/>. These websites will not include information that can identify you. At most, the websites will include a summary of the results. You can search the websites at any time.

The results of this study may 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 see and copy your/your baby's personal information that is collected for as long as this information is held by the Study Doctor.

Your authorization with regard to the disclosure of information is entirely voluntary, and you can withdraw your consent freely at any time by sending a written notice to the study doctor at his/her address listed on the first page. If you cancel this consent, neither the Study Doctor nor your/your baby's doctor will use or share your/your baby's information under this consent, unless doing so is necessary to comply with safety regulations. No new information about you/your baby will be shared, but the Sponsor can still use and distribute any information it received before you canceled your consent for the purposes described in this authorization form.

By signing this authorization, you are authorizing the uses and disclosures of personal information about your/your baby's health and treatment identified in this authorization. This authorization does not have an end date.

Who has reviewed this pregnant partner form?

This form was reviewed and approved by an Ethics Committee.

Who should I contact for more information?

If you have any questions about your or your baby's participation in this pregnancy follow-up, please contact 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

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Investigator Email Address:	drarijitnag@gmail.com & arijit.nag@tmckolkata.com
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If you have any questions relating to privacy, ethical issues, 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 considering taking part in this pregnancy follow-up.

Please ask the study doctor if anything is not clear, or if you would like more information.

By signing below, I give my authorization to the collection of, and access to, and processing and transferring of information about myself, my pregnancy and my baby as described above.

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

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

Name of Investigator:	
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Signature of Investigator

Date

Partner Legally Acceptable Representative's*
Statement

☐

Not Applicable

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I, as the partner's legally acceptable representative, was present during the consenting procedure and understand the preceding information describing this study. All of the questions regarding the authorization and the partner's participation in it have been answered to my satisfaction and that of the participant's partner. I state that all aspects of the study were clearly presented during the consent procedure. The partner is willing to participate in the pregnancy follow-up and I sign 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 partner:	
Phone No:	

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

Witness Declaration of Partner's Informed Authorization**

☐ Not Applicable

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

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

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Signature of the Witness

Date

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***If a partner or her Legally Acceptable Representative has limited ability to read and write, a witness should be present during the entire 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 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 understands the content of the informed consent..*

(Copy of the partner's information sheet and duly filled consent form shall be handed over to the partner or her attendant)

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