

PREGNANCY IN CLINICAL STUDY INFORMED CONSENT FORM

A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide (TRIllogy-5)

Study ID: Protocol 79635322MMY3002

Doctor Jeevan Kumar is conducting this study, sponsored by Janssen Research & Development, LLC, a pharmaceutical company.

You are being asked to share medical information with the clinical staff and sponsor about your pregnancy and the outcome. If you agree, clinical staff will request this information from you after birth. This form explains what is involved if you agree to share this information.

Here are a few things to know:

- Sharing this medical information is entirely voluntary and is not part of routine medical care for the pregnancy nor the baby.
- Take your time to read this Informed Consent Form (ICF) carefully to understand why this is being requested and what it involves.
- Discuss this with your doctors, medical professionals, family and friends.
- Ask questions and request any additional information from the clinical staff at the study site.
- Your participation does not enroll you in the research study.
- By participating, you will not get medical advice or treatment for the pregnancy nor the baby (before or after birth). You should continue to see your own doctor(s).
- You are free to decide to share your/your baby's medical information or not and if you agree now, you can change your mind any time. Whether or not you share it is up to you. Whatever choice you make, you will not lose access to the medical care you already receive, gain any penalty or give up any of your existing rights or benefits.

Thank you for taking the time to consider providing this information

The sponsor may share sensitive Company information with you to help you decide about sharing your/your baby's medical information. We kindly ask you to consider this when discussing details

about the study with people other than your healthcare provider(s), family and friends or when using social media.

YOUR CONTACTS

Study sponsor Janssen Research & Development, LLC	Represented by JOHNSON & JOHNSON PRIVATE LIMITED HIGI house, LBS Marg, Mulund (West), Mumbai – 400080
Name of Principal Investigator: Dr. Jeevan Kumar Site Name and address: Tata Medical Center, 14, MAR (E-W), New-Town, Rajarhat, Kolkata-700160, India. Contact number of Principal Investigator: +91-9007016755 24-hour telephone (if applicable): NA	

OVERVIEW AND GENERAL INFORMATION

Why am I being asked to share information about my pregnancy and outcome?

We are asking for this information because your partner, the biological parent of your unborn baby, is (or was) participating in a clinical research study. Your partner is receiving (or has received) an experimental drug called “JNJ-79635322 or teclistamab” which is being developed as a possible treatment for multiple myeloma.

Since JNJ-79635322 is an experimental drug, there is no information available about risk of pregnancy and effects on an unborn child during treatment with JNJ-79635322 or teclistamab. The effect of the study drug on eggs, sperm and reproductive organs is unknown. It is unknown whether the study drug may reduce the effectiveness of hormonal contraceptives. So, the sponsor would like to collect information from you to learn more about JNJ-79635322 or teclistamab and any possible effect it may have in this circumstance.

We will collect information on the outcome of your pregnancy and the health of the baby.

WHAT ARE THE BENEFITS OF AGREEING TO SHARE THIS INFORMATION?

There is no direct benefit to you or the baby, but by sharing this information, you may help future patients who need to take this medicine.

You can change your mind about sharing this information at any time by telling the clinical staff. Please note that any information collected before you change your mind, will continue to be used by the sponsor. If you do not agree to share this information, it will not affect your partner's participation in the study. Please note by sharing this information you will not receive any payment. There will be no costs to you but all your pregnancy related costs will be covered by you, your insurance or your government health scheme as standard practice.

HOW WILL PRIVACY BE PROTECTED?

Clinical staff and the sponsor will look after your and your child's personal data (information collected from you and your child) as required by The Study Staff and the Sponsor will manage your personal data (information about your child) in compliance with applicable Indian data protection and privacy laws and in the manner described in this consent form. The "Privacy Appendix" in this document describes your rights about the use and protection of your personal data.

PRIVACY APPENDIX TO PREGNANCY INFORMED CONSENT

Sponsor and his representatives will use the information collected about your child for the purposes of the study and for scientific research, such as study of your child's disease and genetic research [if applicable]. Sponsor and his representatives may also use this information to apply for permission to sell the drug in some countries. The information will be stored both on paper and on computer. To protect your privacy, the information will be labeled in a way that will not identify your child. If the results of the study are published your identity is kept confidential. By signing this form, you are permitting this use of your child's information.

Your study doctor will keep your child's personal medical records and a list that links each patient's name to his or her code number for at least 15 years.

Regulatory authorities, members of the ethics committee/institutional review board, employees at the study site and representatives of sponsor will have access to this list and be able to compare and check the study information collected about your child with information in your child's medical records. As far as the law allows, your child's medical records will not be made public. By signing this form, you are allowing direct access to your child's medical records by those who have legitimate reason to look at them.

The information collected may be sent to other members of the Johnson & Johnson group of companies, to contractors working for them and to regulatory authorities.

You can arrange with your child's study doctor to see the information collected about your child, and you can ask for any mistakes to be corrected. Sponsor and his representatives may postpone your access to your child's information if it would interfere with the study itself. If you decide to leave the study at any time, Sponsor and his representatives may still use your child's information collected up to that point, if the law allows.

Medical Record – Information and data, including personal details, recorded by the clinical staff; stays on site.

Study Record– Medical record data from the study participant, pregnant partner and child (without personal identifiers) documented by the clinical staff and shared with the sponsor.

1. What personal data will the clinical staff collect?

If you agree, the clinical staff collect and share your and your child's personal data for research purposes. **Personal data** may include:

- information about your and your child's health. This may include medical images and written descriptions (including records about phone calls, visits and examinations).
- direct personal identifiers such as your and your child's name, initials, date of birth, address,
- other sensitive data such as racial or ethnic origin, sex assigned at birth, gender identity, lifestyle, religious or philosophical beliefs, sexual behaviors or sexual orientation, which are only collected when necessary to evaluate the study results.

2. Who will have access to my and/or my child's medical record?

Your and your child's medical records will be stored in paper files and electronic databases, including those that may be accessed remotely (if approved in your country). The clinical staff will have access to your and your child's medical record. In addition, the people below may have direct access to your and your child's personal data (to ensure that the research study is being conducted properly).

- monitors and auditors from the sponsor or the sponsor's representatives.
- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review research studies to protect the rights and welfare of people participating in research).
- Regulatory Authorities; local and outside your country.
- Other persons or groups, as required by law, who may be located outside your country. Laws in other countries may have a different protection level for your information.

3. How will my and my child's personal data be protected?

The clinical staff will also record information from you and your child's medical records into the **Study Record**. These data are provided to the sponsor for study purposes. This will only be identified by the study number and participant number. Direct personal identifiers such as your or your child's name, initials, date of birth will not be included in the Study Record. The clinical staff can match the Study Record to your name, but this information will be kept confidential and not shared with the sponsor or anyone else, except where required by law.

4. How will my and my child's Study Record be used and shared?

The sponsor and other authorized parties described in this consent form will use and share your and your child's Study Record for scientific research and compatible research purposes such as:

- evaluate and understand the study drug, the disease and associated health problems,
- advance clinical science and medical knowledge.

Authorized parties may include organizations providing services for the sponsor (such as laboratories), researchers, collaborators, and companies who may share an interest in the study drug or the disease.

The sponsor, other authorized parties and Regulatory Authorities may be located outside your country, where laws may provide a different protection level.

5. Transfer of data

As required by applicable laws, there are safeguards in place to protect your and your child's personal data when it is transferred outside your country. This also applies to people who have access to your and your child's data remotely as well as when this is shared as described above.

6. How long will my and my child's personal data be kept?

Clinical staff will retain your and your child's Medical Records at the site according to local laws and requirements. The sponsor may retain your and your child's **Study Record** for as long as required OR 15 years in accordance with applicable laws.

7. What rights do I have concerning my and my child's personal data?

If you would like to review, correct, delete personal data, or make other requests in accordance with the laws in your country, you should contact the clinical staff at +91-9007016755. You may not be able to review your data until after the end of the study. A request to delete your personal data may not be allowed depending on regulations and laws that require clinical research and personal data to be retained.

YOUR CONSENT TO PARTICIPATE

If you consent (agree) to all the following statements, please sign below. You will receive a copy of this signed Informed Consent Form.

I have read the whole Consent document (or it has been read to me) with Appendix which includes information on privacy (or it has been read to me). I understand the information provided and consent to share relevant information as a pregnant partner of a study participant.

- All my questions about sharing pregnancy and the baby's health information have been answered to my satisfaction.
- I understand sharing this information is voluntary and I can change my mind at any time.
- By signing this form, I have not given up any legal rights.
- I agree for my doctor(s) responsible for the pregnancy or baby's health to share health information with the clinical staff for use by the sponsor as described in this form.
- I agree to the processing and transfer of my data as described in this consent form.
- I understand my rights and that I can withdraw at any time.

I consent to share my and my child's health information with the study doctor for use by the sponsor for the research described in this form.

Signature (or Thumb impression) of

Pregnant Partner of Male

Subject/Legally Acceptable

Date: __/__/__

Representative _____

dd-MON-YYYY

Signature of the Investigator _____

Date: __/__/__

dd-MON-YYYY

Study Investigator's Name: _____

Legally Acceptable Representative

The signature of a legally acceptable representative below is only needed if the pregnant partner of the male study participant is a minor or incapacitated adult. Relationship to pregnant partner MUST be included.

Printed Name of Legally Designated Representative, in full (if applicable)

Legally Acceptable Representative _____

Date: __/__/__

dd-MON-YYYY

Relationship of Legally Designated Representative to Pregnant Partner of Male Study Participant:

Impartial Witness Statement I confirm that the information in the consent form was accurately explained to, and apparently understood by Pregnant Partner of Male Subject, and that consent was freely given by the Pregnant Partner of Male Subject.

Signature of the Witness _____

Date: __/__/__

dd-MON-YYYY

Name of the Witness: _____

Copy of the duly filled Informed Consent Form shall be handed over to the Pregnant partner of male subject