Pregnancy Informed Consent to Participate in Research

BMT CTN 2002

A Phase 3, Randomized, Open-Label, Multicenter Study, to Compare T-Guard to Ruxolitinib for the Treatment of Patients with Grade III or IV Steroid-Refractory Acute Graft-Versus-Host Disease (SR-aGVHD)

NCT04934670
EudraCT No. 2021-000343-53

Your Name: _____

Principal Investigator: _____

Study Site Address: _____

Study Site Telephone Number: _____

[Insert local PI information]

Sponsor: This study is sponsored by Xenikos, BV and the National Institutes of Health, through the Blood and Marrow Transplant Clinical Trials Network

<*US country specific language, please delete for other countries*>

The ethics of this study have been reviewed and approved by the NMDP IRB.

<*European country specific language, please delete for other countries*>

The ethics of this study have been reviewed and approved by the EC in your country.

Your study doctor or nurse will review this **Consent Form** with you, including:

- ✓ The purpose of the research
- ✓ Possible risks and benefits
- ✓ Other options available to you
- ✓ Your rights if you consent to the study

1. Study Overview

We invite you to consent to provide information for this clinical trial, also known as a research study. We're requesting this information to see if exposure to T-Guard or ruxolitinib affects an unborn baby.

You're being asked to provide information because you became pregnant while you or your partner was in a study of T-Guard or ruxolitinib. Researchers are studying T-Guard and ruxolitinib to see if it will help to treat acute graft-versus-host disease (aGVHD). aGVHD is a common and serious side effect of an allogeneic blood or marrow transplant (BMT).

If you agree to provide information:

- You'll answer questions about your health and your pregnancy
- We'll collect information about your health, your pregnancy, and the result of your pregnancy, such as childbirth
- We'll collect information about the health of the newborn

Some possible risks and benefits of consenting to provide information for the study include:

Possible Risks: There is a small risk your confidentiality could be lost. The study team will do everything it can to keep your information confidential.

Possible Benefits: Doctors may learn more about T-Guard and ruxolitinib to treat future patients.

If you do **not** agree to provide information for the study, you can continue your usual health care.

Key points:

- Being in any research study is your choice
- Knowledge gained from this study may help others
- If you agree to provide information to the study, you can stop at any time. If you decide to stop providing information to the study, it will not affect your care at [name of facility or institution].
- Ask the study staff questions about anything you do not understand, or if you would like more information. You can ask questions now or at any time.
- Take time to talk about the study with your doctor, study staff, and your family and friends. It is **your** choice to provide information to the study. If you agree to provide

information, please sign the end of this Consent Form. You'll get a copy to keep. No one can force you to consent to this study.

2. Study Purpose

We are requesting this information to learn if exposure to T-Guard or ruxolitinib affects the pregnancy. You or your partner may have received either T-Guard or ruxolitinib. At this time, it is not known whether T-Guard or ruxolitinib has an effect on an unborn baby, sperm or egg, and it is not known if T-Guard or ruxolitinib is passed through sperm or human milk. There are animal reproduction studies using ruxolitinib that have shown some possible harm to the fetus, but the effects on human fetuses are not known.

<*US country specific language, please delete for other countries*>

Ruxolitinib has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of aGVHD. Ruxolitinib has an FDA pregnancy category of C. An FDA pregnancy category of C means that a drug should only be used in pregnancy if the potential benefit justifies the potential risk to the fetus. T-Guard has NOT been approved by the FDA for the treatment of aGVHD. This research study is registered with the FDA, and they will monitor it.

<*European country specific language, please delete for other countries*>

In Europe T-Guard and ruxolitinib have not been approved for the treatment of aGVHD. This research study is registered with the European Medicines Agency (EMA), and they will monitor it.

3. Study Tests

The study doctor will **not** do any examinations, tests, or procedures on you.

You will answer questions about you and your pregnancy, and we will collect information from your medical records. We will also request information on the newborn until one year after birth.

We will collect information about:

- Your age, sex, and race/ethnicity

- Your physical or mental health
- Any medicines that you take during your pregnancy
- Any previous pregnancies, including any complications
- Your current pregnancy
- Your delivery
- Your baby's health

If you have an abortion or a miscarriage, we'll ask for health information from your doctor so we can learn if T-Guard or ruxolitinib affects pregnancy.

4. Risks and Benefits

Possible Benefits

You will receive no benefits or payment for consenting to this study. The information we learn may help us care for people in the future who become pregnant while they or their partner is taking T-Guard or ruxolitinib.

Possible Risks

There are very few risks with sharing your medical information and answering questions about your pregnancy. The main risk is that your confidentiality could be lost. The study team will do everything it can to keep your answers confidential.

5. Your Rights to Withdraw, Ask Questions, and Seek Other Treatment

Being part of this study is your choice. You can choose **not** to be part of this study or leave this study at any time. If you choose to share information about your pregnancy, it won't affect your or your partner's regular medical care in any way.

If you do **not** want to share information about your pregnancy, you may still contact the study doctor at any time to get updated information about the safety of T-Guard or ruxolitinib.

You have the right to ask questions about the study at any time. If you have questions about the study, please contact:

[Insert contact details]

If you want to talk with someone not directly involved in the study, or have any complaints or questions about your rights as a research participant or about potential risks and injuries, you

may contact:

[Insert contact details]

You must tell [insert name of Principal Investigator] if you decide to leave the study. If you decide to leave this study, your medical care will not be affected in any way.

6. New Information Available During the Study

During this study, the study doctors may learn new information about T-Guard and ruxolitinib or the risks and benefits of taking part in the study. If they learn new information, they'll tell you as soon as it's available.

7. Privacy, Confidentiality, and Use of Information

<UK country specific language, please delete for other countries>

Xenikos, BV (Xenikos) is the sponsor for this study taking place in the United Kingdom and elsewhere. Xenikos will be using information from you in order to undertake this study and will act as the data controller for this study. This means that Xenikos will be responsible for looking after your information and using it properly. [*<Optional if applicable>* Xenikos has appointed [CRO] as its 'representative' to fulfil its obligations under this law.] Xenikos will keep identifiable information about you for 25 years after the study has finished. The information may be stored for longer, for example, when used in applications for approval to market a medicine.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

We use personally-identifiable information to conduct research to improve health and care. As a pharmaceutical company we have a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. This means that we will use your data, collected in the course of a research study, in the ways needed to conduct and analyse the research study.

Your personal information may be shared with:

- Xenikos and its present or future affiliates,
- Research partners/service providers (such as laboratories conducting tests on behalf of Xenikos) and authorized representatives of Xenikos,
- Study monitors appointed by Xenikos or Xenikos' service providers to check how the study is going,
- Auditors/inspectors appointed by Xenikos or Xenikos' service providers or by health and regulatory authorities to check that the study is being run properly,
- Relevant health and regulatory authorities such the Food and Drug Administration (FDA) in the United States of America and the European Medicines Agency (EMA).

Recipients of your information may be in countries that do not provide the same standard of legal protection for your information as in the United Kingdom, raising the risk that you will not be able to enforce the above rights and recipient organisations may not be legally required to fully secure your data. Xenikos is taking appropriate safeguards to make sure that your personal information is protected. These include implementing special contract clauses, known as Standard Contractual Clauses, which protect transfers of personal information between companies in Xenikos, which can be provided on request. Xenikos is implementing similar appropriate safeguards with third party service providers and partners, and further details can be provided upon request. If you wish to obtain a copy of the Standard Data Protection Clauses, 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.

[NHS/other site] will keep your name, NHS number and contact details confidential and will not pass this information to Xenikos. [NHS/other site] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Xenikos and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Xenikos will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Xenikos may forward information about you (again, without any identifying information) to its service providers, for activities related to the study, such as laboratory analysis.

[NHS/other site] will keep identifiable information about you from this study [for x years after the study has finished/until x].

Xenikos will collect information about you for this research study from your medical records. Identifying information about you that is included in your medical records will not be shared with

Xenikos. We will use this information for the purpose of the research study.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations, or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, including future research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

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. The trial may also be registered on national registries and a summary of the results may be posted on publicly accessible databases (such as https://www.clinicaltrialsregister.eu or other national databases), if required by local laws or regulations.

<*All other countries specific language, please delete for UK*>

Your privacy is very important to us. The study doctors will do everything they can to protect it. The study doctors can protect your records if there is a court case. However, some of your medical information may be shared if required by law. If this happens, the study doctors will do their best to make sure that any information that goes out to others will **not** identify you.

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept confidential (private). However, we cannot promise total privacy.

To make sure the study is running ethically, some government agencies or other groups may need to access part of your medical records. For this study, those groups include:

- [Institution]
- The Center for International Blood and Marrow Transplant Research (CIBMTR)
- The National Marrow Donor Program (NMDP)
- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood

Institute (NHLBI) and the National Cancer Institute (NCI)

- Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
- Data Safety and Monitoring Board (DSMB), not part of [Institution]
- [Study investigators/ Study doctor(s) at this institution]
- Food and Drug Administration (FDA) in the United States of America and the European Medicines Agency (EMA) in Europe
- Regulatory authorities, both local and from other countries
- Xenikos, BV (Xenikos) (the study sponsor)
- Other authorized study organizations that represent Xenikos
- Study monitors

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Study information may also be used for research in the future.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov/, as required by U.S. Law, and under http://www.clinicaltrialsregister.eu. These websites will not include information that can identify you or your partner. At most, the websites will include a summary of the results. You can search the websites at any time.

<*US country specific language, please delete for other countries*>

You will **not** be able to access your study results before the study is done. This helps keep the study results accurate and trustworthy.

When the study is complete, you can ask your study doctor for your health information from the study. **By signing this Consent Form, you agree to ask for your results only after the study is done.** You will still have access to your regular medical records.

8. Leaving the Study

You may choose to leave the study at any time.

If you leave the study, the information already collected from you will still be included in the study. If you don't want your information to be used, you **must** let your study doctor know.

9. Cost and Reimbursement

You will receive **no** benefits or payment for taking part in this research. This research will not cover any costs related to your pregnancy, delivery, newborn care, abortion, or miscarriage.

<*US country specific language, please delete for other countries*>

10. Health Insurance Portability and Accountability Act 1 (HIPAA) Authorization to use health information for research

Your local study site will give you a separate form with information about the Health Insurance Portability and Accountability Act 1 (HIPAA). You will need to sign this form as well before you are able to join this study.

11. Informed Consent Form

TITLE: BMT CTN 2002: A Phase 3, Randomized, Open-Label, Multicenter Study, to Compare T-Guard to Ruxolitinib for the Treatment of Patients with Grade III or IV Steroid-Refractory Acute Graft-Versus-Host Disease (SR-aGVHD)

- I have read and understood this Consent Form. The purpose and description of the research study has been explained to me.
- I have had the chance to ask questions and understand the answers I have been given. I understand that I may ask questions at any time during the study.
- I freely agree to be a participant in the study.
- I have had the chance to discuss my participation in this research study with a family member or friend if I chose to.
- I understand that…
    - I may not directly benefit from taking part in the study.
    - My name and personal information will not be identified even if information gained during the study is published.
    - I can leave this study at any time and doing so will not affect my current care or prevent me from receiving future treatment.
    - I will be given a copy of this signed consent form.
    - I do not give up any legal rights by signing this form.

Printed Participant Name	Date (MM/DD/YYYY)
Participant (or Legally Authorized Representative) Signature	Date (MM/DD/YYYY)
Printed Legally Authorized Representative Name (if applicable)	Date (MM/DD/YYYY)

Physician certification

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

Printed Counseling Physician Name	Date (MM/DD/YYYY)
Counseling Physician Signature	Date (MM/DD/YYYY)

Interpreter certification (if needed)

I certify that I have provided an accurate interpretation of this consent form. I believe the participant has understood the information provided.

Printed Interpreter Name	Date (MM/DD/YYYY)
Interpreter Signature	Date (MM/DD/YYYY)