INFORMED CONSENT FORM-Pregnant Partner

Official title: INNATE: Immunotherapy during neoadjuvant therapy for rectal cancer, a phase II randomized multi-center trial with and without APX005M, an anti-CD40 agonist

NCT number: NCT04130854

IRB Approved Document date: 02-15-23

Title of Study: INNATE: Immunotherapy during neoadjuvant therapy for rectal cancer, a phase II randomized multi-center trial with and without APX005M, an anti-CD40 agonist

Pregnancy/Pregnant Partner Informed Consent Form
To be conducted at:
The University of Texas Southwestern Medical Center
Parkland Health & Hospital System

Key Information about this Study

You became pregnant while you or your partner is participating, or has recently participated, in the research study listed above. As part of this treatment, you or your partner has been receiving an experimental therapy. Because we do not know all of the possible effects this treatment may have on sperm and the development of an unborn child, the Sponsor is collecting information on pregnancies of the partners of study participants who received or are receiving an experimental therapy.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the UT Southwestern Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Todd Aguilera, MD, PhD, Department of Radiation Oncology at the University of Texas Southwestern Medical Center (UTSW).

Funding
Apexigen America, Inc. is funding a portion of this study. Apexigen America, Inc. is providing money to UTSW so that the researchers can conduct the study.

Conflict of Interest
There are no conflicts of interest to disclose.

If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the Study Doctor and/or Principal Investigator.

Title of Study: INNATE: Immunotherapy during neoadjuvant therapy for rectal cancer, a phase II randomized multi-center trial with and without APX005M, an anti-CD40 agonist

Purpose – "Why is this study being done?"

This study is being done to determine the possible effects on your pregnancy from the experimental therapy you or your partner is receiving or has received.

You are asked to participate in this research study because you became pregnant while you or your partner is/was receiving experimental therapy by participating in the study listed above.

The researchers hope to learn the possible effects this experimental therapy may have on sperm and the development of an unborn child.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you became pregnant while you or your partner is participating, or has recently participated, in the research study listed above.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend 0 visits with the researchers or study staff.

Study Procedures:

The following personal health information will be collected about you, your pregnancy, and your baby from your doctor:

- Medical information related to the current pregnancy
- Medications being taken, including use of contraceptives
- Complications during the pregnancy or delivery
- The method of delivery and the result of your pregnancy (i.e., healthy baby, death of the unborn child, miscarriage, or abortion)
- Information about your baby (such as weight, height, gender, and your baby's general health (APGAR [Appearance, Pulse, Grimace, Activity, Respiration] score) at the time of delivery.

Risks – "What are the risks of participation in the research?"

Risks from the research
The risk to you from allowing us to collect this information is possible loss of confidentiality of your/your baby's medical records information.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

You may not receive any personal benefits from being in this study. But what we learn from your information might lead to better understanding of the effect on pregnant women and their unborn babies who are exposed to the study drug taken by the baby's father or mother during a research study.

Neither you nor your partner will receive any compensation for providing this information, nor will this affect any medical treatment that you or your partner receives.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

Your alternative is to not allow us to collect and use this information for research purposes.

Costs – Will taking part in this study cost anything?

There will be no cost to you for allowing us to collect this information about your pregnancy.

The regular medical care costs related to your pregnancy and the birth and care of your baby will be billed to you and/or your health insurance in the usual way.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

How will my information be used?
With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use

about you will include: medical information related to the current pregnancy, medications being taken, including use of contraceptives, complications during the pregnancy or delivery, the method of delivery and the result of your pregnancy (i.e., healthy baby, death of the unborn child, miscarriage, or abortion), information about your baby (such as weight, height, gender, and your baby's general health (APGAR [Appearance, Pulse, Grimace, Activity, Respiration] score) at the time of delivery.

We will get this information by asking you and/or asking your doctor.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- Apexigen America, Inc. is helping fund the study and providing the drug. They will receive written reports about your participation in the research. They may look at your de-identified health information to assure the quality of the information used in the research.
- The following collaborators at other institution that are involved with the study: Adel Kardosh, MD and his team for Division of Hematology and Oncology at Oregon Health & Science University
- The Simmons Comprehensive Cancer Center Data Safety Monitoring Board: the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center, Parkland Health and Hospital System.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
The researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Todd Aguilera, MD, PhD
UTSW Department of Radiation Oncology
UT Southwestern Medical Center
2280 Inwood Road
Dallas, TX. 75390
Tel: 214-645-8525

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop unless you request to not disclose any information.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments, or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Dr. Todd Aguilera can be reached at 214-645-8525 during regular business hours, after hours, and on weekends & holidays.

If primary is not available, contact
The Radiation Oncology Clinic can be reached 24 hours a day at 214-645-8525.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Title of Study: INNATE: Immunotherapy during neoadjuvant therapy for rectal cancer, a phase II randomized multi-center trial with and without APX005M, an anti-CD40 agonist

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)

I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of Interpreter	Signature of Interpreter	Date	Time AM PM

Witness Signature (required when interpreter is not physically present-e.g., Language Line is used):

By signing below:

I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of witness	Signature of witness	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM

IRB Approved Date: 2/15/2023