

## Main Participant Information Sheet and Informed Consent Form

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24-Hour (7 days per week) Study Doctor's Number: 020 3448 3805

IRAS number: 1006544

**Study Title:** A Randomized, Placebo-Controlled, Double-Blind Study of XPro1595 in Patients with Early Alzheimer's Disease with Biomarkers of Inflammation

**Protocol Number:** XPro1595-AD-02

**Sponsor:** INmune Bio Inc.

You are invited to take part in a research study because you have mild cognitive impairment (MCI) of probable Alzheimer's Disease (AD) or early dementia. Your participation is voluntary and requires your written consent. If you decide not to take part in this study, you can continue with your current medical care.

This study involves research. Participating in a research study is not the same as getting regular medical care. The purpose of a research study is to collect information about a medical treatment; the purpose of regular medical care is to improve your health. Being in this study does not replace your regular medical care. This study is in addition to your regular medical care, so you may have other tests or changes in your treatments during the study.

INmune Bio is sponsoring this study and it will take place in approximately 70 centres in 10 countries with about 201 people with early AD participating.

The study has received favourable opinion by the ethics committee (East Midlands - Leicester South Research Ethics Committee) and an authorisation from the applicable competent authorities, Medicines, and Healthcare products Regulatory Agency (MHRA). Before agreeing to participate in this study, it is important that you read and understand this form. It explains the purpose, procedures, benefits, risks, discomforts, and safeguards of the study. It also explains the different choices that are available to you and your right to withdraw from the study at any time. Please read this information carefully and ask the study doctor or study staff for an explanation if you have any questions. You may take home this participant information sheet and an unsigned copy of the informed consent form to think about it or to talk about it with your partner, family, or friends before deciding whether to take part in the study. The option to participate will remain open to you as long as the research study is being offered by your study centre. You will have up to 45 days from the time you sign the informed consent form until you have your first dose of study drug if you remain eligible to participate.

**1. If you choose to participate in this study, you will be asked to sign the informed consent form. You will receive a copy of this form to keep. Your caregiver will also be asked to act as your support person and sign as a participant in the XPro1595-AD-02 study. Why is this study being done?**

INmune Bio has begun a study of an investigational drug called XPro1595 as a possible treatment for early AD. An investigational drug is one that has not been approved by regulatory agencies, such as the MHRA.

XPro1595 is a protein made in a laboratory that works like a protein found in the human body and disables a protein that is thought to cause AD.

The main aim of this research study is to learn how well XPro1595 works and how safe XPro1595 is compared with placebo. A placebo is an inactive material that looks like the study drug but does not have any active XPro1595 in it. Researchers use a placebo to see if the study drug works better or is safer than taking nothing. From here on, XPro1595 and placebo will be referred to as the “study drug”.

If you agree to take part in this study, your General Practitioner (GP) will be informed of your participation.

**2. How long will my participation in this study last?**

You will be in this study for approximately 33 weeks (about 8 months), and you will need to come to the study centre at least 9 times over this period.

### **3. What will happen during this study?**

The study is divided into 3 periods: a screening period, a treatment period, and a follow up period. During each study period, you will have 1 or more visits with your study doctor at the centre. The screening visit will last about 6-8 hours, but all other visits will last about 2-4 hours. The screening procedures may be conducted over several days.

Before any study-related tests and procedures can be done, you will be asked to read this participant information sheet and sign the informed consent form. After you sign the informed consent form, the study will begin with a screening visit. The goal of the screening visits is to decide whether you meet the requirements to take part in this study. You may be permitted to go through screening again if you do not meet the requirements the first time. If you do not meet the requirements, the study doctor will explain why and will discuss other treatment options with you.

If the study doctor decides that you meet all the requirements to be in this study, you will be randomly assigned (like flipping a coin) to receive 1 of the following:

- 1.0 mg/kg XPro1595
- placebo

You will have a 66% (2 in 3) chance of receiving XPro1595 and a 33% (1 in 3) chance of receiving placebo. You will not be told if you are receiving XPro1595 or placebo. The study doctor and any other people involved in the study will not know whether you are receiving XPro1595 or placebo. However, this information will be given to the study doctor if it becomes necessary for your safety (i.e., in the event of an emergency).

If your study doctor approves it, you may choose to receive the study drug injections at home by injecting them yourself or by a care giver trained by the study staff. If you choose to do so, this may begin after at least the 3<sup>rd</sup> or 4<sup>th</sup> visit as directed by the study staff who provide this training including instructions on how to store, prepare and inject the study drug. You will be given enough drug to last until the next scheduled visit.

#### **Home Health Care**

If the study doctor agrees, specified visits may be carried out off-site. The off-site research nurse will visit your location and complete procedures, including collecting medical data, according to the protocol. The off-site research nurse may be from your doctor's office or from another home healthcare vendor (Illingworth Research Group) that is contracted to perform these visits on behalf of your doctor.

If you agree to these visits from the outside company, a Registration Form is completed to provide contact information to Illingworth, or another home healthcare vendor. Your identifying information (name, date of birth, address, contact number, and carer details) and medical information will be collected by the Investigator and passed on to the home healthcare vendor (its affiliates and subcontractors, if applicable) to allow coordination of visits.

Some personal information (e.g., address) will be passed on to a third-party courier for transport of the study drug, but no medical information will be shared with such third party.

Any identifying information leaving the Site will be kept confidential by the home healthcare vendor, its affiliates and subcontractors, and the courier company, as applicable. In addition, your information may leave the locale in which it was collected (e.g., from USA to EEA [European Economic Area], etc.).

Signing of this consent form acknowledges that personal data (from you and/or your study partner) will be provided to Illingworth Research Group or another home healthcare vendor (its affiliates and subcontractors, and the courier, as applicable) for the purpose of carrying out off-site visits and treated with strict confidentiality as detailed in this ICF (the lawful basis for processing this data).

### **Description of the procedures and assessments**

- **Physical examination**: Includes checking your heart, chest, lungs, stomach, abdomen, nervous system, and any other notable physical conditions. Your height and weight will also be measured.
- **Medical history and previous therapy**: Include questions about your health and AD. You and/or the caregiver will also be asked about any medicines and any treatments for AD you have used in the past.
- **Vital signs**: Includes heart rate, breathing rate, blood pressure, and body temperature.
- **Electrocardiogram (ECG)**: A technician will place patches on your chest that will be connected by wires to a machine. The machine will record the electrical activity of your heart.
- **Laboratory tests**: Blood and urine samples will be collected.
  - A urine sample will be collected to check that you are healthy and that you may safely take part in the study.
    - If you are a woman able to become pregnant, a urine sample will be collected before you receive/take the study drug to make sure you are not pregnant.
  - Blood will be taken during the study. The blood will be taken from a vein in your arm for the following:

- 156 mL (a little under 26 teaspoons during the study) for different blood tests to check the cells and chemicals in your blood, if you have a sign (biomarker) of inflammation, the study drug's effects (if any) in your body, and your body's immune response to the study drug (these examples include: APOE4, amyloid, serology, haematology, chemistry, biomarkers, anti-drug and anti-PEG antibodies).
- At screening, you will be checked for human immunodeficiency virus (HIV), hepatitis B and hepatitis C. You can only participate in the study if you have negative HIV, hepatitis B and hepatitis C tests. You will be informed about these tests results.
- Questionnaires: You will be asked to fill out some questionnaires during the study. With your responses, the study doctors, and the Sponsor hope to understand how your early AD or your MCI affects you. These will take up to 45 minutes to complete. The time of completion of the questionnaires might be longer at screening than at other visits. One of the questionnaires is about assessing suicide risk. Some of the questions in this questionnaire may make you feel uncomfortable. Please notify the investigator or study staff if you would like to discuss any concerns privately. In addition, the study team may also make audio recordings of you for some of the questionnaires, which will be kept as part of your study records and retained just like all data for this study. This will be discussed with you when required.
- Magnetic Resonance Imaging (MRI): Scan used to take a detailed picture of your brain. An MRI scan uses magnetic field and radio waves to take images of your brain and to check whether there is any damage to it. It will also be used to measure the size and volume of specific regions of the brain involved in memory patterns, to see if there is any change over time. You will be asked to lie still while the scan is taken. The total time for this procedure will be approximately 45 minutes. The technique is painless and harmless.
- Study drug administration: The study drug is a liquid that will be given as an injection under the skin (subcutaneously). You will be injected with study drug weekly for the first two visits. You and/or your caregiver will be trained on how to administer the study drug during your first or second injection. After visit 3 and 4, injections may be administered by you or your caregiver under the supervision of the study staff. The last dose of study drug will be administered at Week 23.

The table on the next page shows which procedures and assessments will occur at which visit(s). In addition to the visits described below, the study doctor may ask you to come in for extra visits, if necessary for your safety.

Procedure	Screening	Treatment Period (weeks)												Safety Follow-up phone call (28 days after last dose)	
		1	2	3	4	5	6	7-11	12	13-17	18	19-23	24/End of study		
Read and sign informed consent form; review eligibility criteria; questions about demographics; questions about your medical history (including substance use); questions about prior medications you have taken; urine sample for pregnancy test; height measurements; blood sample for genetic biomarker and biomarker related to AD; and questions to measure how well your brain is working (such as orientation, attention, memory, and language)	X														
Full physical examination; weight measurements; electrocardiogram; and MRI	X								X					X	
Urine sample for safety tests	X													X	
Vital signs	X	X							X					X	
Administer the study drug		X	X	X	X	X	X	X	X	X	X	X	X		
Questions about how you are feeling and any side effects		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Questions about other medications you are taking and any suicidal thoughts or behaviours	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood sample for safety tests; biomarkers; and antibodies against the study drug	X		X		X				X					X	
Questions completed by your caregiver(s) about how AD affects your daily life activities, behaviour, and everyday activities; and questions about your symptoms of dementia and ability to function		X							X					X	

Questions about your personal goals, and how AD affects your abilities (such as memory, concentration, reasoning, and speaking)	X	X							X				X	
Questions to measure your abilities (such as learning, language, and memory)	X	X				X		X		X			X	
Questions completed by you and your caregiver(s) about your personality	X	X												

#### **4. What do I have to do?**

During the study, you will have the following responsibilities:

- Tell your study doctor if you have any allergies, including drug allergies. If you are not sure, ask your GP.
- Attend all scheduled visits.
- Administer the study drug as directed.
- Follow the study doctor's instructions about whether or not you may continue to take your regular prescribed medications or over-the-counter medicines during the study period.
- You may enter the study so long as you are on stable doses of symptomatic medications for your memory (donepezil, rivastigmine, galantamine and memantine). However, if you wish to start any of these treatments or change dose during the study, you would need to withdraw from the study.
- Tell the study doctor of any changes to your current medications, illnesses, or injuries, unexpected or troublesome side effects, or problems that occur during the study.
- Tell the study doctor if you plan to have an elective surgery or any other medical treatment or procedure.
- You should continue to make regular visits to your GP or any other special doctors you were seeing before starting the study because being in the study does not replace your regular medical care.
- If you are not coming to the study centre, then you should administer the study drug at home:
  - Make sure that the study drug is kept out of the reach of children and people who have a limited capacity to read or understand. You are the only person who should be administered the study drug.
  - Make sure study drug is stored as instructed by study staff.
  - Return any unused study drug and containers as instructed by the study staff.
  - Make sure study staff is aware if study drug was not stored at home as instructed by study staff.
- Contact the study doctor if you find you have any questions about the study after you sign the informed consent form.
- You will be given a research study participant card. Please ensure you always carry this card.

#### **5. What are the risks and possible discomforts?**

Any study has risks, which may include things that could make you sick, make you feel uncomfortable, or harm you. You might experience side effects related to the study drug while

participating in the study. All participants in the study will be watched carefully for any side effects; however, the study team does not know all the side effects that the study drug may have on you. The study team may give you medicines to help reduce side effects. These side effects may be mild or serious. In some cases, these side effects might be long lasting or permanent and may even be life threatening.

Taking part in this study involves some risks and possible discomfort to you.

Possible risks/side effects associated with the study drug:

- If you are assigned to be administered placebo or if XPro1595 does not work for you, you may see an increase in your AD symptoms.
- The study drug may cause unpleasant side effects or reactions. As of August 11, 2023, 13 patients with AD have participated in the current study. The following mild reactions were reported: injection site reactions (extreme sensitivity, redness, swelling, bruising, and itching, itchy skin on the stomach, chest infection, constipation, cough, COVID-19 infection, headache, nasal/facial stuffiness or pressure, decreased appetite, lack of energy, weakness, extreme sleepiness, loose stool, joint pain, stomach pain, chest pain (not related to the heart), stomach ulcer, feeling depressed, thoughts of suicide, and increased energy. The following moderate reactions were reported: injection site itchiness and redness, lack of energy, inflammation near the joints, hip pain (likely in the muscle), back pain, headache, feeling depressed, fainting, inflammation of the stomach lining, and a possible urinary tract infection. Because the study is ongoing, it is not known whether these patients received placebo or study drug. Some of these side effects may be related to the study drug.
- As of June 30, 2023, 2 patients are being treated with the study drug in a related study. Side effects reported in the study include mild sleepiness and redness.
- As of June 30, 2023, 3 patients are being treated with the study drug (not placebo) in another related study. The following mild reactions were reported: injection site reaction, redness at the injection site, on and off buzzing sensation in the lower stomach area and testicles, feeling down, lack of energy, stomach pain, constipation, left thumb clicking/clacking, and left knee swelling and redness. The following moderate reactions were reported: increased lack of energy and worsening rheumatoid arthritis. Because the study drug is investigational, there may be risks and side effects that are unknown. All drugs have a possible risk of an allergic reaction.

Possible discomforts and risks associated with the study procedures:

- **Study drug injection:** For most people, injections under the skin do not cause any serious problems. Sometimes they may cause bleeding or bruising where the injection is given. There is a small risk of discomfort, infection, and/or pain at the site where the needle is inserted.
- **Blood samples:** Taking blood from your arm may cause faintness and/or swelling, pain, redness, bruising, bleeding, or infection (infection rarely happens) at the site where the needle is inserted.
- **ECG:** Skin irritation is rare but could occur during an ECG from the electrode patches or gel that is used.
- **MRI scan:** Tell the doctor or staff if you have metal in your body or if you are uncomfortable in small spaces. Because an MRI scanner uses strong magnets, you cannot have any metal implants in your body. People with an artificial heart valve, metal plate, pin, or other metallic objects in their body (including gunshot or shrapnel) are not eligible for MRI scans. Some patients experience anxiety or claustrophobia (fear of being in small places) with being in the scanner. Staff at the imaging centre use ways to help reduce these feelings in patients. Your study doctor may also prescribe mild sedatives or anti-anxiety drugs to help manage your symptoms.

## **6. What about birth control, pregnancy, and breastfeeding?**

Taking the study drug may involve unknown risks to a pregnant woman, an embryo, a foetus (unborn baby), or a breastfeeding infant.

All females of childbearing potential (FCBP) must have a negative urine pregnancy test and agree to use a highly effective method of contraception during the treatment period and 30 days after the last dose of treatment.

No one method of contraception is 100% effective.

Male participants who are sexually active and their female partners who are able to become pregnant should be compliant with a highly effective method of contraception during the treatment period and until 90 days after the last dose of treatment. Highly effective birth control methods include: combined (oestrogen and progestogen containing) hormonal birth control (pill, ring, patch); progestogen-only birth control associated with inhibition of ovulation (pill, injection, implant); intrauterine device (IUD); intrauterine hormone-releasing system (IUS); bilateral tubal occlusion (similar to having your tubes tied); vasectomised partner (a male who has had surgery to stop him from being able to release sperm); or abstinence (not have sex). ),

and double barrier methods (i.e.: male condom with female diaphragm and spermicide). Male participants are required to inform their female partner of the pregnancy risks and should refrain from donating sperm during the study and for 90 days after receiving the last dose of study drug. If your female partner is planning to become pregnant, you should discuss with your study doctor.

If a female participant becomes pregnant, the study drug may be stopped, and involvement in this study may end. The pregnant female participant may be allowed to continue receiving the study drug; the study doctor will discuss this option with you. If allowed to continue receiving the study drug while pregnant, you will need to sign another informed consent form. The Sponsor may want to receive updates on the progress of the pregnancy and its outcome for female participants and pregnant partners. If a pregnant partner agrees to this, she will be asked to sign a separate informed consent form.

### **7. What are the benefits of being in this study?**

There is no guarantee that you will receive any benefits. However, you will be helping others by contributing to medical research. You may feel that you are benefiting in the following ways:

- Your condition will be checked as long as your participation in the study lasts. However, services provided, and evaluations carried out as part of the study should not be seen as a substitute for a careful evaluation, ongoing medical care, or follow up by your GP.

You have the right to be informed of the overall results of the study.

### **8. What other options are available if I do not take part in this study?**

You do not have to take part in the study to receive treatment for your AD. There are other options of therapies, such as Donepezil, Rivastigmine, Galantamine and Memantine. Any other treatments will be discussed with you.

Your GP or the study doctor can answer any questions that you have about other treatments.

You can also contact your GP to ask about other research currently being done in the treatment of AD.

### **9. What if I get harmed or injured during the study?**

If you require medical treatment for an illness or injury that is a direct result of taking the study drug, INmune Bio will pay for reasonable and routine costs of such treatments.

## **10. What are the costs for participation, and will I be paid?**

The study is being funded by INmune Bio, the Sponsor. The study treatment, and all tests, procedures and visits required by the study are provided at no cost to you. The Sponsor will pay for them.

You will not be paid for being in this study. However, reasonable expenses related to clinic visits (eg, travel, meals) will be reimbursed, after receipts for the payments are provided, and in agreement with the study doctor.

The costs of other medications and treatments that you take or use independently of the study are covered according to NHS standard of care.

The hospital/institution will be paid for their work in this study.

If you have insurance such as life assurance, travel insurance, private medical insurance, etc., you should check with the insurance company before agreeing to take part in this study, to ensure your participation will not affect any cover that you have.

## **11. May I or someone else stop my participation after the study has begun?**

Taking part in this study is voluntary, and you can leave the study at any time for any reason. A decision to stop study participation will not impact your regular medical care or benefits to which you are entitled.

If you are considering or have already decided to leave the study, you should contact the study doctor to discuss the safest way to leave the study. This may involve completing some final tests and examinations. You should also contact your GP so he or she can provide you with the best course of continuing care.

If new findings that would affect your safety and willingness to participate in the study are identified while you are in the study, you will be told as soon as possible so you can decide whether to leave the study or continue. If you decide to continue, you will be required to sign a new informed consent form.

Sometimes the study doctor or INmune Bio may decide it best for you to stop your participation and remove you from the study (even if you do not agree). He or she will discuss this with you. Possible reasons for doing so include the following:

- It is in your best interest.
- You have a side effect that requires stopping the research study.
- You need a treatment not allowed in this research study.

- You become pregnant.
- The research is cancelled by the applicable regulatory authorities or the Sponsor.
- You are unable to be administered the research medication.
- You are unable to keep your scheduled appointments.

### **12. What medical care will I receive when my participation in this study stops?**

When you leave the study, you will be under the care of your regular health care provider, who will decide the best way to treat your early AD. All participants that complete the 23 weeks of treatment (XPro1595 or placebo) will be eligible to enrol in a separate open-label extension study (once approved by the required regulatory authorities and ethics committee) for 12 months where all participants, including those treated with placebo, will receive 1 mg/kg of XPro1595.

### **13. What will happen to the samples that I provide?**

The routine blood samples that you give for safety testing will be sent to a central laboratory (PPD laboratories' Central Lab in Belgium) and used only for the tests specified in the table and destroyed once all protocol-defined procedures are completed.

Any remaining blood samples you provided for biomarkers will be processed and stored at a central laboratory (PPD laboratories' Central Lab SG in Belgium with long term storage facility and stored for up to 15 years.

### **14. What happens with my data and other personal information?**

#### **How will we use information about you?**

We will need to use information from you, from your medical records, your GP, or other specialist for this research project.

This information will include your initials/ NHS number/ name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

If any of your information is to be sent to another country, they must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can determine that you took part in the study.

### **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records/ your hospital/ your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information.

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- a leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- by sending an email to [london@re-cognitionhealth.com](mailto:london@re-cognitionhealth.com), or
- by ringing us on +44 (0) 20 3355 3536.

### **15. Whom should I reach if I have a question?**

If you would like to ask questions about the study, please use the contact information at the beginning of this document.

If you have question regarding your rights as a study participant before, during, and after the study, please contact the [PALS (Patient Advice and Liaison Service) or [compliance@re-cognitionhealth.com](mailto:compliance@re-cognitionhealth.com)]. Study results will be published on a publicly accessible database, ClinicalTrials.gov.

**To be printed on site headed paper  
Main Informed Consent Form**

<p>Emer Macsweeney</p> <p>Re:Cognition Health London</p> <p>45 Queen Anne Street, London</p> <p>W1G 9JF</p> <p>Office Hours Tel: 020 3355 3536</p> <p>24-Hour (7 days per week) Study Doctor's Number: 020 3448 3805</p> <p>IRAS number: 1006544</p>
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**Study Title:** A Randomized, Placebo-Controlled, Double-Blind Study of XPro1595 in Patients with Early Alzheimer's Disease with Biomarkers of Inflammation

**Protocol Number:** XPro1595-AD-02

**Sponsor:** INmune Bio Inc.

By signing this informed consent form, I agree to the following:

Please initial each box

<ul style="list-style-type: none"> <li>I have read and I understand the participant information sheet and this informed consent form.</li> </ul>	
<ul style="list-style-type: none"> <li>I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand the risks of taking part in this study as described in the participant information sheet and this informed consent form.</li> </ul>	
<ul style="list-style-type: none"> <li>I freely consent to receive study drug under the study doctor's care. I understand that there is no guarantee that I will receive any benefits from taking part in this study.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand that I am free to withdraw from the study at any time for any reason. I will tell the study doctor if I decide to withdraw so that my participation may end in an orderly manner and my future care can be</li> </ul>	

discussed. I understand that my study doctor can stop my participation in the study at any time.	
<ul style="list-style-type: none"> <li>I understand that I will be told of any new information that might relate to my willingness to continue in the study.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand that I cannot participate in another research study while taking part in this study.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand that shipping and storage of samples and data storage will be outside of the UK.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand that I will receive a signed and dated copy of this informed consent form for my records.</li> </ul>	

My consent to participate in this study does not take away any legal rights in the case of negligence (carelessness) or other legal fault of anyone who is involved with this study.

\_\_\_\_\_  
Name of participant (print)

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date (dd/Mmm/yyyy)

I confirm that all the contents of this informed consent form were discussed and that any questions have been answered.

\_\_\_\_\_  
Name of study doctor or person administering consent (print)

\_\_\_\_\_  
Signature of study doctor or person administering consent

\_\_\_\_\_  
Date (dd/Mmm/yyyy)

### Impartial Witness

I am an impartial witness and I confirm I was present during the entire informed consent discussion. I attest that the information in this informed consent form was accurately explained, apparently understood, and that the consent to participate was given freely.

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Name of participant (print)

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Name of impartial witness (print)

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Signature of impartial witness

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Date (dd/Mmm/yyyy)

## Appendix 1: Privacy Notice

**Identification of Data Controller:** During the study, the Sponsor will direct the collection and use of your personal information (data) needed for the study. The Sponsor is the data controller of your personal data under applicable data protection laws. You can contact the Sponsor at:

*R.J. Tesi, MD*  
980 North Federal Highway, Suite 110  
Boca Raton, FL 33432

The Data Controller can be contacted in relation to data protection matters by addressing your correspondence to:

*R.J. Tesi, MD*  
980 North Federal Highway, Suite 110  
Boca Raton, FL 33432

The study center may also be considered a data controller of your personal data under applicable data protection laws. You may contact the study doctor using the contact information for the study doctor on the first page of this informed consent form.

If you have any questions or would like to see the data collected about you for this study, you should contact the study doctor.

**Data to Be Collected and Processed:** The study staff will collect data about you for the study. These data may include your name or initials, date of birth, sex, contact details, and information needed for payment processing. In addition, the following sensitive personal data about you may be collected: health, ethnicity, and race.

**How Your Personal Data Will Be Used:** The personal data collected about you will be recorded in your study file by the study staff to run the study and to monitor your safety as a participant. Your personal data may be processed on a computer, on paper, or both. The collection of these data is necessary to conduct the study and comply with applicable laws. You will not be able to participate in the study if you fail or refuse to provide your information.

There are laws about the recording, forwarding, storage, and analysis of your personal data, including sensitive personal data. These laws require your voluntary and explicit consent before you participate in the study. If you do not consent to the collection and use of your personal information, you will not be able to be in the study.

Results of this study may be presented at meetings or in publications; however, your identity will never be shared. Your personal data will not be used for any direct marketing purposes.

**Storage of Your Personal Data:** According to legal requirements, your personal data will be stored in the study databases and/or paper files for whichever period is longer, as required by applicable laws:

- 15 years after the study ends, OR
- 2 years after the drug being studied has received its last approval for sale, OR
- 2 years after the drug's development has stopped.

The above retention periods may be extended to meet regulatory requirements or based on a legal requirement to which the Sponsor must comply.

**Access to Your Personal Data:** Your medical records (including uncoded personal data) may be reviewed by the Sponsor and other individuals and/or companies that act on the Sponsor's behalf, including Syneos Health (such as monitors, auditors); regulatory agencies in countries where the study drug may be considered for approval (such as the US FDA, EU EMA); [IRB/IEC name], a group that reviews and approves studies; and independent auditors for the purposes of confirming your participation in the study, monitoring your safety during the study, and monitoring the conduct of the study. Further, your personal information may be disclosed in response to lawful requests by public authorities, including those to meet national security or law enforcement requirements. In some situations, it may be necessary to make a copy of some of your medical records and send the copy via email or fax to the Sponsor and/or companies acting on the Sponsor's behalf. If this is necessary, your name will be blacked out and replaced with your coded identification number before being sent, except as it relates to the use of home health nursing services where your personal information is required for chain of custody.

**Transferring the Personal Data to a Third Party:** To keep your identity private, all data sent or provided outside of the study center will show only a coded identification number instead of your name. Only the study doctor and authorized personnel will be able to connect this code to your name. They will use a list that will be kept in a secure place to link this code to your name in case of an emergency. The coded data from the study showing your involvement (including uncoded personal information) will be provided to the Sponsor and other individuals and/or companies that act on the Sponsor's behalf, including Syneos Health.

If your personal data are shared with other companies that are located outside of the country where you live, the Sponsor will make sure your data are protected as required by your country's data protection laws. Some of these other companies may be located in countries whose data

protection and privacy laws may be less strict than in your own country (e.g., US, Canada). You may contact the study doctor to get more information about the precautions used to protect your personal data outside of your country. You may also ask the study doctor for a copy of those precautions.

**Your Rights as a Data Subject:** If you live in the European Union (EU) or a country that provides these specific rights for individuals, you have the right to access and correct the data collected about you during the study and submit any questions or concerns about the collection or processing of your personal data. If applicable, you may also have the right to request

- the deletion of your personal data,
- restriction on or objection to the processing of your personal data, and
- the receipt of your personal data (data portability).

You may make these requests by contacting the study doctor. You may also have the right to file a complaint regarding the handling of your personal information with your local data protection authority.

You have the right to withdraw your consent for the processing of your personal data at any time. However, data collected before you remove your consent is still legally allowed to be used. If you withdraw your consent, you will no longer be able to take part in the study.

### **Consent to the Collection, Processing, and Use of Personal Data**

By signing below, I agree that:

- (1) My personal data, including sensitive personal data, can be collected, used, and archived for purposes of carrying out the study as described in this Privacy Notice.
- (2) My personal data, including sensitive personal data, can be transferred to other countries for processing, including countries that may not have the same level of data protection as in my country of residence, as described in this Privacy Notice.
- (3) My coded personal data may be retained and used for future research into my medical indication.

This consent is valid unless you change your mind and provide a written notice to the study doctor.

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Name of participant (print)

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Signature of participant

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Date (dd/Mmm/yyyy)

