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Caregiver Information Sheet and Informed Consent Form

Emer Macsweeney

Re:Cognition Health London

45 Queen Anne Street, London

W1G 9JF

Office Hours Tel: 020 3355 3536

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 Mild Alzheimer's Disease with Biomarkers of Inflammation

Protocol Number: XPro1595-AD-02

Sponsor: INmune Bio Inc.

Introduction

You are being asked if you would like to act as a caregiver (support person) for a participant in the XPro1595-AD-02 study listed above, the main purpose of which is to learn how well XPro1595 (the study drug) works and how safe the study drug is compared with placebo when given to patients with Alzheimer's Disease (AD). A placebo is an inactive material that looks like the study drug but does not have any active study drug in it. Researchers use a placebo to see if the study drug works better or is safer than taking nothing.

Before you decide, we would like you to understand what this would involve for you. One of the study staff will go through this Information Sheet and informed consent form with you and answer any questions you may have. Talk to others about the study if you wish.

A caregiver is someone assigned to care for the participant on a regular basis, has adequate contact to describe any symptoms of the participant in his or her care, and has direct observation of behaviour of the participant in his or her care. The caregiver must interact with the participant daily at least 4 hours per day and on at least 4 days per week.

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As the caregiver for the participant, you must be able to support the participant through the research study and have sufficient knowledge and understanding of him or her to be able to identify changes in his or her condition or symptoms.

Your participation as a caregiver is completely voluntary. You may decide to stop acting as a caregiver at any time. If for any reason you are no longer able to be the participant's caregiver, please inform the study doctor or a member of the study team immediately, as a new participant caregiver will need to be nominated.

If you agree to be a caregiver in this study, you will be asked to read this Information Sheet and sign the caregiver informed consent form before participating in the study. You will receive information about the study as well as a copy of the Participant Information Sheet and informed consent form, a copy of this Information Sheet and informed consent form, the study doctor's name, and a 24-hour emergency contact number, before your participation as a caregiver begins.

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)

1. Study procedures

During the study, the study staff may ask you about the participant's health and wellbeing between study visits, including any signs of confusion and/or anxiety, how the participant is tolerating the study drug, if there are any side effects, and whether the participant has started taking any new prescribed or over the counter medications.

The study is divided into 3 periods: a screening period, a treatment period, and a follow up period. The participant will be in this study for approximately 33 weeks (about 8 months) and will need to come to the study centre at least 9 times over this period.

During each study period, the participant will have 1 or more visits with the study doctor at the centre. The screening visit (to confirm if the participant is eligible to take part) will last about 6 to 8 hours, but all other visits will last about 2 to 4 hours. The screening procedures may be conducted over several days. The visits, tests and procedures that occur at each visit for the participant are outlined in the table in the participant information sheet and informed consent form.

Questionnaires: As the participant's caregiver, we will give you some questionnaires to complete. With your responses, the study doctors, and the Sponsor hope to understand how mild AD affects the participant's daily life activities, behaviour and everyday activities, symptoms, and ability to function. These may take up to 45 minutes to complete.

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The questionnaires will need to be completed at Week 1, Week 12 and Week 24 (end-of-study) visits.

During the screening and first treatment visit, you will be asked to answer questions about your personality. This will help the researchers review the other information you provide on questionnaires.

During the screening and first treatment visit, you will be asked to answer questions related to the participant's personal goals. This will help identify goals of the treatment in this study and the goals will be related to the participant's condition and be measured over the course of the study (Week 12 and end-of-study visits). One of the study staff will go through this with you in detail.

Study Drug Administration: You will also need to assist with the study drug administration at the participant's home if this is approved by the study doctor.

The study drug is a liquid that will be given as an injection under the skin (subcutaneously). The participant will be injected with study drug weekly for the first 2 visits at the site.

The study drug needs to be taken by the participant once a week for 23 weeks. After visits 3 and 4, unless otherwise agreed, administration of the study drug will be performed at the centre weekly. Home administration of the study drug may be available to some participants, and this will be approved by the study doctor on a case-by-case basis. If home administration of the study drug is approved by the study doctor, you will be trained and given instructions on how to store, prepare, and administer the study drug during the participant's first or second injection.

The study team will organise and coordinate the amount of study drug required and when it will be sent, if the participant is having the study drug administered at home. The last dose of study drug will be administered at Week 23.

If the participant receives the study drug at home, a member of the study team will contact you and the participant via telephone to discuss any medications and side effects.

2. Responsibilities

By agreeing to be a caregiver, you will also have the following responsibilities:

- Attend each study visit throughout the study with the participant you care for and make sure he or she complies with the study procedures (a table detailing study visits and procedures is in the participant information sheet and informed consent form).
- Tell the study doctor about the medical condition, behavioural symptoms, and activities of daily living of the participant you care for.
- Help keep track of and report changes in all medications that the participant you care for is taking, including over-the-counter medication.

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- If the participant is not coming to the study centre, then you should oversee the administration and storage of 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. The participant is the only person who should take the study drug.
    - Make sure that the study drug is stored as instructed by the study staff.
    - Return any unused study drug and containers as instructed by the study staff.
    - Make sure the study staff is aware if the study drug was not stored at home as instructed by study staff.
- Contact the study doctor immediately if you no longer are able to act as a caregiver in this study.
- Keep any contact information given to you by the study team (e.g. 24-hour emergency contact) with you at all times.

3. Risks and discomforts

During the study, you will be asked to provide your thoughts on the participant's AD symptoms and his or her overall health. There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms that the participant develops.

The study doctor may give medication to the participant to help lessen the side effects. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop treatment. Tell the participant's study doctor if he or she has any problems. The participant's study doctor will discuss the best way of managing any side effects with you and with the participant as appropriate.

If you become upset or distressed as a result of your participation in this study, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the study team, and this will be completely independent of the study and Sponsor.

4. Confidentiality and data protection

How will we use information about you?

We will need to use information from you for this research project.

This information will include your 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.

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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.

Some of your information will be sent to **the United States, Canada, Belgium, Switzerland,** 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.
- 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/
- a leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to **London@re-cognitionhealth.com** or
- by ringing us on 020 3355 3536

5. Compensation

This study is being funded by INmune Bio Inc., who appreciates your involvement in the study. You will receive no direct payment for taking part. However, you will be compensated for your time and reimbursed for transportation or parking payments related to visiting the study centre.

6. Potential benefit

There will be no clear benefit to you from taking part in this research study. However, your participation in this research study may help to further knowledge regarding scientific information and knowledge that could contribute to developing new medication for people who have AD.

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Brain and Mind Experts

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7. Contact person

If you have any questions about this research study or about a research-related injury, please contact the study doctor, Dr Emer Macsweeney at 020 3448 3805 or Dr Maciej Zak at 020 3355 3536

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

Please initial each box

• I have read and I understand the caregiver information sheet and this informed consent form.	
• I confirm that the caregiver responsibilities have been explained to me.	
• I have been given the chance to ask questions that I had about the study, and all questions that I asked were answered to my satisfaction.	
• I know whom to contact if I have any further questions.	
• I confirm that I voluntarily agree to assist the participant in this study.	

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An original copy of the information sheet and signed consent form will be given to you to keep.

_____
Name of caregiver (print)

_____ _____
Signature of caregiver Date (dd/Mmm/yyyy)

_____
Participant's first and last name and study ID number (print)

_____
Name of study doctor or person administering consent (print)

_____ _____
Signature of study doctor or person administering consent Date (dd/Mmm/yyyy)

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