Study Title: A Phase 2 multi-center, randomized, double-blind, placebocontrolled, parallel group study to evaluate the efficacy and safety of T-817MA in patients with mild cognitive impairment due to Alzheimer's Disease or mild Alzheimer's Disease

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Subject information for participation in medical scientific research: A study to evaluate the efficacy and safety of T-817MA in patients with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease.

Official title: A Phase 2 multi-center, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of T-817MA in patients with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease

Dear Sir/Madam,

We would like to ask you to take part in a clinical study (further referred as 'study'). Participation requires your written consent. You have received this letter because you have been diagnosed with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease. In the remainder of this information leaflet only the term Alzheimer's disease will be used.

Participation is voluntary, and you can also decide NOT to participate. Before you decide whether or not you want to participate in this study, you will be given an explanation about what the study involves. Please read this information carefully and ask the study doctor for an explanation if you have any questions. You may also discuss it with your partner, friends or family. Additional information about participating in a study can be found in the enclosed general brochure on medical research {*Only applicable for The Netherlands or per local guideline*}. If you have had sufficient time for reflection, you will be asked to decide whether or not you want to participate in this study.

1. General information

This study has been designed by the company FUJIFILM Toyama Chemical Co., Ltd., a subsidiary of FUJIFILM Corporation, and is being carried out by doctors at various study clinics. FUJIFILM Corporation is paying for the costs of this study. FUJIFILM Toyama Chemical Co., Ltd. is the sponsor of the study and will be responsible for ensuring that it is conducted in accordance to Good Clinical Practise (GCP) and relevant regulations. A total of 200 participants from different study clinics in different countries are required for this (so-called multicenter) study. Ethics Committee {Name EC} has approved this study.

2. Purpose of the study

The purpose of this study is to find out if the study drug T-817MA is safe to use in subjects with Alzheimer's disease and determine if T-817MA can slow down worsening of your

disease. The efficacy of T-817MA will be compared to the efficacy of a placebo. A placebo is a product without any active ingredient (a 'fake' medicine).
The human body is built up of small functional units, called 'cells'. Some of these cells are further differentiated - dependent on their function in the body. The human brain contains specialized cells which are called neurons. These neurons are connected to each other thereby forming networks which are essential for memory and other cognitive functions (the mental action or process of acquiring knowledge and understanding through thought, experience, and the senses). Alzheimer's disease disrupts these networks, resulting in loss of function of the neurons. Subsequently, Alzheimer's disease leads to death of the neurons. This causes impairment in memory and other cognitive functions. T-817MA has been investigated in both animals and humans. These studies have shown that T-817MA inhibits death of the neurons and promotes their function. This suggests that T-817MA can slow down the development of Alzheimer's disease. It could therefore be a valuable therapeutic option in Alzheimer's disease. To find out if T-817MA is a valuable treatment option, this additional (so-called phase 2) study needs to be performed. The data from this study will provide more information on the safety and efficacy of T-817MA.

3. What participation involves

On your first visit, before any study-related assessments are performed, your study doctor will review with you this information leaflet. If you want to participate in the study, and once you have had ample time to consider your participation and all your questions have been addressed sufficiently, you will be asked to sign the Participant Informed Consent Form. You cannot take part in this study if you are currently participating in another medical drug study.
The maximum duration of the study is 90 weeks. First, there is a screening visit where some tests and procedures will be performed to find out if you meet the clinical criteria to participate in this study (for tests and procedures see the table below in this section). The total duration of the tests and procedures for this visit is approximately 8 hours and may be performed over several days.
If you meet the clinical criteria for this study, you will start in 1 of the 2 treatment groups: placebo ('non-active' study drug) or T-817MA ('active' study drug). The odds to receive placebo is one in two, i.e. 50%. Whether you receive T-817MA or placebo will be determined by chance (this is called randomisation). Neither you nor the study doctor will know which group you are in. However, this can be found out if important for your health. Both placebo and T-817MA are further referred as 'study drug' in this information leaflet.
During the treatment period (a total of 78 weeks), visits will take place at the so-called baseline visit and in weeks 4, 16, 28, 40, 52, 65 and 78. At week 82 you will be asked to visit the study clinic for a so-called follow-up visit. The duration of the tests and procedures for the visits in the treatment period and follow-up period varies from 1,5 hours to 6 hours. Tests and procedures may be performed over several days.

At the end of the trial your study doctor will inform you about the outcome of the trial, including the treatment group you were in.
Please find a summary of the assessments during the screening, treatment and follow-up period in the table below.

Assessment	**Visit type**	**Estimated duration**
Study explanation and signature of this inform consent form.	Screening	45 min.
Documentation of age, gender, education, smoking habits and the clinical medical history.	Screening	45 min.
Physical and neurological examination	Screening, Treatment period (Weeks 28, 52 and 78) *	10 min.
Measurement of your blood pressure, heart rate and weight.	Screening, Treatment period (every visit), Follow-up period	10 min.
Concomitant medication (you will be asked about medications you are using at that moment)	Screening, Treatment period (every visit), Follow-up period	10 min.
Scan of your brain (so-called MRI).	Screening, Treatment period (Week 52 and 78)	60 min.
Measurement of your heart activity (so-called ECG).	Screening, Treatment period (Week 28, 52 and 78) *	5 min.
Lumbar puncture to collect a sample of cerebrospinal fluid (CSF). (CSF is a clear, colorless body fluid available in the brain and spinal column that contains proteins that can provide more information about Alzheimer's Disease)	Screening, Treatment period (Week 52 and 78)	15-30 min.
Blood sample	Screening, Treatment period (every visit), Follow-up period	10 min.
Urine sample	Screening, Treatment period (every visit except Baseline), Follow-up period	5 min.
Examination of your brain activity (so called EEG).	Treatment period (Baseline, Week 52 and 78)	60 min.
Tablet count of the study drug to verify compliance with study treatment.	Treatment period (Every visit except Baseline)	5 min.
Documentation of side effects from time of consent regardless if you think it is related to the study drug or not.	Screening, Treatment period (every visit), Follow-up period	5 min.

Completion of several computer tests which can provide information about your cognition, mental abilities, mental status and the status of your Alzheimer's disease.	Screening, Treatment period (Baseline, Weeks 28, 52 and 78)	60 min.
Completion of a questionnaire by your study partner (see further below in this leaflet who can fulfil the role of study partner) providing information on the level you can perform daily living activities	Screening, Treatment period (Baseline, Weeks 28, 52 and 78)	30 min.

* Might be examined also at other visits when clinically relevant

The intake of your first dose of the study drug will be at the study clinic during the baseline visit. Following your first administration you will have to take the study drug at approximately the same time for a total of 78 weeks. You are asked to take 2 tablets daily for the entire period of 78 weeks.

Tablets should not be broken or crushed. In case a dose is missed for longer than a period of 12 hours after the scheduled time, it may be skipped.

You may be asked by your study doctor to reduce your study drug doses if:

- You start using certain medication(s) that may have impact on the study drug;
- You experience side effects;
- The study doctor believes it is necessary for your health.

At the end of the treatment period you will be asked to stop the study drug intake completely.

Computer tests

The tests are either oral questions or tasks that you should perform on a computer. The tests may be slightly frustrating, or you may feel tired and/or bored.

Blood and urine test

During most study visits blood and urine will be collected (approximately 7 to 15 mL blood).

The blood samples will be used for 4 different analyses:

- *Safety:* function of some major organs (e.g. liver, kidney, thyroid);
- *Biomarker levels:* biomarkers in your blood plasma can tell more about the development of your Alzheimer's disease;
- *Pharmacokinetics:* pharmacokinetics detects what happens with the study drug after it has been taken (e.g. how quick the study drug enters the blood circulation and is removed from your body);
- *Genotyping:* genotyping is an analysis of your DNA in order to look for the presence of the protein (so-called ApoE) which is associated with development of Alzheimer's disease.

EEG (brain activity test)

You will undergo an examination of your brain activity, a so-called electro-encephalography (EEG). An EEG examination measures the electrical activity of the brain and can provide information of the development Alzheimer's disease. In addition, it can provide information about the effect of the study drug in relation to the development of Alzheimer.

Preparations

- Please ensure that you have washed your hair thoroughly and that it is dry
- Do not use hairspray, foam or gel
- You may wear your glasses and/or contact lenses
- You should not wear any jewellery (earrings, etc.)

The examination

A technician will perform the examination. You will lie down on the examination table. You will receive a cap with holes in it (a type of hat), containing about twenty electrodes. The technician will spray a conducting paste in the holes. This paste ensures proper contact between your scalp and the electrodes in the cap. Next, the technician will gently scratch the skin under each electrode. Sometimes a cap will not be used, instead the electrodes will be attached in-between the hair. The electrodes are connected to an EEG machine with wires. Next, the EEG will be performed. Please follow the instructions of the technician.
Once the EEG has been completed, the technician will remove the cap or the electrodes.

<u>MRI-scan (scan of the brain)</u>

MRI stands for Magnetic Resonance Imaging. This is a technique used to visualise organs and tissues. This examination uses a magnetic field and radio waves. Signals are created in the body and captured by a computer. The computer converts these signals into images. These images provide information about the development of Alzheimer's disease.

Precautionary measures

A number of precautionary measures are necessary for an MRI examination:

- Due to the magnetic field, it is not possible to perform this examination on people with a pacemaker or hearing implants.
- If you have a stent in your heart and/or blood vessels, this stent must have been in place in your heart and/or blood vessels for a minimum of two months before an MRI scan can be performed.
- You must report your study doctor prior to the examination if your body contains metal objects, for example: heart valves, vascular clips, plates, screws, joint prostheses, jaw implants.
- If you have a tattoo, you must report this to your study doctor prior to the examination.
- If you suffer from claustrophobia (fear of enclosed spaces), please tell your study doctor before the examination.

Preparations

- Do not use mascara or hairspray. These can contain small metal particles.

- Please ensure that you wear a T-shirt or vest without zippers and metal during the examination. If you wear a bra, then you will have to remove this for the examination.
- Please ensure that you wear pants without zippers, buttons and other metal embellishments during the examination, for example sweat pants.
- Do not bring any objects that contain metal into the examination room, for example: (bank) cards with a magnetic strip, cell phones, coins, jewellery, watches, keys, hair pins, dental prostheses, hearing aids.

The examination

A radio diagnostic technician will perform the examination. You will lie on your back on the examination table in the MRI room. The technician will slide you into the machine. The machine looks like a large, long tunnel that is open at both ends. You need to keep your head still during the MRI examination. Therefore, your head will be held in position using implements. Although you may not talk during the MRI scan, you will be able to communicate with the technician, for example by pressing a button. The MRI staff will talk to you in between recordings and they will ask you if you are feeling ok. You will hear a thumping, drilling, vibrating noise – varying in strength – whilst in the tunnel. This is normal. You will be given earplugs, or perhaps headphones, to reduce the noise. You can resume your normal activities immediately after the scan.

<u>Electrocardiogram (ECG)</u>

The Electrocardiogram (ECG) is a test that detects the electrical activity of the heart-beat and takes a picture of that activity. Small metal electrodes are stuck on to your chest. Wires from the electrodes are connected to the ECG machine. The machine detects and amplifies the electrical impulses that occur at each heartbeat and records them on to a paper or computer.

<u>Lumbar puncture</u>

During lumbar puncture, a needle is inserted between two spinous processes of the lumbar vertebrae to collect a sample of CSF of a maximum of 7 mL. The lumbar puncture will be performed in the lower (lumbar) section of the spinal column. The level of the puncture location ensures that damage to the spinal cord is highly unlikely. The examination of CSF can provide information about conditions affecting the brain, the spinal cord and the nerve roots. The CSF will be tested for proteins that provide more information about the development of Alzheimer's disease. In addition, the amount of study drug is measured in the CSF to determine how quickly the study drug is absorbed and removed from the CSF.
CSF collection will be performed with all patients, including those using the product without the active substance.

Preparations

The lumbar puncture cannot be performed safely if certain blood thinning medication is being used. Discuss this with your study doctor before the examination.

The examination

For the lumbar puncture, you will either lie on your left side on the bed, or you will be in a sitting position with your back flexed (bent forward). You should draw your knees up to your nose as far as possible. Flexing your back makes the space between the vertebrae as big as possible.
Your back will be covered with disinfectant and then a needle will be inserted in-between two spinous processes of the lumbar vertebrae. The lumbar puncture will be performed using a thin needle. Occasionally the correct site is not found immediately. The needle will then be moved. This moving can cause a painful sensation in your back. Once the needle is in the correct position, it takes only a few minutes to collect enough fluid for the examination. Once enough fluid has been collected, the needle will be removed.

Study partner

A study partner is required to participate in this study. This can be either a family member or a close friend. The following actions are being expected (mandatory) from your study partner
-To accompany you during the study visits at screening, baseline, week 28, week 52 and week 72;
-To complete a questionnaire about your activities of daily living.

The following supporting actions can be done by the study partner (not mandatory), but can also be done by other persons close to you:
-To support you with the planning of the study visits;
-To ensure that you will take the study drug as prescribed;
-To ensure that you will bring your unused study drug during each visit to the study clinic, including all empty boxes and wallets;
-To inform the study team in case of new or worsening medical symptoms;
-To inform the study team in case of changes in use of medication.

Prior to your study participation we will also ask your study partner to sign a separate Study Partner Informed Consent Form to assist you during the study for the mandatory actions as mentioned above. It is recommended that your study partner can participate during the entire course of the study. If you get a new study partner during the study we will also ask the new study partner to sign the Study Partner Informed Consent. There is no need for the person(s) close to you to sign an Informed Consent Form for their support with the non-mandatory actions.

4. What is expected of you

To carry out the study properly and for your own safety, it is important that you follow the study instructions. The study instructions require that you:

- Take the study drug as directed;

- Do not participate in another medical drug study;
- Adhere to appointments for visits;
- Carry your participant card for the study with you. This card states that you are participating in this study. It also states whom to contact in the event of an emergency. Show this card if you visit any other doctor, then the study doctor.

It is important that you contact the study doctor:

- Before you start using other medicines. Even if they are homeopathic or natural remedies, vitamins and/or over-the-counter medicines;
- If you are admitted to hospital or are going for treatment, there;
- If you suddenly develop any health problems;
- If you no longer want to participate in the study;
- If your contact details change.

Pregnancy

For women:

You cannot participate in this study if you are of childbearing potential, if you are pregnant or if you are breast-feeding.

For male participants:

You must agree that you will not donate sperm during the study and until 104 days after your last dose of the study drug. You must use a condom during the study and until 104 days after your last dose of the study drug, even when you are vasectomized. In addition, if your female partner is of childbearing potential, she must use a highly effective method of contraception as well during the study and until 104 days after your last dose of the study drug. The study doctor will talk to you about the most suitable methods of contraception.

5. Advantages and disadvantages for participation in this study

It is important that you properly consider the possible benefits and disadvantages before you decide to join in this study. In this section both advantages and disadvantages for participation in this study are mentioned.

Advantages

If you participate in this study, your current condition of Alzheimer's disease will be assessed carefully. You may experience an improvement in your Alzheimer's disease symptoms, even though such improvement cannot be predicted with any certainty. It may be that participation to this study does not provide you any benefit for your health. However, you will contribute to increase the knowledge about the treatment of Alzheimer's disease. The knowledge gained from studies carried out based on your collected data and those of many others may contribute to medical progress and, therefore, the benefit of other people's health.

Disadvantages

There are also some risks associated with participation this study. These risks are described below. Up to now, more than one thousand elderly patients and healthy volunteers received at least one dose of T-817MA during the previous studies. In these studies administration of T-817MA has been shown safe and well-tolerated with various tablet strengths.
This study is designed to monitor the health and safety of the study participants treated for a longer time as closely as possible. Your study doctor may give you medication to help control side effects. It cannot be excluded that side effects can be serious, long lasting or may never go away. All efforts will be used to reduce any discomfort from your participation in this study.
Please see below table for most common side effects of T-817MA that were reported in previous phase 2 studies. The incidence is based on the following convention:

- Very common: occurs in 1 patient or more out of 10 patients
- Common: occurs in 1 to 10 patients out of 100 patients

You can ask your study physician if you would like to know more about the uncommon and rare side effects. These side effects occur in less than 1 patient out of 100 patients. During this study there is a possibility that you might suffer from side effects that have not been reported before in other patients.

Incidence	**Side effect**
Very common	Diarrhoea
Common	Nausea, headache, decreased appetite, dizziness, vomiting, decreased weight, fatigue

There might also be side effects/complications associated with the use of concomitant medications. Furthermore, side effects can occur during assessments like a blood draw and a lumbar puncture. There are also risks related to the process of undergoing brain scans, EEG and ECG assessment.

When blood samples are drawn, there may be some pain and there is a small risk of becoming light-headed when blood is drawn. Bruising, swelling and, on rare occasions, an infection may occur at the injection site.

The EEG is a painless test. Placement of the electrodes on your head may be slightly uncomfortable. Your hair may be greasy as well. When the technician will gently scratch the skin under each electrode it can be somewhat painful.

The potential risk of the MRI examination is that the MRI scanner attracts metal. If you have metal within your body (e.g., artificial joints such as those used for hip replacement or knee replacement or pacemakers), the examination can’t be performed. Some people can feel

"closed in" and get nervous (claustrophobia) or become uncomfortable of the loud noise when having an MRI scan in certain MRI scanners.

During the ECG assessment you may feel some pain when the electrodes are removed from your skin after the test.

During the lumbar puncture most people do not experience any side effects but the following might happen to you:

- (Temporary) pain locally in the lower back;
- Headache, which is likely caused by a leakage of spinal fluid after removal of the needle (occurs in 1 of 4 persons). Headache typically occurs 24-48 hours after the lumbar puncture. If this headache doesn't go away, you may be asked to drink fluids, or it may require additional treatment, such as paracetamol tablet or, in rare cases, a procedure called 'blood patch'. A blood patch is an injection of some of your own blood into the lumbar puncture site to plug the leak. This helps the headache immediately;
- Local anaesthetic (Lidocaine 1%) used prior to the lumbar puncture may cause an allergic reaction. The symptoms of an allergic reaction after the injection of the local anaesthetic include the following: excessive pain, redness or swelling near the injection site, body rash, wheezing and difficulty breathing;
- There is a small chance that an infection is introduced by the needle used for the lumbar puncture. This could be an infection of the skin, subcutaneous tissue, or vertebrae, which require antibiotic treatment and hospitalisation;
- During the procedure a nerve root can be touched by the needle (occurs rarely), resulting in a temporary electrical sensation in the leg. Resulting severe complications are very unlikely but can be: neck pain, blood thrombus, paralysis, permanent nerve damage, bleeding at the puncture location or even death. The collection of the fluid itself is painless.

The study drug you use during the study will not be available after your participation has ended, regardless of whether you have experienced an improvement in your symptoms of Alzheimer's disease. At the end of the study, your study doctor will discuss with you the other treatment options. In case you have experienced improvements in your symptoms of Alzheimer's disease during this study, these other treatment options do not guarantee continuation of this improvement after the study.

Participation in the study also means: investment of personal time, additional or longer study clinic stays, additional tests and instructions you need to follow.

6. If you do not want to participate or you want to stop participating in the study

It is up to you to decide whether or not to participate in the study. Participation is voluntary. If you do not want to participate, you will be treated as usual for your disease. The study doctor can tell you more about the various treatment options that exist, and the benefits and risks associated with them.
If you do participate in the study, you can always change your mind and decide to stop, at any time during the study. This won't affect your relationship with your doctor or causes any penalty to your treatment. You will then be treated as usual for your disease. You do not have to say why you are stopping, but you do need to inform the study doctor if you decide to withdraw. The data collected until that time will still be used for the study. If you want, your physical and genetic material will be destroyed after your consent has been withdrawn.
If there is any new information about the study that is important for you, the study doctor will let you know in a timely manner. You will then be asked whether you still want to continue your participation.

7. End of the study

Your participation in the study stops when:

- You have completed all the visits (see point 3)
- You choose to stop
- The study doctor considers it best for you to stop
- FUJIFILM Toyama Chemical Co., Ltd., State Institute for Drug Control (insert name), European Medicines Agency or Medical Research Ethics Committee, decides to stop the study.
- The end of the entire study has been reached for any other reason

The study is concluded once all the participants have completed the study. The medication you have used during the study will not be available once your participation has ended. The study doctor will discuss the options for further medical care with you.

After processing the data, the study doctor will inform you about the most important results of the study. This will happen after the end of your participation. The study doctor will also tell you which treatment you received. If you do not want this to happen, please tell the study doctor. He/she will then not be permitted to tell you.

8. Confidentiality and protection of personal data, physical and genetic material

The collection, use and storage of your personal data and your physical and genetic material are required to answer the questions in this study. All records will be stored and handled in accordance with applicable {insert country name} legislation, including the General Data Protection Regulation (GDPR). A statement on the handling of personal data is laid down in a separate leaflet which is handed out to you. We would like to ask you to read this leaflet and give your permission on handling of your personal data.

All data and physical and genetic samples taken within the study will be sent to the sponsor only in coded form. Data determining your identity will thus not leave the study clinic. Only the study doctor, authorized representatives of the sponsor (e.g. monitors and auditors), persons authorized by the National Audit Institutions and members of the ethics committee, i.e. persons entrusted with the supervision of the course of the study will have access to your personal data in the medical records. These persons are bound by mandatory secrecy.

Information about unexpected findings

During this study, something may be found by chance that is not important to the study but may be important to you. If this is important for your health, you will be informed by the study doctor. You can then discuss with your doctor or specialist what needs to be done.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the website of the local Data Protection Authority. If you have questions about your rights, please contact the person responsible for the processing of your personal data. If you have questions or complaints about the processing of your personal data, the sponsor advises you to first contact the research location. You can also contact the Data Protection Officer of the institution or the local Data Protection Authority. See section 12 for contact details.

9. Insurance information

Insurance has been taken out by sponsor for everyone participating in this study. The insurance covers damage due to participation in the study. This applies to damage manifesting during the study or within four years of the end of your participation in the study {add # of years according to country insurance certificate}. You must notify the insurance company about the damage within those
four years {see country insurance certificate}.
This is set out in the Medical Research (Human Subjects) Compulsory Insurance Decree. This decree is listed on the website of the Central Committee on Research Involving Human Subjects www.ccmo.nl (see “Library” and then “Legislation and regulations”) {Netherlands only?}.
In the event of damage please contact the insurance company directly.

The insurance company for the study is:
Name:
Address:
Telephone number:

E-mail:
Contact person:

The insurance offers a cover of <copy policy amount, this must be at least €650,000> per study participant and <copy policy amount, this must be at least €5,000,000> for the entire study.

{add below text if required per country and check with the insurance certificate: for ESP delete this part per METC comments}
The insurance policy does not cover the following damage:

- Damage as a result of a risk that you were informed about in the written information. This does not apply if the risk occurs in a more severe form than envisaged, or if the risk was very unlikely to occur
- Damage to your health that would also have occurred if you had not participated in the study
- Damage resulting from not or not entirely following directions or instructions
- Damage to descendants as a result of a negative effect of the study on you or your descendants
- Damage as a result of an existing treatment method for research into existing methods of treatment

10. Will my general practitioner be informed if I participate?

We will always send your general practitioner a letter to let them know that you are participating in the study. This is for your own safety. If you do not agree to this, you cannot participate in this study. {This should be added per local country regulations: }

11. No compensation for participation

The study medication for the study is free of charge for you. You will not be paid for your participation in this study. Reasonable travel, food and beverage expenses and study partner allowance will be reimbursed for the visits to the study clinic considering this study.

12. Any questions?

If you have any questions about this study, have any concerns at any time, or require additional information, please contact your study doctor or study nurse.
Following text is only applicable for The Netherlands:
If you have doubt about taking part in this study you can call an independent doctor, who is not directly involved in the study, but is an expert on this study and your disease. Also, if you

have any questions about this study that you rather not ask your study doctor, you can contact the independent doctor.

If you have any complaints, you may contact the complaints officer/committee {name} at {clinic}.

Healthcare professionals:

- Study doctor: [name, contact details and times of availability]
- Study nurse: [name, contact details and times of availability]
- Independent doctor: [name, type of doctor, contact details and times of availability]

Complaints:

[Department or person with contact details and times of availability]

Data Protection Officer of the institution:

[Name, contact details and times of availability]

For more information about your rights:

https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en

Emergency contact details:

[Name, contact details]

13. Signing the consent form

When you have had sufficient time for reflection, you will be asked to decide on participation in this study. If you give permission, we will ask you to confirm this in writing on the appended consent form. By your written permission you indicate that you have understood the information and consent to participation in the study. Both you and the study doctor will receive a signed copy of the Participant Informed Consent Form.

Thank you for your attention.

Following text is only applicable for The Netherlands:

A. Medical Scientific Research Brochure. General Information for Study Participants (version [number and/or date])

Participant Informed Consent Form

Subject information for participation in medical scientific research: A phase 2 study to evaluate the efficacy and safety of T-817MA in patients with mild cognitive impairment due to mild Alzheimer's disease or mild Alzheimer's disease.

- I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
- The study may be stopped without my consent by the study doctor conducting the study or by the sponsor.
- I do not give up my legal rights by signing this Participant Informed Consent Form.
- I take part in this research study upon request by my study doctor. {*Only applicable* per local guideline}
- I give permission for my GP to be informed that I am participating in this study {Only applicable for The Netherlands or per local guideline}
- I know that some people may have access to all my data to verify the study. These people are mentioned in this information sheet. I consent to the inspection by them.
- I have freely signed this Participant Informed Consent Form prior to any study-related procedures being performed.
- I agree that my research data will be stored for 25 years.
- *(For male participants only)* I know that I should not make women pregnant during the study. The study doctor has discussed with me the most suitable contraception for me (if applicable).
- I
  - □ **do**
  - □ **do not**

  want to be informed about what treatment I have received / in which group I was.
- I want to participate in this study.

Name of study participant:

Signature: Date: __ / __ / __

I hereby declare that I have fully informed this study participant about this study.

If information comes to light during the course of the study that could affect the study participant's consent, I will inform him/her of this in a timely fashion.

Name of study doctor (or his/her representative):

Signature: Date:__ / __ / __

The study participant will receive the full information sheet, together with a signed copy of the Participant Informed Consent Form.