

**WHO CAN I CONTACT ABOUT PARTICIPATING IN
THE IDENTITY STUDY?**

To learn more about participating in the Identity Study, please contact:



**The Identity Study for Alzheimers
Patient FAQ Brochure**



Thank you for your interest in the Identity Study for Alzheimer's disease.

When thinking about joining any clinical study, it is important that you, your caregiver, and/or family talk it through with the doctor. This brochure describes the key aspects of the study, why we are doing this research, and what will happen should you decide to participate. This information is meant to complement the discussions that you and your caregiver, study partner, or family have with the doctor.

Your study partner or caregiver is someone who:

- **Spends at least 10 hours a week with you**
- **Will be able to come to your study visits with you**
- **Will give you the study medication at the same time every morning.**

Therefore, it is important that both of you fully understand what will happen if you decide to participate in the Identity Study.

Your family and/or study partner will also be receiving some additional information about the study. You may also find this brochure and the additional information useful to refer to when discussing the study.



WHAT IS A CLINICAL TRIAL?

Before any medication can be approved as a treatment for an illness, it must be proven to be safe and effective in research studies. These are often called clinical trials, clinical studies, or clinical research studies.

People participate in clinical trials for a variety of reasons, including gaining access to new research medications and helping researchers understand if and how an investigational medication works to treat people with a particular disease or condition.

Without clinical trials new medications could not be developed.

WHAT IS THE PURPOSE OF THE IDENTITY STUDY?

The purpose of the Identity Study is to find out whether or not taking the investigational medication, in addition to your current medications, is safe and effective in slowing the progression of Alzheimer's disease.

WHAT IS THE STUDY MEDICATION?

The medication being studied is known as LY450139. It has not been approved by any government agency for sale as a treatment for any condition. Researchers conducting this study are hoping that this investigational medication will slow the progression of Alzheimer's disease by blocking the production of certain proteins in the brain. These proteins cause plaques that are thought to kill nerve cells in the brain of people with Alzheimer's disease.

WHO CAN PARTICIPATE IN THE IDENTITY STUDY?

Up to 1,500 people from all over the world will participate in the Identity Study. To be considered for this study, you must meet certain conditions. The study site staff will discuss your medical history and current medical condition with you and your study partner to see if you are eligible to participate.

Some of the basic study inclusion criteria require that you:

- Be at least 55 years of age
- Have mild to moderate Alzheimer's disease
- Have a caregiver / study partner who spends at least 10 hours a week with you, and who can attend study visits with you, or be available on the telephone at arranged times
- Be able to swallow tablets whole
- Not have other conditions that may affect your participation in to the study

Additional criteria will be assessed by the study doctor to confirm your eligibility.

In the Identity Study, the investigational medication will be given in addition to any Alzheimer's medications you are currently taking. You would not have to stop taking your current medications to be in this study.

WHAT HAPPENS DURING THIS STUDY?

If you and the study doctor determine that the Identity Study is right for you, then the study doctor will discuss this study with you and your study partner in great detail. Once you have had all of your questions answered about the study, you and your study partner will be asked to sign an informed consent form (ICF).

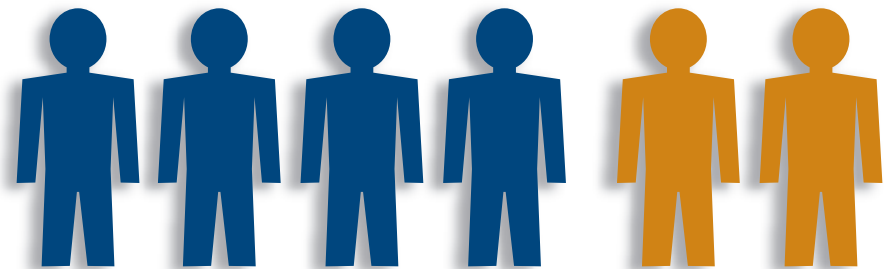
All qualified adults who participate in the Identity Study will:

- Undergo a complete physical exam and complete two questionnaires to confirm eligibility
- Take three tablets once a day of the study medication or placebo
- Attend up to 20 study visits over approximately 22 months
- Be asked to comply with all study procedures and requirements

Study participants can choose to end their participation in this study at any time, for any reason. However, we suggest that you discuss this with your study team first to ensure you are withdrawn from the study appropriately.

WILL EVERYONE RECEIVE THE STUDY MEDICATION?

All study participants will be randomly assigned to receive either the study medication or placebo (a pill that has a similar appearance to the study medication, but has no medicine) in addition to taking current medications. There is a 67% chance of receiving the study medication from the very start of the study.



67% of participants will receive the investigational medication in addition to any current Alzheimer's medications

33% of participants will receive the placebo (a pill that has a similar appearance to the study medication but has no medicine) as well as any current Alzheimer's medication

33% of participants will receive the placebo. However, sometime after week 64 of the study, all participants will receive the study medication, even if they were previously taking the placebo. Keep in mind that during the entire study (including those first 64 weeks) all of the study participants will be able to continue taking their current Alzheimer's medications.

Neither you, nor your doctor will know which study group you are in. This is to ensure that everyone on the study receives exactly the same treatment and care regardless of whether they are taking the investigational medication or placebo.

HOW LONG IS THE STUDY?

Each study participant will be involved in this study for up to 22 months.

WHAT HAPPENS AT THE STUDY VISITS?

There are four phases of the study: screening, initial treatment, treatment phase 2, and end of study follow-up. The chart to the right shows the purpose and timing of each phase.

For the first 2 months that you are taking the study medication tablets, you will need to visit the clinic every week or every 2 weeks. For the remainder of the study, you will need to visit the clinic once every month.

At your study visits, you and your study partner / caregiver will be asked questions to determine how Alzheimer's disease is affecting your life. This will include questions and tests to determine any changes to memory, problem solving, judgement, home life and hobbies, and the need for help with daily activities.

(continues after charts)



Screening Period

To make sure you can be in the study

1 visit, up to 30 days



Initial Treatment

To slowly increase dose of study medication and tests to see how your body is responding

12 visits, 16 months



Treatment Phase 2

To transition those who are taking placebo over to taking the active study medication

7 visits, 6 months



End of Study Follow-up

To check patient safety, adjust medications if needed for those who discontinue early or opt out of open-label extension phase

1 visit

You'll visit the doctor up to 20 times over 22 months that you are in the study

Below is a chart that shows the timing of the study visits and what will happen at each visit.

VISIT	LENGTH OF VISIT*	PHYSICAL / NEURO-LOGICAL EXAM	LABORATORY (BLOOD / URINE) TESTS	ECG	QUESTION-NAIRES	TABLETS GIVEN
Screening Phase To confirm eligibility; screening phase (the time between Visit 1 and Visit 2) is 3 – 14 days, but may take up to 30 days to allow for completion of Visit 1 screening procedures						
Visit 1	4-6 hours	●	●	●	●	
Initial Treatment Phase To slowly increase dose of study medication and conduct tests to see how participant is doing on the study						
Visit 2 (Week 0)	4-6 hours		●	●	●	●
Visit 3 (Week 2)	2-3 hours		●	●		●
Visit 4 (Week 3)	2-3 hours			●		●
Visit 5 (Week 4)	2-3 hours			●		●
Visit 6 (Week 5)	2-3 hours			●		●
Visit 7 (Week 6)	7-8 hours		●	●		●
Visit 8 (Week 8)	2-3 hours			●		●
Visit 9 (Week 12)	6-8 hours		●	●	●	●
Visit 10 (Week 20)	1-2 hours			●		●
Visit 11 (Week 28)	2-3 hours		●	●	●	●
Visit 12 (Week 40)	2-3 hours		●		●	●
Visit 13 (Week 52)	3-8 hours	●	●	●	●	●

VISIT	LENGTH OF VISIT*	PHYSICAL / NEURO-LOGICAL EXAM	LABORATORY (BLOOD / URINE) TESTS	ECG	QUESTION-NAIRES	TABLETS GIVEN
Delayed Start Phase Participants receiving placebo will be given the active study medication sometime after this point in the study						
Visit 14 (Week 64)	2-3 hours		●	●	●	●
Visit 15 (Week 68)	1-2 hours			●		●
Visit 16 (Week 72)	1-2 hours			●		●
Visit 17 (Week 76)	3-6 hours	●	●	●	●	●
Visit 18 (Week 80)	1-2 hours		●	●		●
Visit 19 (Week 84)	1-2 hours		●	●		●
Visit 20 (Week 88) Patients may opt into open-label extension phase at this visit	2-3 hours	●	●	●	●	
End of Study Follow-Up For participants who discontinue before Visit 20 or choose not to participate in the open-label extension phase						
Visit 801 (Week 92) For patients who discontinue prior to visit 20, this will be one month after last dose of study medication	Approx 1 hour		●			
6-month Follow-up	Via telephone or certified mail					

*All time estimates are approximate.

WHAT HAPPENS AT THE STUDY VISITS? (CONTINUED)

As the research doctor and nurses monitor how you're doing in the study, information will be collected. Your privacy will be respected, and all information will be treated confidentially.

In addition, you will have medical examinations such as blood pressure, pulse and heart rate readings, and blood and urine tests. This is to make sure that your body is not experiencing any unacceptable side effects. The tables on the previous pages show what will happen at the clinic visits.

WILL IT COST ME ANYTHING TO PARTICIPATE IN THE IDENTITY STUDY?

No. All study-related clinic visits, laboratory tests, examinations, and study medication will be provided to you at no cost while you are taking part in this study.

In addition, you may be reimbursed for travel expenses, such as car parking or public transportation. The study doctor will be able to provide more information about this.

WHAT IF I HAVE QUESTIONS?

If you have any questions regarding the study, your doctor and study team will be happy to answer any questions you may have.

