

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

VISTA STUDY

VISTA study

1. Study Information	
Name of the study	A study to assess the efficacy and safety of ML-007C-MA for the treatment of Alzheimer's disease psychosis
Study sponsor	MapLight Therapeutics
Disease	Alzheimer's disease psychosis
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	ML-007C-MA
Administration	Oral administration (tablet) twice a day, within approximately 1 hour after consuming food
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	<p>Participants will be selected by chance to receive one of the following options:</p> <ul style="list-style-type: none">• An oral administration of ML-007C-MA• An oral administration of placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect). <p>Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo.</p>

3. Information about participating in the trial	
What are the researchers trying to find out?	<ul style="list-style-type: none">• The purpose of the study is to evaluate the efficacy and safety of ML-007C-MA in people aged 55 to 90 years with hallucinations and delusions associated with Alzheimer's disease psychosis.
How long will the treatment last?	<ul style="list-style-type: none">• 7 weeks
What your involvement will entail?	<ul style="list-style-type: none">• During the study, participants will be asked to complete tests that will assess their cognitive function, agitation, hallucinations and delusions

	<ul style="list-style-type: none"> • Undergo brain scan (PET) or CSF examination (lumbar puncture). <p>Further information on the procedures, tests and number of visits can be obtained from the study team.</p>
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4. Who can participate in this study?

<p>Who can participate in the study?</p>	<p>To take part in the study, participants must:</p> <ul style="list-style-type: none"> • Be between 55 and 90 years old • Meets clinical criteria for possible or probable Alzheimer’s disease • Have psychotic symptoms • Reside at the same home, residential assisted living, or nursing home facility for a minimum of 6 weeks before screening • Have a study partner who has a sufficient contact with the participant and is willing to participate in study procedures throughout the study duration.
<p>Who cannot participate in the study?</p>	<p>Exclusion criteria include:</p> <ul style="list-style-type: none"> • Under the care of hospice, bed-bound, or receiving end-of-life palliative care • Psychotic symptoms that are primarily attributable to substance abuse or a medical, neurological or psychiatric condition other than Alzheimer's disease • Moderate or severe major depressive episode within the past 3 months • Alcohol or substance abuse

	<ul style="list-style-type: none"> • Has previously participated in any clinical study with ML-007 or ML-007C-MA. <p>The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.</p>
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5. Where and when will the study be conducted?	
European countries involved in the trial (active)	<ul style="list-style-type: none"> • Bulgaria • Czechia • France • Romania
European countries that will be involved in the trial (planned)	<ul style="list-style-type: none"> • Italy • Hungary • Poland • Portugal • Slovakia
Estimated start date of recruitment	January 2026

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06887192	EU CT Number	2024-519820-26-00
Study contact information	ML-007C-MA-ADP@maplightrx.com		
Link to full text	https://clinicaltrials.gov/study/NCT06887192 https://euclinicaltrials.eu/ctis-public/view/2024-519820-26-00		

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